

# DRAFT comparison

[www.maschinenrichtlinie.de](http://www.maschinenrichtlinie.de)

[www.maschinenbautage.eu](http://www.maschinenbautage.eu)

## Machinery Regulation vs. Machinery Directive

Comparison of full text

On 25 January the European Council released the final version of the Draft for a Machinery Regulation to the public:

[https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL:ST\\_5617\\_2023\\_INIT](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CONSIL:ST_5617_2023_INIT)

The text and numbering of Articles and chapters will change slightly before its final release in April / May 2023, but the meaning of the text will remain.

Thus, in this publication we have put the old text of the Machinery Directive 2006/42/EC next to the new text of the Machinery Regulation Draft from 25 January and highlighted the changes.

The Correlation table in Annex XI of the draft was looked at. Since it was not updated since the first Commission proposal, it was too outdated in many instances. Thus, all decisions which old text to compare to the new draft are the authors choice.

We would like to acknowledge Stephano Boy and his co-authors, who published their [comparison of the old and new Machinery Directive](#)<sup>1</sup> in 2008.

...



Get up to date on  
all changes!

In order to give the European industry the best start possible, MBT Ostermann GmbH will conduct a special conference on

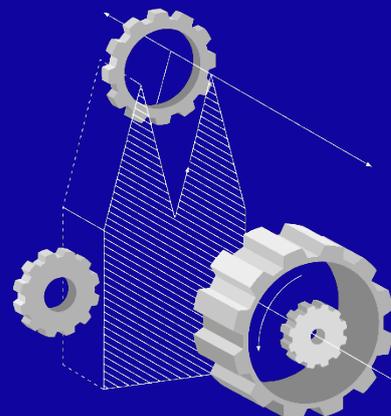
16 May 2023

online (ZOOM) and live in  
Cologne.

We will present all important changes and their impact to industries, notified bodies and market surveillance.

All talks will be translated by skilled interpreters in German/English.

<http://www.maschinenbautage.eu/index.php?id=1122#c7612>



<sup>1</sup> ISBN 978-3-88383-914-1

## **Index**

Introduction .....	5
Recital .....	7
Chapter 1: General Provisions .....	56
Chapter 2: Obligations of economic operators .....	85
Chapter 3: Conformity of products within the scope of this regulation.....	120
Chapter 4: Conformity assessment .....	130
Chapter 5: Notification of conformity assessment bodies.....	134
Chapter 6: Union market surveillance and Union safeguard procedures .....	158
Chapter 7: Delegated powers and committee procedure .....	173
Chapter 8: Confidentiality and penalties .....	177
Chapter 9: Transitional and final provisions.....	180
Annex I: Categories of machinery or related products to which ... ..	185
Annex II: Indicative list of safety components .....	190
Annex III: Essential Health and Safety Requirements ... ..	194
Annex IV: Technical Documentation for machinery and related products .....	349
Annex V: EU Declaration of Conformity and Incorporation .....	360
Annex VI: Modul A – Internal production control.....	368
Annex VII: Modul B – EU Type-Examination .....	371
Annex VIII: Modul C – Conformity to type based on internal production control .....	386
Annex IX: Modul H – Conformity based on full quality assurance .....	388
Annex X: Assembly instructions for partly completed machinery .....	405
Annex XI: Correlation table.....	409



Dr.-Ing. Björn Ostermann  
[www.maschinenrichtlinie.de](http://www.maschinenrichtlinie.de)

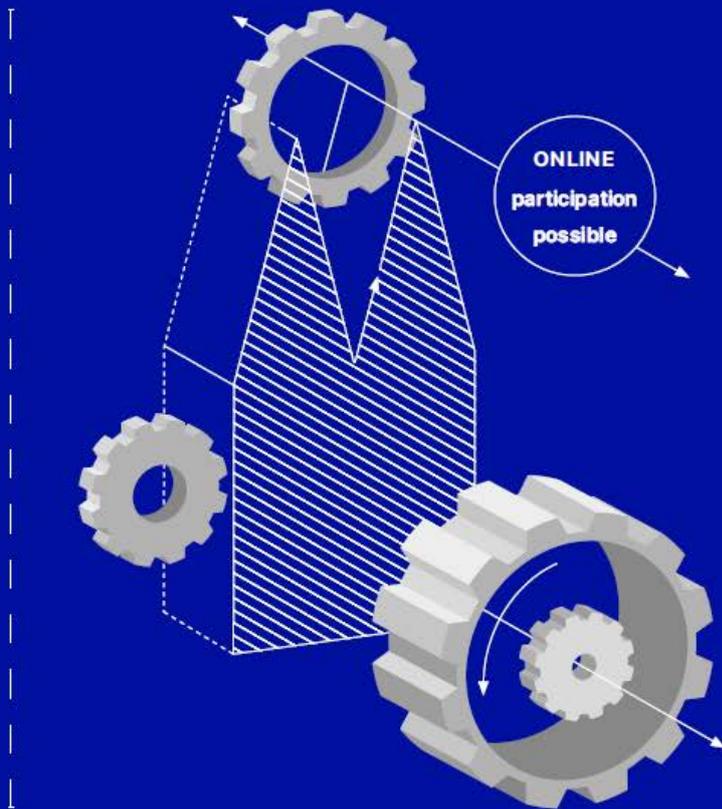
Version: 8 February 2023

**Changes:**

- 8.2.23 Moves several recitals 2 rows down. They got mixed up in the database.

# EU-Machinery Regulation COLOGNE

One Day, all changes from the Machinery Directive:  
**Tu 16/05/2023, Maritim Hotel Cologne**



## CONFERENCE MACHINERY REGULATION

What do you need to know before the new regulation comes into force?  
Compressed knowledge about machinery law.

### Topics:

- Responsible economic operators in the MR
- Changes in the scope of the MR
- Amendments to Annex III MR (currently Annex I MD)
- Dangerous products: integration of the notified bodies
- New digital documents
- Significant change after MR
- National adjustments to the MR
- Legal text vs. EU guidelines

### Dipl.-Ing.

**Hans J. Ostermann**  
[www.maschinenrichtlinie.de](http://www.maschinenrichtlinie.de)

### Dr.-Ing.

**Björn Ostermann**  
DCEM - Die CE Mentoren  
Dr. Ostermann und Partner  
Ingenieure

## Introduction

DRAFT Machinery Regulation	Comparison	Machinery Directive
Formula		
2021/0105 (COD)	<u>2021/0105 (COD)</u>	
Proposal Title		
Proposal for a	Proposal for a	
		Title
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	<u>REGULATION</u> <del>DIRECTIVE 2006/42/EC</del> OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL <del>of 17 May 2006</del>	DIRECTIVE 2006/42/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 May 2006
on machinery	on machinery, <del> and amending Directive 95/16/EC (recast)</del>	on machinery, and amending Directive 95/16/EC (recast)
(Text with EEA relevance)	(Text with EEA relevance)	(Text with EEA relevance)
Formula		Formula
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
Citation 1		Citation 1
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	Having regard to the Treaty <u>on the Functioning of</u> <del>establishing</del> the European <u>Union</u> <del>Community</del> , and in particular Article <u>114</u> <del>95</del> thereof,	Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,
Citation 2		Citation 2
Having regard to the proposal from the European Commission,	Having regard to the proposal from the <u>European Commission</u> ,	Having regard to the proposal from the Commission,
Citation 3		
After transmission of the draft legislative act to the national parliaments,	<u>After transmission of the draft legislative act to the national parliaments,</u>	
Citation 4		Citation 3
Having regard to the opinion of the European Economic and Social Committee <sup>1</sup> ,	Having regard to the opinion of the European Economic and Social <u>Committee</u> <del>1Committee</del> ,	Having regard to the opinion of the European Economic and Social Committee,

DRAFT Machinery Regulation	Comparison	Machinery Directive
1. OJ C [...], [...], p. [...].	1. OJ C [...], [...], p. [...].	
Citation 5		Citation 4
Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the <u>ordinary legislative</u> procedure <del>laid down in Article 251 of the Treaty,</del>	Acting in accordance with the procedure laid down in Article 251 of the Treaty,
Formula		Formula
Whereas:	Whereas:	Whereas:

**Recital**

DRAFT Machinery Regulation	Comparison	Machinery Directive
Recital 1		
(1) Directive 2006/42/EC1 of the European Parliament and of the Council was adopted in the context of establishing the internal market, in order to harmonise health and safety requirements for machinery in all Member States and to remove obstacles to trade in machinery between Member States.	<u>(1) Directive 2006/42/EC1 of the European Parliament and of the Council was adopted in the context of establishing the internal market, in order to harmonise health and safety requirements for machinery in all Member States and to remove obstacles to trade in machinery between Member States.</u>	
1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).	<u>1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).</u>	
Recital 2		
(2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Union economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.	(2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the <del>Union</del> Community economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.	(2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Community economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.
Recital 3		
(3) Experience with the application of Directive 2006/42/EC has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. It is therefore necessary to improve, simplify and adapt	<u>(3) Experience with the application of Directive 2006/42/EC has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. It is therefore necessary to improve, simplify and adapt</u>	(1) Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery codified Directive 89/392/EEC. Now that new substantial amendments are being

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>the provisions set out in that Directive to the needs of the market and provide clear rules in relation to the framework within which products within the scope of this Regulation may be made available on the market.</p>	<p><u>the provisions set out in that Directive to the needs of the market and provide clear rules in relation to the framework within which products within the scope of this Regulation may be made available on the market.</u> <del>(1) Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery codified Directive 89/392/EEC. Now that new substantial amendments are being made to Directive 98/37/EC, it is desirable, in order to clarify matters, that that Directive should be recast.</del></p>	<p>made to Directive 98/37/EC, it is desirable, in order to clarify matters, that that Directive should be recast.</p>
<p>Recital 4</p>		
<p>(4) Since the rules setting out the requirements for products within the scope of this Regulation, in particular the essential health and safety requirements and the conformity assessment procedures, need to be of uniform application for all operators across the Union, and not give room for divergent implementation by Member States, Directive 2006/42/EC should be replaced by a regulation.</p>	<p><u>(4) Since the rules setting out the requirements for products within the scope of this Regulation, in particular the essential health and safety requirements and the conformity assessment procedures, need to be of uniform application for all operators across the Union, and not give room for divergent implementation by Member States, Directive 2006/42/EC should be replaced by a regulation.</u></p>	
<p>Recital 5</p>		
<p>(5) Member States are responsible for protecting, on their territory, the health and safety of persons, in particular workers and consumers, and, where appropriate, domestic animals and property, and, where applicable, the environment, notably in relation to the</p>	<p><del>(5)</del> <u>Member States are responsible for protecting, on their territory,</u> <del>ensuring</del> the health and safety <del>on their territory</del> of persons, in particular <del>of</del> workers and consumers, and, where appropriate, <del>of</del> domestic animals and <u>property, and, where applicable, the environment</u> <del>goods,</del></p>	<p>(3) Member States are responsible for ensuring the health and safety on their territory of persons, in particular of workers and consumers and, where appropriate, of domestic animals and goods, notably in relation to the risks arising out of the use of machinery.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>risks arising out of the intended use or reasonably foreseeable misuse of machinery or related products. For the avoidance of doubt, domestic animals should be considered to include farm animals.</p>	<p>notably in relation to the risks arising out of the <u>intended use or reasonably foreseeable misuse</u> <del>use</del> <u>of machinery or related products</u>. For the avoidance of <u>doubt, domestic animals should be considered to include farm animals</u>.</p>	
Recital 6		
<p>(6) Regulation (EC) No 765/2008 of the European Parliament<sup>1</sup> lays down rules on the accreditation of conformity assessment bodies, and lays down the general principles of the CE marking. That Regulation should be applicable to products within the scope of this Regulation in order to ensure that those products, which are benefiting from the free movement of goods within the Union, fulfil requirements providing a high level of protection of public interests such as the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.</p>	<p><u>(6) Regulation (EC) No 765/2008 of the European Parliament<sup>1</sup> lays down rules on the accreditation of conformity assessment bodies, and lays down the general principles of the CE marking. That Regulation should be applicable to products within the scope of this Regulation in order to ensure that those products, which are benefiting from the free movement of goods within the Union, fulfil requirements providing a high level of protection of public interests such as the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.</u></p>	
_____		
<p>1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).</p>	<p><u>1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).</u></p>	
Recital 7		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>(7) Regulation (EU) No 2019/1020 of the European Parliament and of the Council sets out rules on market surveillance and control of products entering the Union market. As Directive 2006/42/EC is listed in Annex I of Regulation (EU) No 2019/1020, that Regulation already applies to products within the scope of this Regulation. However, Regulation (EU) No 2019/1020 applies to products within the scope of this Regulation in so far as there are no specific provisions with the same objective, which regulate in a more specific manner particular aspects of market surveillance and enforcement.</p>	<p><u>(7) Regulation (EU) No 2019/1020 of the European Parliament and of the Council sets out rules on market surveillance and control of products entering the Union market. As Directive 2006/42/EC is listed in Annex I of Regulation (EU) No 2019/1020, that Regulation already applies to products within the scope of this Regulation. However, Regulation (EU) No 2019/1020 applies to products within the scope of this Regulation in so far as there are no specific provisions with the same objective, which regulate in a more specific manner particular aspects of market surveillance and enforcement.</u></p>	
<p>1. Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L169, 25.6.2019, p. 1.)</p>	<p><u>1. Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L169, 25.6.2019, p. 1.)</u></p>	
<p>Recital 7a</p>		
<p>(7a) Article 4 of Regulation (EU) No 2019/1020 lays down the tasks of economic operators regarding products subject to certain Union harmonisation legislation. It also provides that such products are to be placed on the market only if there is an economic operator established in the Union who is responsible for those tasks. That Union harmonisation legislation includes</p>	<p><u>(7a) Article 4 of Regulation (EU) No 2019/1020 lays down the tasks of economic operators regarding products subject to certain Union harmonisation legislation. It also provides that such products are to be placed on the market only if there is an economic operator established in the Union who is responsible for those tasks. That Union harmonisation legislation includes</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Directive 2006/42/EC. As a result, products within the scope of this Regulation are to be placed on the market only if there is an economic operator established in the Union who is responsible for the tasks set out in Article 4 of Regulation (EU) No 2019/1020 in their respect.</p>	<p><u>Directive 2006/42/EC. As a result, products within the scope of this Regulation are to be placed on the market only if there is an economic operator established in the Union who is responsible for the tasks set out in Article 4 of Regulation (EU) No 2019/1020 in their respect.</u></p>	
<p>Recital 8</p>		
<p>(8) Decision No 768/2008/EC of the European Parliament and of the Council<sup>1</sup> lays down common principles and reference provisions intended to apply across sectoral legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the rules on presumption of conformity, the rules on EU declaration of conformity, the rules on CE marking, the requirements for conformity assessment bodies, the rules on notification procedures and conformity assessment procedures and the rules on procedures to deal with machinery or related products and, where applicable, with partly completed machinery, presenting a risk should be adapted to the reference provisions laid down in that Decision.</p>	<p><u>(8) Decision No 768/2008/EC of the European Parliament and of the Council<sup>1</sup> lays down common principles and reference provisions intended to apply across sectoral legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the rules on presumption of conformity, the rules on EU declaration of conformity, the rules on CE marking, the requirements for conformity assessment bodies, the rules on notification procedures and conformity assessment procedures and the rules on procedures to deal with machinery or related products and, where applicable, with partly completed machinery, presenting a risk should be adapted to the reference provisions laid down in that Decision.</u> <del>(19)</del> <b>In view of the nature of the risks involved</b></p>	<p>(19) In view of the nature of the risks involved in the use of machinery covered by this Directive, procedures for assessing conformity to the essential health and safety requirements should be established. These procedures should be devised in the light of the extent of the danger inherent in such machinery. Consequently, each category of machinery should have its appropriate procedure in conformity with Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (9), taking account of the nature of the verification required for such machinery.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>in the use of machinery covered by this Directive, procedures for assessing conformity to the essential health and safety requirements should be established. These procedures should be devised in the light of the extent of the danger inherent in such machinery. Consequently, each category of machinery should have its appropriate procedure in conformity with Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives (9), taking account of the nature of the verification required for such machinery.</del></p>	
<p>1. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.08.2008, p. 82).</p>	<p><u>1. Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.08.2008, p. 82).</u></p>	
<p>Recital 9</p>		
<p>(9) This Regulation should cover products which are new to the Union market when placed on the market, i.e. either new products made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country.</p>	<p><u>(9) This Regulation should cover products which are new to the Union market when placed on the market, i.e. either new products made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country.</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Recital 10</p> <p>(10) Where there is a possibility that the machinery or related products will be used by a consumer, that is to say, a non-professional user, the manufacturer should take account of the fact that the consumer does not have the same knowledge and experience with handling machinery or related products in the design and construction of the products. The same applies where a machinery or related product is normally used to provide a service to a consumer.</p>	<p>(10<del>15</del>) Where <u>there is a possibility that the machinery or related products will</u><del>may</del> be used by a consumer, that is to say, a non-professional <u>user</u><del>operator</del>, the manufacturer should take account of <u>the fact that the consumer does not have the same knowledge and experience with handling machinery or related products</u><del>this</del> in the design and construction <u>of the products.</u>- The same applies where a <u>machinery or related product</u><del>machine</del> is normally used to provide a service to a consumer.</p>	<p>(15) Where the machinery may be used by a consumer, that is to say, a non-professional operator, the manufacturer should take account of this in the design and construction. The same applies where a machine is normally used to provide a service to a consumer.</p>
<p>Recital 11</p> <p>(11) Recently, more advanced machinery, which is less dependent on human operators, has been introduced on the market. Such machinery is working on defined tasks and in structured environments, yet it can learn to perform new actions in this context and become more autonomous. Further refinements to machinery, already in place or to be expected, include real-time processing of information, problem solving, mobility, sensor systems, learning, adaptability, and capability of operating in unstructured environments (e.g. construction sites). The Commission Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics<sup>1</sup>, states that the emergence of new digital</p>	<p>(11) Recently, more advanced machinery, <u>which is less dependent on human operators, has been introduced on the market. Such machinery is working on defined tasks and in structured environments, yet it can learn to perform new actions in this context and become more autonomous. Further refinements to machinery, already in place or to be expected, include real-time processing of information, problem solving, mobility, sensor systems, learning, adaptability, and capability of operating in unstructured environments (e.g. construction sites). The Commission Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics<sup>1</sup>, states</u> that the emergence of new digital</p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>technologies, like artificial intelligence, the Internet of things and robotics, raises new challenges in terms of product safety. The report concludes that the current product safety legislation, including Directive 2006/42/EC, contains a number of gaps in this respect that need to be addressed. Thus, this Regulation should cover the safety risks stemming from new digital technologies.</p>	<p><u>technologies, like artificial intelligence, the Internet of things and robotics, raises new challenges in terms of product safety. The report concludes that the current product safety legislation, including Directive 2006/42/EC, contains a number of gaps in this respect that need to be addressed. Thus, this Regulation should cover the safety risks stemming from new digital technologies.</u></p>	
<p>1. Report from the Commission to the European parliament, the Council and the European economic and social committee on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics (COM/2020/64 final)..</p>	<p><u>1. Report from the Commission to the European parliament, the Council and the European economic and social committee on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics (COM/2020/64 final)..</u></p>	
<p>Recital 12</p>		
<p>(12) In order to ensure protection of the health and safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment, this Regulation should apply to all forms of supply of products within the scope of this Regulation, including distance selling as referred to in Article 6 of Regulation (EU) 2019/1020.</p>	<p><u>(12) In order to ensure protection of the health and safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment, this Regulation should apply to all forms of supply of products within the scope of this Regulation, including distance selling as referred to in Article 6 of Regulation (EU) 2019/1020.</u></p>	
<p>Recital 13</p>		
<p>(13) In order to ensure legal certainty , the scope of this Regulation should be set out in a clear manner and the concepts relating to its application should be defined as precisely as possible.</p>	<p><u>(13<del>4</del>) In order to ensure legal certainty <del>for users</del>, the scope of this Regulation should be set out in a clear manner</u><del>Directive</del> and the concepts relating to its application</p>	<p>(4) In order to ensure legal certainty for users, the scope of this Directive and the concepts relating to its application should be defined as precisely as possible.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	should be defined as precisely as possible.	
Recital 13a		
<p>(13a) In order to ensure that the scope of this Regulation is sufficiently clear, a distinction should be made between machinery, related products and partly completed machinery. Moreover, related products should be understood as comprising interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing, and removable mechanical transmission devices, which are all products within the scope of this Regulation.</p>	<p><u>(13a) In order to ensure that the scope of this Regulation is sufficiently clear, a distinction should be made between machinery, related products and partly completed machinery. Moreover, related products should be understood as comprising interchangeable equipment, safety components, lifting accessories, chains, ropes and webbing, and removable mechanical transmission devices, which are all products within the scope of this Regulation.</u></p>	
Recital 14		
<p>(14) In order to avoid legislating twice the same product, is appropriate to exclude from the scope of this Regulation weapons, including firearms that are subject to Directive (EU) 2017/853 of the European Parliament and of the Council1.</p>	<p><u>(14) In order to avoid legislating twice the same product, is appropriate to exclude from the scope of this Regulation weapons, including firearms that are subject to Directive (EU) 2017/853 of the European Parliament and of the Council1.</u>  <del>(6) It is appropriate to exclude from the scope of this Directive weapons, including firearms, that are subject to Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons; the exclusion of firearms should not apply to portable cartridge-operated fixing and other impact machinery designed for industrial or technical purposes only. It is necessary to provide for transitional arrangements enabling Member States to authorise the</del></p>	<p>(6) It is appropriate to exclude from the scope of this Directive weapons, including firearms, that are subject to Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons; the exclusion of firearms should not apply to portable cartridge-operated fixing and other impact machinery designed for industrial or technical purposes only. It is necessary to provide for transitional arrangements enabling Member States to authorise the placing on the market and putting into service of such machinery manufactured in accordance with national provisions in force upon adoption of this Directive, including those implementing the Convention of 1 July 1969 on the</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>placing on the market and putting into service of such machinery manufactured in accordance with national provisions in force upon adoption of this Directive, including those implementing the Convention of 1 July 1969 on the Reciprocal Recognition of Proofmarks on Small Arms. Such transitional arrangements will also enable the European standardisation organisations to draft standards ensuring the safety level based on the state of the art.</del></p>	<p>Reciprocal Recognition of Proofmarks on Small Arms. Such transitional arrangements will also enable the European standardisation organisations to draft standards ensuring the safety level based on the state of the art.</p>
<p>1. Directive (EU) 2017/853 of the European Parliament and of the Council of 17 May 2017 amending Council Directive 91/477/EEC on control of the acquisition and possession of weapons (OJ L 137, 24.5.2017, p.22).</p>	<p><u>1. Directive (EU) 2017/853 of the European Parliament and of the Council of 17 May 2017 amending Council Directive 91/477/EEC on control of the acquisition and possession of weapons (OJ L 137, 24.5.2017, p.22).</u></p>	
<p>Recital 15</p>		
<p>(15) The purpose of this Regulation is to address the risks stemming from machinery function and not from the transport of goods, persons or animals. Consequently, this Regulation should not apply to means of transport by air, on water and on rail networks with the exclusion of machinery mounted on those means of transport. Means of transport by road that are not yet covered by a specific Union legal act should be regulated by this Regulation with the exception of the risks that may arise from the circulation. This means that vehicles,</p>	<p><u>(15) The purpose of this Regulation is to address the risks stemming from machinery function and not from the transport of goods, persons or animals. Consequently, this Regulation should not apply to means of transport by air, on water and on rail networks with the exclusion of machinery mounted on those means of transport. Means of transport by road that are not yet covered by a specific Union legal act should be regulated by this Regulation with the exception of the risks that may arise from the circulation. This means that vehicles,</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>including e-bikes, e-scooters and other personal mobility devices that are not subject to EU type approval under Regulation (EU) No 167/2013 1 or Regulation (EU) 168/2013 2 are covered by this Regulation.</p>	<p><u>including e-bikes, e-scooters and other personal mobility devices that are not subject to EU type approval under Regulation (EU) No 167/2013 1 or Regulation (EU) 168/2013 2 are covered by this Regulation.</u></p>	
<p>1 Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).</p>	<p><u>1 Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).</u></p>	
<p>2 Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).</p>	<p><u>2 Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).</u></p>	
<p>Recital 16</p>		
<p>(16) Household appliances intended for domestic use which are not electrically operated furniture, audio and video equipment, information technology equipment, office machinery, low-voltage switchgear and control gear and electrical motors fall within the scope of Directive 2014/35/EU of the European Parliament and of the Council<sup>1</sup> and should therefore be excluded from the scope of this Regulation. Some of those products are progressively incorporating Wi-Fi functions, e.g. washing machines, and are therefore covered by Directive 2014/53/EU of the European Parliament</p>	<p><u>(16) Household appliances intended for domestic use which are not electrically operated furniture, audio and video equipment, information technology equipment, office machinery, low-voltage switchgear and control gear and electrical motors fall within the scope of Directive 2014/35/EU of the European Parliament and of the Council<sup>1</sup> and should therefore be excluded from the scope of this Regulation. Some of those products are progressively incorporating Wi-Fi functions, e.g. washing machines, and are therefore covered by Directive 2014/53/EU of the European Parliament</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>and of the Council<sup>2</sup> as radio equipment. Those products should also be excluded from the scope of this Regulation.</p>	<p><u>and of the Council<sup>2</sup> as radio equipment. Those products should also be excluded from the scope of this Regulation.</u></p>	
<p>1. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 35).</p>	<p><u>1. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 35).</u></p>	
<p>2. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).</p>	<p><u>2. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).</u></p>	
<p>Recital 17</p>		
<p>(17) The evolution of the machinery sector has resulted in the growing use of digital means and software plays a more and more important role in the machinery design. Consequently, the definition of machinery should be adapted. In this respect, machinery missing only the upload of a software intended for the specific application foreseen by the manufacturer and which is the subject of the conformity assessment procedure of the machinery should fall under the definition of machinery and not under the definitions of related products or partly</p>	<p><u>(17) The evolution of the machinery sector has resulted in the growing use of digital means and software plays a more and more important role in the machinery design. Consequently, the definition of machinery should be adapted. In this respect, machinery missing only the upload of a software intended for the specific application foreseen by the manufacturer and which is the subject of the conformity assessment procedure of the machinery should fall under the definition of machinery and not under the definitions of related products or partly</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>completed machinery. Furthermore, the definition of safety components should cover not only physical devices but also digital devices. In order to take into account the increasing use of software as a safety component, software that performs a safety function and is placed independently on the market should be considered a safety component.</p>	<p><u>completed machinery. Furthermore, the definition of safety components should cover not only physical devices but also digital devices. In order to take into account the increasing use of software as a safety component, software that performs a safety function and is placed independently on the market should be considered a safety component.</u><del>(16)</del>  <del>Although the requirements of this Directive do not apply to partly completed machinery in their entirety, it is nevertheless important that the free movement of such machinery be guaranteed by means of a specific procedure.</del></p>	
<p>Recital 17a</p>		
<p>(17a) Considering their critical protective function, certain components included in the indicative list of safety components in Annex II should also be subject to specific conformity assessment procedure and included in Annex I.</p>	<p><u>(17a) Considering their critical protective function, certain components included in the indicative list of safety components in Annex II should also be subject to specific conformity assessment procedure and included in Annex I.</u></p>	
<p>Recital 18</p>		
<p>(18) Partly completed machinery is a product within the scope of this Regulation which must undergo further construction in order to be able to perform its specific application, i.e. the well-defined operations for which the product is designed. It is not necessary that all requirements of this Regulation apply to partly completed machinery but in order to ensure the safety of the</p>	<p><u>(18) Partly completed machinery is a product within</u><del>(16)</del> <del>Although</del> <u>the scope of this Regulation which must undergo further construction in order to be able to perform its specific application, i.e. the well-defined operations for which the product is designed. It is not necessary that all requirements of this Regulation</u>  <del>Directive do not</del> apply to partly completed machinery <u>but in order to</u></p>	<p>(16) Although the requirements of this Directive do not apply to partly completed machinery in their entirety, it is nevertheless important that the free movement of such machinery be guaranteed by means of a specific procedure.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>product as a whole, it is nevertheless important that the free movement of such partly completed machinery be guaranteed by means of a specific procedure.</p>	<p><u>ensure the safety of the product as a whole</u><del>in their entirety</del>, it is nevertheless important that the free movement of such <u>partly completed</u> machinery be guaranteed by means of a specific procedure.</p>	
<p>Recital 19</p>		
<p>(19) Where products within the scope of this Regulation present risks that are addressed by the essential health and safety requirements set out in this Regulation but are also wholly or partly covered by other more specific Union legislation, this Regulation should not apply to the extent that those risks are covered by that other Union legislation. In other cases, products within the scope of this Regulation may present risks that are not covered by the essential health and safety requirements set out in this Regulation. For example, products incorporating a Wi-Fi function may present risks not addressed by the essential health and safety requirements set out in this Regulation, as this Regulation does not deal with risks specific to such systems.</p>	<p><u>(19) Where products within the scope of this Regulation present risks that are addressed by the essential health and safety requirements set out in this Regulation but are also wholly or partly covered by other more specific Union legislation, this Regulation should not apply to the extent that those risks are covered by that other Union legislation. In other cases, products within the scope of this Regulation may present risks that are not covered by the essential health and safety requirements set out in this Regulation. For example, products incorporating a Wi-Fi function may present risks not addressed by the essential health and safety requirements set out in this Regulation, as this Regulation does not deal with risks specific to such systems.</u></p>	
<p>Recital 20</p>		
<p>(20) For trade fairs, exhibitions and similar events, it should be possible to exhibit products within the scope of this Regulation which do not meet the requirements of this Regulation, since this would not present any safety risk.</p>	<p><del>(20)</del><sup>(17)</sup> For trade fairs, exhibitions and <u>similar events</u><del>such like</del>, it should be possible to exhibit <u>products within the scope of this Regulation</u><del>machinery</del> which <del>do</del><sup>does</sup> not <del>meet</del><sup>satisfy</sup> the requirements of this <u>Regulation</u>, since this would not</p>	<p>(17) For trade fairs, exhibitions and such like, it should be possible to exhibit machinery which does not satisfy the requirements of this Directive. However, interested parties should be properly informed that the machinery does not</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>However, for the sake of transparency, interested parties should be properly informed that the products within the scope of this Regulation are not compliant and cannot be purchased.</p>	<p><del>present any safety risk.</del><del>Directive:</del>                      However, <u>for the sake of transparency,</u> interested parties should be properly informed that the <u>products within the scope of this Regulation are not compliant</u><del>machinery does not conform</del> and cannot be purchased <del>in that condition.</del>  <u>condition.</u></p>	<p>conform and cannot be purchased in that condition.</p>
Recital 21		
<p>(21) The evolution of the state of the art in the machinery sector has an impact on the classification of machinery or related products listed in Annex I.</p>	<p><u>(21) The evolution of the state of the art in the machinery sector has an impact on the classification of machinery or related products listed in Annex I.</u></p>	
<p>With a view to properly reflecting any machinery or related products presenting a higher risk factor, criteria should be established for the assessment of products which should be included in the list of machinery or related products subject to a stricter conformity assessment procedure</p>	<p><u>With a view to properly reflecting any machinery or related products presenting a higher risk factor, criteria should be established for the assessment of products which should be included in the list of machinery or related products subject to a stricter conformity assessment procedure</u></p>	
Recital 22		
<p>(22) Other risks related to new digital technologies are those provoked by malicious third parties that have an impact on the safety of products within the scope of this Regulation. In this respect, manufacturers should be required to adopt proportionate measures which are limited to the protection of the safety of the product within the scope of this Regulation. This does not preclude the application to products within the scope of this Regulation of other Union</p>	<p><u>(22) Other risks related to new digital technologies are those provoked by malicious third parties that have an impact on the safety of products within the scope of this Regulation. In this respect, manufacturers should be required to adopt proportionate measures which are limited to the protection of the safety of the product within the scope of this Regulation. This does not preclude the application to products within the scope of this Regulation of other Union</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>legislation specifically addressing cybersecurity aspects.</p>	<p><u>legislation specifically addressing cybersecurity aspects.</u></p>	
<p>Recital 23</p>		
<p>(23) In order to ensure that machinery or related products, when placed on the market or put into service, do not entail health and safety risks for persons or domestic animals and do not cause harm to property and, where applicable, the environment, essential health and safety requirements should be set out which have to be met in order for the machinery or related products to be allowed on the market. Machinery or related products should comply with the essential health and safety requirements when placed on the market or put into service. Where such products are subsequently modified, by physical or digital means, in a way that is not foreseen nor planned by the manufacturer and which affects the safety of such products by creating a new hazard or increasing an existing risk, the modification should be considered as substantial when new significant protective measures are required. However, repair and maintenance operations which do not affect the machinery or related product's compliance with the relevant essential health and safety requirements should not be considered to be substantial modifications. In order to ensure the compliance of such a product with the</p>	<p><u>(23) In order to ensure that machinery or related products, when placed on the market or put into service, do not entail health and safety risks for persons or domestic animals and do not cause harm to property and, where applicable, the environment, essential health and safety requirements should be set out which have to be met in order for the machinery or related products to be allowed on the market. Machinery or related products should comply with the essential health and safety requirements when placed on the market or put into service. Where such products are subsequently modified, by physical or digital means, in a way that is not foreseen nor planned by the manufacturer and which affects the safety of such products by creating a new hazard or increasing an existing risk, the modification should be considered as substantial when new significant protective measures are required. However, repair and maintenance operations which do not affect the machinery or related product's compliance with the relevant essential health and safety requirements should not be considered to be substantial modifications. In order to ensure the compliance of such a product with the</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>relevant essential health and safety requirements, the person that carries out the substantial modification should be required to perform a new conformity assessment before placing the modified product on the market or putting it into service. In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to aspects of the machinery or related product that are not impacted by the modification.</p>	<p><u>relevant essential health and safety requirements, the person that carries out the substantial modification should be required to perform a new conformity assessment before placing the modified product on the market or putting it into service. In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to aspects of the machinery or related product that are not impacted by the modification.</u></p>	
Recital 24		
<p>(24) In the machinery sector, around 98 % of the companies are small or medium sized enterprises (SMEs). In order to reduce the regulatory burden on SMEs, it is important that notified bodies consider adapting the fees for conformity assessments and reducing them proportionately to the specific interests and needs of SMEs.</p>	<p><u>(24) In the machinery sector, around 98 % of the companies are small or medium sized enterprises (SMEs). In order to reduce the regulatory burden on SMEs, it is important that notified bodies consider adapting the fees for conformity assessments and reducing them proportionately to the specific interests and needs of SMEs.</u></p>	
Recital 25		
<p>(25) Economic operators should be responsible for the compliance of products within the scope of this Regulation with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as protection of the health and safety of persons, in particular</p>	<p><u>(25) Economic operators should be responsible for the compliance of products within the scope of this Regulation with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as protection of the health and safety of persons, in particular</u></p>	

<b>DRAFT Machinery Regulation</b>	<b>Comparison</b>	<b>Machinery Directive</b>
<p>consumers and professional users, where appropriate, domestic animals, property and, where applicable, the environment , as well as the fair competition on the Union market.</p>	<p><u>consumers and professional users, where appropriate, domestic animals, property and, where applicable, the environment , as well as the fair competition on the Union market.</u></p>	
<p>Recital 26</p>		
<p>(26) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only products within the scope of this Regulation, which are in conformity with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations, which correspond to the role of each economic operator in the supply and distribution chain.</p>	<p><u>(26) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only products within the scope of this Regulation, which are in conformity with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations, which correspond to the role of each economic operator in the supply and distribution chain.</u></p>	
<p>Recital 27</p>		
<p>(27) In order to facilitate communication between economic operators, market surveillance authorities and users, Member States should encourage economic operators to include a website, email address or other digital contact in addition to the postal address.</p>	<p><u>(27) In order to facilitate communication between economic operators, market surveillance authorities and users, Member States should encourage economic operators to include a website, email address or other digital contact in addition to the postal address.</u></p>	
<p>Recital 28</p>		
<p>(28) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.</p>	<p><u>(28) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Recital 29</p> <p>(29) The manufacturer should also ensure that a risk assessment is carried out for the product within the scope of this Regulation, which the manufacturer wishes to place on the market or put into service. In this context, the manufacturer should determine which of the essential health and safety requirements that are applicable to the product within the scope of this Regulation and in respect of which measures must be taken to address the risks that the product may present. The risk assessment should also address future updates or developments of a software installed in the machinery or related product, which are foreseen when the machinery or related product is placed on the market or put into service. The risks identified during the risk assessment should include those risks that may appear during the product's lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy.</p>	<p><del>(29)</del><sup>(23)</sup> The manufacturer <del>or his authorised representative</del> should also ensure that a risk assessment is carried out for the <u>product within the scope of this Regulation, machinery which the manufacturer</u><del>he</del> wishes to place on the market <del>or put into service. In this context, the manufacturer. For this purpose, he</del> should determine which <del>of</del><sup>are</sup> the essential health and safety requirements <u>that are applicable to the product within the scope of this Regulation his machinery</u> and in respect of which <del>he must take</del> measures <u>must be taken to address the risks that the product may present. The risk assessment should also address future updates or developments of a software installed in the machinery or related product, which are foreseen when the machinery or related product is placed on the market or put into service. The risks identified during the risk assessment should include those risks that may appear during the product's lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy.</u></p>	<p>(23) The manufacturer or his authorised representative should also ensure that a risk assessment is carried out for the machinery which he wishes to place on the market. For this purpose, he should determine which are the essential health and safety requirements applicable to his machinery and in respect of which he must take measures.</p>
<p>Recital 30</p> <p>(30) The safety of the entire machinery or related product relies on the dependencies and interactions between its components, including partly completed machinery, and, if relevant,</p>	<p><u>(30) The safety of the entire machinery or related product relies on the dependencies and interactions between its components, including partly completed machinery, and, if relevant,</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>with other machinery or related product that participate in a coordinated assembly of a machinery system, which can also result in an assembly of machinery. Therefore, manufacturers should be required to assess all those interactions in the risk assessment.</p>	<p><u>with other machinery or related product that participate in a coordinated assembly of a machinery system, which can also result in an assembly of machinery. Therefore, manufacturers should be required to assess all those interactions in the risk assessment.</u></p>	
<p>Recital 31</p>		
<p>(31) It is essential that, before drawing up the EU declaration of conformity or the EU declaration of incorporation, the manufacturer prepares a technical documentation, which the manufacturer should be required to make available to national authorities on request or to notified bodies in the frame of the relevant conformity assessment procedure. Detailed plans of subassemblies used for the manufacture of the product within the scope of this Regulation should only be required as part of the technical documentation where knowledge of such plans is essential for assessing conformity with the essential health and safety requirements set out in this Regulation.</p>	<p><del>(31)</del><sup>(24)</sup> It is essential that, before drawing up the <del>EU</del><sup>EUEG</sup> declaration of conformity <del>or the EU declaration of incorporation</del>, the manufacturer <del>prepares or his authorised representative established in the Community should prepare</del> a technical <del>construction file. However, it is not essential that all</del> documentation, <u>which the manufacturer should be required to make permanently available to national authorities in material form, but it must be possible to make it available on request or to notified bodies in the frame of the relevant conformity assessment procedure. Detailed.</u> <del>It need not include detailed</del> plans of subassemblies used for the manufacture of <u>the product within the scope of this Regulation should only be required as part of the technical documentation where</u> <del>machinery, unless</del> knowledge of such plans is essential <u>for assessing</u> <del>in order to ascertain</del> conformity with the essential health and safety requirements <u>set out in this Regulation.</u></p>	<p>(24) It is essential that, before drawing up the EC declaration of conformity, the manufacturer or his authorised representative established in the Community should prepare a technical construction file. However, it is not essential that all documentation should be permanently available in material form, but it must be possible to make it available on request. It need not include detailed plans of subassemblies used for the manufacture of machinery, unless knowledge of such plans is essential in order to ascertain conformity with the essential health and safety requirements.</p>
<p>Recital 31a</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>(31a) A person who manufactures machinery or related products for his or her own use is considered as a manufacturer and must fulfil all the related obligations. In that case, the machinery or related product is not placed on the market, since it is not made available by the manufacturer to another person but used by the manufacturer himself or herself. However, such machinery must comply with this Regulation before it is put into service.</p>	<p><u>(31a) A person who manufactures machinery or related products for his or her own use is considered as a manufacturer and must fulfil all the related obligations. In that case, the machinery or related product is not placed on the market, since it is not made available by the manufacturer to another person but used by the manufacturer himself or herself. However, such machinery must comply with this Regulation before it is put into service.</u></p>	
Recital 32		
<p>(32) It is necessary to ensure that products within the scope of this Regulation from third countries entering the Union market comply with the requirements of this Regulation and do not present a risk to the health and safety of persons, in particular consumers and professional users, where appropriate, domestic animals and property and, where applicable, the environment, and in particular, that appropriate conformity assessment procedures have been carried out by manufacturers with regard to such products. Provision should therefore be made for importers to ensure that products within the scope of this Regulation that they place on the market comply with the requirements of this Regulation and do not present a risk to the health and safety of persons, where appropriate, domestic animals and</p>	<p><u>(32) It is necessary to ensure that products within the scope of this Regulation from third countries entering the Union market comply with the requirements of this Regulation and do not present a risk to the health and safety of persons, in particular consumers and professional users, where appropriate, domestic animals and property and, where applicable, the environment, and in particular, that appropriate conformity assessment procedures have been carried out by manufacturers with regard to such products. Provision should therefore be made for importers to ensure that products within the scope of this Regulation that they place on the market comply with the requirements of this Regulation and do not present a risk to the health and safety of persons, where appropriate, domestic animals and</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>property and, where applicable, the environment. For the same reason, provision should also be made for importers to ensure that the conformity assessment procedures have been carried out and that the CE marking, in case of machinery and related products, is affixed and technical documentation drawn up by manufacturers is available for inspection by the competent national authorities.</p>	<p><u>property and, where applicable, the environment. For the same reason, provision should also be made for importers to ensure that the conformity assessment procedures have been carried out and that the CE marking, in case of machinery and related products, is affixed and technical documentation drawn up by manufacturers is available for inspection by the competent national authorities.</u></p>	
Recital 33		
<p>(33) As the distributor makes products within the scope of this Regulation available on the market after they have been placed on the market by the manufacturer or the importer, the distributor should act with due care to ensure that his or her handling of the product within the scope of this Regulation does not adversely affect its compliance with the requirements set out in this Regulation.</p>	<p><u>(33) As the distributor makes products within the scope of this Regulation available on the market after they have been placed on the market by the manufacturer or the importer, the distributor should act with due care to ensure that his or her handling of the product within the scope of this Regulation does not adversely affect its compliance with the requirements set out in this Regulation.</u></p>	
Recital 34		
<p>(34) When placing products within the scope of this Regulation on the market, the importer should indicate on these products his or her name, registered trade name or registered trade mark, website, email address or other digital contact and the postal address at which he or she can be contacted. Exceptions should be provided for in cases where the size or nature of the product does not</p>	<p><u>(34) When placing products within the scope of this Regulation on the market, the importer should indicate on these products his or her name, registered trade name or registered trade mark, website, email address or other digital contact and the postal address at which he or she can be contacted. Exceptions should be provided for in cases where the size or nature of the product does not</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>allow it. This includes cases where the importer would have to open the packaging to put his or her name and address on the product.</p>	<p><u>allow it. This includes cases where the importer would have to open the packaging to put his or her name and address on the product.</u></p>	
<p>Recital 35</p>		
<p>(35) In view of ensuring the health and safety of the users of products within the scope of this Regulation, economic operators should ensure that all relevant documentation, such as the instructions for use, whilst containing precise and comprehensible information, is easily understandable and available in a language which can be easily understood by users, as determined by the Member State concerned, takes into account technological developments and changes to user behaviour, and is as up to date as possible. When products within the scope of this Regulation are made available on the market in packages containing multiple units, the instructions and information should accompany the smallest commercially available unit.</p>	<p><u>(35) In view of ensuring the health and safety of the users of products within the scope of this Regulation, economic operators should ensure that all relevant documentation, such as the instructions for use, whilst containing precise and comprehensible information, is easily understandable and available in a language which can be easily understood by users, as determined by the Member State concerned, takes into account technological developments and changes to user behaviour, and is as up to date as possible. When products within the scope of this Regulation are made available on the market in packages containing multiple units, the instructions and information should accompany the smallest commercially available unit.</u></p>	
<p>Recital 35a</p>		
<p>(35a) Instructions and other relevant documentation may be provided in a digital printable format. However, the manufacturer should ensure that distributors can provide, upon request of the purchaser at the time of the purchase, the instructions for use in a paper format free of charge. The manufacturer should also consider</p>	<p><u>(35a) Instructions and other relevant documentation may be provided in a digital printable format. However, the manufacturer should ensure that distributors can provide, upon request of the purchaser at the time of the purchase, the instructions for use in a paper format free of charge. The manufacturer should also consider</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>providing the contact details where the purchaser can request the instructions to be dispatched by mail.</p>	<p><u>providing the contact details where the purchaser can request the instructions to be dispatched by mail.</u></p>	
Recital 36		
<p>(36) Any economic operator who either places a product within the scope of this Regulation on the market under his or her own name or trademark or modifies a product within the scope of this Regulation in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.</p>	<p><u>(36) Any economic operator who either places a product within the scope of this Regulation on the market under his or her own name or trademark or modifies a product within the scope of this Regulation in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.</u></p>	
Recital 37		
<p>(37) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the product within the scope of this Regulation concerned.</p>	<p><u>(37) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the product within the scope of this Regulation concerned.</u></p>	
Recital 38		
<p>(38) Ensuring traceability of products within the scope of this Regulation throughout the whole supply chain enables a simpler and more efficient market surveillance. The economic operators should therefore be required to keep the information on their transactions of products within the scope of this Regulation for a certain period of time.</p>	<p><u>(38) Ensuring traceability of products within the scope of this Regulation throughout the whole supply chain enables a simpler and more efficient market surveillance. The economic operators should therefore be required to keep the information on their transactions of products within the scope of this Regulation for a certain period of time.</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>However, that obligation should be proportionate to the role of each economic operator in the supply chain and the economic operators should not be required to update information that they have not produced.</p>	<p><u>However, that obligation should be proportionate to the role of each economic operator in the supply chain and the economic operators should not be required to update information that they have not produced.</u></p>	
<p>Recital 39</p>		
<p>(39) This Regulation should be limited to setting out the essential health and safety requirements, supplemented by a number of more specific requirements for certain categories of products within the scope of this Regulation. In order to facilitate the assessment of conformity with those health and safety requirements it is necessary to provide for a presumption of conformity for products within the scope of this Regulation which are in conformity with harmonised standards that are developed and which references are published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>1</sup> for the purpose of expressing detailed technical specifications of those requirements.</p>	<p><u>(39) This Regulation should be limited to setting out the essential health and safety requirements, supplemented by a number of more specific requirements for certain categories of products within the scope of this Regulation. In order to facilitate the assessment of conformity with those health and safety requirements it is necessary to provide for a presumption of conformity for products within the scope of this Regulation which are in conformity with harmonised standards that are developed and which references are published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>1</sup> for the purpose of expressing detailed technical specifications of those requirements.</u></p>	
<p>1. Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52),</p>	<p><u>1. Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52),</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).</p>	<p><u>95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).</u></p>	
<p>Recital 40</p>		
<p>(40) The current EU standardisation framework which is based on the New Approach principles and on Regulation (EU) No.1025/2012 represents the framework by default to elaborate standards that provide presumption of conformity with the relevant essential health and safety requirements of this Regulation. European standards should be market-driven, take into account the public interest, as well as the policy objectives clearly stated in the Commission’s request to one or more European standardisation organisations to draft harmonised standards, within a set deadline and be based on consensus. However, in the absence of relevant references to harmonised standards, the Commission should be able to establish, via implementing acts, common specifications for the essential health and safety requirements of this Regulation, provided that in doing so it duly respects the standardisation organisations’ role and functions, as an exceptional fall back</p>	<p><u>(40) The current EU standardisation framework which is based on the New Approach principles and on Regulation (EU) No.1025/2012 represents the framework by default to elaborate standards that provide presumption of conformity with the relevant essential health and safety requirements of this Regulation. European standards should be market-driven, take into account the public interest, as well as the policy objectives clearly stated in the Commission’s request to one or more European standardisation organisations to draft harmonised standards, within a set deadline and be based on consensus. However, in the absence of relevant references to harmonised standards, the Commission should be able to establish, via implementing acts, common specifications for the essential health and safety requirements of this Regulation, provided that in doing so it duly respects the standardisation organisations’ role and functions, as an exceptional fall back</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>solution to facilitate the manufacturer's obligation to comply with the health and safety requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards. If such delay is due to the technical complexity of the standard in question, this should be considered by the Commission before contemplating the establishment of common specifications.</p>	<p><u>solution to facilitate the manufacturer's obligation to comply with the health and safety requirements, when the standardisation process is blocked or when there are delays in the establishment of appropriate harmonised standards. If such delay is due to the technical complexity of the standard in question, this should be considered by the Commission before contemplating the establishment of common specifications.</u></p>	
<p>Recital 40a</p>		
<p>(40a) With a view to establishing, in the most efficient way, common specifications that cover the essential health and safety requirements of this Regulation, the Commission should involve relevant stakeholders in the process.</p>	<p><u>(40a) With a view to establishing, in the most efficient way, common specifications that cover the essential health and safety requirements of this Regulation, the Commission should involve relevant stakeholders in the process.</u></p>	
<p>Recital 40b</p>		
<p>(40b) Reasonable period should mean, in relation to the publication of reference to harmonised standards in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, a period of time in which the publication of reference to the standard, its corrigendum or amendment in the Official Journal of the European Union is expected and which should not exceed the period of 1 year after the deadline set in accordance with Article 10(1) of the Regulation (EU) 1025/2012.</p>	<p><u>(40b) Reasonable period should mean, in relation to the publication of reference to harmonised standards in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, a period of time in which the publication of reference to the standard, its corrigendum or amendment in the Official Journal of the European Union is expected and which should not exceed the period of 1 year after the deadline set in accordance with Article 10(1) of the Regulation (EU) 1025/2012.</u></p>	
<p>Recital 41</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>(41) Compliance with harmonised standards and with common specifications established by the Commission should be voluntary. Alternative technical solutions should therefore be acceptable where compliance of products within the scope of this Regulation with the relevant essential health and safety requirements is demonstrated in the technical file.</p>	<p><u>(41) Compliance with harmonised standards and with common specifications established by the Commission should be voluntary. Alternative technical solutions should therefore be acceptable where compliance of products within the scope of this Regulation with the relevant essential health and safety requirements is demonstrated in the technical file.</u></p>	
Recital 42		
<p>(42) The essential health and safety requirements should be satisfied in order to ensure that the product within the scope of this Regulation is safe. Those requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.</p>	<p><del>(42)</del><sup>14</sup> The essential health and safety requirements should be satisfied in order to ensure that <u>the product within the scope of this Regulation</u> <del>machinery</del> is safe. <del>Those</del>; <del>these</del> requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.</p>	<p>(14) The essential health and safety requirements should be satisfied in order to ensure that machinery is safe; these requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.</p>
Recital 43		
<p>(43) In view of addressing the risks stemming from malicious third party actions that have an impact on the safety of products within the scope of this Regulation, this Regulation should include essential health and safety requirements for which a presumption of conformity may be given to the appropriate extent by a certificate or statement of conformity issued under a relevant cybersecurity scheme adopted pursuant to and in accordance with Article 54(3) of</p>	<p><u>(43) In view of addressing the risks stemming from malicious third party actions that have an impact on the safety of products within the scope of this Regulation, this Regulation should include essential health and safety requirements for which a presumption of conformity may be given to the appropriate extent by a certificate or statement of conformity issued under a relevant cybersecurity scheme adopted pursuant to and in accordance with Article 54(3) of</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Regulation (EU) 2019/881 of the European Parliament and of the Council <sup>1</sup> .	<u>Regulation (EU) 2019/881 of the European Parliament and of the Council<sup>1</sup>.</u>	
1. Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).	<u>1. Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).</u>	
Recital 44		
(44) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not satisfy or entirely satisfy the requirements of this Regulation.	<u>(44) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not satisfy or entirely satisfy the requirements of this Regulation.</u>	
Recital 45		
DELETED - see 46b	DELETED - see 46b	
Recital 46		
(46) Manufacturers should draw up an EU declaration of conformity to provide information on the conformity of machinery or related products with this Regulation. Manufacturers may also be required to draw up an EU declaration of conformity by other Union legislation. To ensure effective access to information for market surveillance purposes, a single EU declaration of conformity should be drawn up in respect of all Union acts. In order to reduce the administrative burden	<u>(46) Manufacturers should draw up an EU declaration of conformity to provide information on the conformity of machinery or related products with this Regulation. Manufacturers may also be required to draw up an EU declaration of conformity by other Union legislation. To ensure effective access to information for market surveillance purposes, a single EU declaration of conformity should be drawn up in respect of all Union acts. In order to reduce the administrative burden</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.</p>	<p><u>on economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.</u></p>	
<p>Recital 46a</p>		
<p>(46a) The harmonised standards relevant to this Regulation should take into account the requirements of Directive (EU) 2019/882 (European Accessibility Act) and the United Nations Convention on the Rights of Persons with Disabilities<sup>1</sup>.</p>	<p><u>(46a) The harmonised standards relevant to this Regulation should take into account the requirements of Directive (EU) 2019/882 (European Accessibility Act) and the United Nations Convention on the Rights of Persons with Disabilities<sup>1</sup>.</u></p>	
<p>1. OJ L 23, 27.1.2010, p. 35.</p>	<p><u>1. OJ L 23, 27.1.2010, p. 35.</u></p>	
<p>Recital 46b</p>		
<p>(46b) The list of products in Annex IV of Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of those products or their critical protective function. Nevertheless, the machinery field embraces new ways of designing and constructing machinery or related products that may present higher risk factors, regardless of such intended use or any reasonably foreseeable misuse. For example, systems with self evolving behavior ensuring safety functions, should be included in Annex I due to their characteristics such as data dependency, opacity, autonomy and connectivity, which might considerably increase the probability and severity of harm and</p>	<p><u>(46b) The list of products in Annex IV of Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of those products or their critical protective function. Nevertheless, the machinery field embraces new ways of designing and constructing machinery or related products that may present higher risk factors, regardless of such intended use or any reasonably foreseeable misuse. For example, systems with self evolving behavior ensuring safety functions, should be included in Annex I due to their characteristics such as data dependency, opacity, autonomy and connectivity, which might considerably increase the probability and severity of harm and</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>seriously affect the safety of the machinery or related product. Therefore, the conformity assessment of a safety components or a system with self evolving behavior ensuring safety functions should be carried out by a third party, whether or not the safety component has been placed independently on the market or is part of a system embedded in machinery that is placed on the market. However, machinery that embeds a system where the safety component has already been subject to third party conformity assessment when it was placed independently on the market should not have to be re-certified by a third party solely on the basis of it embedding that system.</p>	<p><u>seriously affect the safety of the machinery or related product. Therefore, the conformity assessment of a safety components or a system with self evolving behavior ensuring safety functions should be carried out by a third party, whether or not the safety component has been placed independently on the market or is part of a system embedded in machinery that is placed on the market. However, machinery that embeds a system where the safety component has already been subject to third party conformity assessment when it was placed independently on the market should not have to be re-certified by a third party solely on the basis of it embedding that system.</u></p>	
<p>Recital 46c</p>		
<p>(46c) Provisions related to the third-party conformity assessment of software ensuring safety functions set out in this Regulation should only apply to systems with a fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions. On the contrary, those provisions should not apply to software incapable of learning or evolving, and programmed only to execute certain automated functions of machinery or related products.</p>	<p><u>(46c) Provisions related to the third-party conformity assessment of software ensuring safety functions set out in this Regulation should only apply to systems with a fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions. On the contrary, those provisions should not apply to software incapable of learning or evolving, and programmed only to execute certain automated functions of machinery or related products.</u></p>	
<p>Recital 47</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>(47) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on machinery or related products should be laid down in this Regulation.</p>	<p><u>(47) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on machinery or related products should be laid down in this Regulation.</u></p>	
<p>Recital 48</p>		
<p>(48) The CE marking should be the only marking, which guarantees that machinery or related products comply with the requirements of this Regulation. Member States should therefore take appropriate action as regards other markings which are likely to mislead third parties as to the meaning or the form of the CE marking.</p>	<p><del>(48<sup>24</sup>)</del> The CE marking should be <b>fully recognised as being</b> the only marking, which guarantees that machinery <u>or related products comply with</u> <del>conforms to</del> the requirements of this Regulation. <u>Member States should therefore take appropriate action as regards</u> <del>Directive.</del> <b>All other markings which are likely to mislead third parties as to the meaning or the form of the CE marking, or both, should be prohibited.</b></p>	<p>(21) The CE marking should be fully recognised as being the only marking which guarantees that machinery conforms to the requirements of this Directive. All other markings which are likely to mislead third parties as to the meaning or the form of the CE marking, or both, should be prohibited.</p>
<p>Recital 49</p>		
<p>(49) In order to enable economic operators to demonstrate and the competent authorities to ensure that machinery or related products made available on the market are in conformity with the essential health and safety requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures</p>	<p><u>(49) In order to enable economic operators to demonstrate and the competent authorities to ensure that machinery or related products made available on the market are in conformity with the essential health and safety requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.</p>	<p><u>from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.</u></p>	
Recital 50		
<p>(50) Manufacturers should be responsible for ensuring that a conformity assessment is carried out in respect of their machinery or related products in accordance with this Regulation. Nevertheless, for certain categories of machinery or related products that have a higher risk factor, a stricter conformity assessment procedure requiring the participation of a notified body should be required.</p>	<p><u>(50) Manufacturers should be responsible for ensuring that a conformity assessment is carried out in respect of their machinery or related products in accordance with this Regulation. Nevertheless, for certain categories of machinery or related products that have a higher risk factor, a stricter conformity assessment procedure requiring the participation of a notified body should be required.</u></p>	
Recital 51		
<p>(51) It is essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.</p>	<p><u>(51) It is essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.</u></p>	
Recital 52		
<p>(52) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.</p>	<p><u>(52) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Recital 53</p> <p>(53) In order to ensure a consistent level of quality in the performance of conformity assessment of machinery or related products, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.</p>	<p><u>(53) In order to ensure a consistent level of quality in the performance of conformity assessment of machinery or related products, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.</u></p>	
<p>Recital 54</p> <p>(54) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.</p>	<p><u>(54) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.</u></p>	
<p>Recital 55</p> <p>(55) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by</p>	<p><u>(55) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.</p>	<p><u>other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.</u></p>	
Recital 56		
<p>(56) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the machinery to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries.</p>	<p><u>(56) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the machinery to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries.</u></p>	
Recital 57		
<p>(57) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during</p>	<p><u>(57) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.</p>	<p><u>which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.</u></p>	
<p>Recital 58</p>		
<p>(58) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.</p>	<p><u>(58) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.</u></p>	
<p>Recital 59</p>		<p>Recital 9</p>
<p>(59) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of Union legislation. It is therefore appropriate to put in place a legal framework within which market surveillance can be carried out in an appropriate manner.</p>	<p><del>(59)</del> Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of <u>Union legislation</u>. <del>Directives</del>. It is therefore appropriate to put in place <del>a</del>the legal framework within which market surveillance can <u>be carried out in an appropriate manner</u> <del>proceed harmoniously</del>.</p>	<p>(9) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of Directives. It is therefore appropriate to put in place the legal framework within which market surveillance can proceed harmoniously.</p>
<p>Recital 60</p>		<p>Article 4, point 1</p>
<p>(60) Member States should take all appropriate measures to ensure that machinery within the scope of this Regulation may be placed on the market or put into service only if, when properly installed and used for its intended</p>	<p><del>(60)</del>1- Member States <del>should</del><b>shall</b> take all appropriate measures to ensure that machinery <u>within the scope of this Regulation</u> may be placed on the market <del>and</del>/or put into service only if, <u>when properly installed and used for its</u></p>	<p>1. Member States shall take all appropriate measures to ensure that machinery may be placed on the market and/or put into service only if it satisfies the relevant provisions of this Directive and does not endanger the health and</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons, in particular consumers and professional users, and, where appropriate, domestic animals and property and, where applicable, the environment. In particular, the proper installation of lifting machinery is essential to ensure the compliance with applicable essential health and safety requirements. Machinery within the scope of this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use, which could result from lawful and readily predictable human behaviour.</p>	<p><u>intended purpose, or under conditions of use which can be reasonably foreseen, it satisfies the relevant provisions of this Directive</u> and does not endanger the health <del>or</del> safety of persons, <u>in particular consumers and professional users,</u> and, where appropriate, domestic animals and property and, where applicable, the environment. <u>In particular, the proper installation of lifting machinery is essential to ensure the compliance with applicable essential health and safety requirements. Machinery within the scope of this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use, which could result from lawful and readily predictable human behaviour;</u> <del>when properly installed and maintained and used for its intended purpose or under reasonably foreseeable conditions.</del></p>	<p>safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, when properly installed and maintained and used for its intended purpose or under reasonably foreseeable conditions.</p>
		Article 4, point 2
	<p><del>2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of this Directive.</del></p>	<p>2. Member States shall take all appropriate measures to ensure that partly completed machinery can be placed on the market only if it satisfies the relevant provisions of this Directive.</p>
		Article 4, point 3
	<p><del>3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery and partly completed machinery with the provisions set out in paragraphs 1 and 2.</del></p>	<p>3. Member States shall institute or appoint the competent authorities to monitor the conformity of machinery and partly completed machinery with the provisions set out in paragraphs 1 and 2.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>4. Member States shall define the tasks, organisation and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment.</del></p>	<p>Article 4, point 4 4. Member States shall define the tasks, organisation and powers of the competent authorities referred to in paragraph 3 and shall notify the Commission and other Member States thereof and also of any subsequent amendment.</p>
<p>Recital 61 (61) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on products within the scope of this Regulation and the safeguard clause relating to products within the scope of this Regulation.</p>	<p><del>(61)</del> (11) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on <u>products within the scope of this Regulation</u> <del>machinery</del> and the safeguard clause relating to <u>products within the scope of this Regulation</u> <del>machinery</del>.</p>	<p>(11) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on machinery and the safeguard clause relating to machinery.</p>
<p>Recital 62 (62) Directive 2006/42/EC already provides for a safeguard procedure, which is necessary to allow for the possibility of contesting the conformity of products within the scope of this Regulation. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.</p>	<p><u>(62) Directive 2006/42/EC already provides for a safeguard procedure, which is necessary to allow for the possibility of contesting the conformity of products within the scope of this Regulation. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.</u></p>	
<p>Recital 63 (63) The existing safeguard procedure should be supplemented by a procedure</p>	<p><u>(63) The existing safeguard procedure should be supplemented by a procedure</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>under which interested parties are informed of measures intended to be taken with regard to products within the scope of this Regulation posing a risk to the health or safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment. It should allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such products.</p>	<p><u>under which interested parties are informed of measures intended to be taken with regard to products within the scope of this Regulation posing a risk to the health or safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment. It should allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such products.</u></p>	
<p>Recital 64</p>		
<p>(64) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.</p>	<p><u>(64) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.</u></p>	
<p>Recital 65</p>		
<p>(65) In order to take into account technical progress and knowledge or new scientific evidence and to ensure a sufficient level of data availability, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the list of machinery and related products and the indicative list of safety components in Annex I and Annex II, and if necessary of supplementing the obligations of Member</p>	<p><u>(65) In order to take into account technical progress and knowledge or new scientific evidence and to ensure a sufficient level of data availability, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the list of machinery and related products and the indicative list of safety components in Annex I and Annex II, and if necessary of supplementing the obligations of Member</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>States to communicate information on the categories of machinery and related products which are subject to a specific conformity assessment procedure through the establishment of a common methodology. Where a new machinery or related product is added to the list in Annex I, the Commission should ensure that economic operators are provided with sufficient time to comply with their obligations under this Regulation. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including the stakeholders concerned. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.</p>	<p><u>States to communicate information on the categories of machinery and related products which are subject to a specific conformity assessment procedure through the establishment of a common methodology. Where a new machinery or related product is added to the list in Annex I, the Commission should ensure that economic operators are provided with sufficient time to comply with their obligations under this Regulation. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including the stakeholders concerned. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.</u></p>	
<p>Recital 66</p>		
<p>(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission establishing a uniform template for the collection of data and information for the purpose of adding a category of machinery or related product to Annex I or withdrawing a category of machinery or related product from Annex I, and establishing common specifications for the essential health and safety</p>	<p><u>(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission establishing a uniform template for the collection of data and information for the purpose of adding a category of machinery or related product to Annex I or withdrawing a category of machinery or related product from Annex I, and establishing common specifications for the essential health and safety</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>requirements, requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet the requirements for its notification and establishing whether a national measure in respect of compliant machinery which a Member State finds to pose a risk to health and safety of persons, in particular consumers and professional users is justified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>1</sup></p>	<p><u>requirements, requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet the requirements for its notification and establishing whether a national measure in respect of compliant machinery which a Member State finds to pose a risk to health and safety of persons, in particular consumers and professional users is justified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>1</sup></u></p>	
<p>75a) In order to facilitate the proper implementation of this Regulation, when adopting the implementing acts setting out and updating a template concerning the collection of the data and the information by the Member States on accidents or damage to health caused by machinery or related products, the Commission should adopt a guidance regarding the collection and transmission of comparable, high-quality data and information.</p>	<p><u>75a) In order to facilitate the proper implementation of this Regulation, when adopting the implementing acts setting out and updating a template concerning the collection of the data and the information by the Member States on accidents or damage to health caused by machinery or related products, the Commission should adopt a guidance regarding the collection and transmission of comparable, high-quality data and information.</u></p>	
<p>1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of</p>	<p><u>1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
implementing powers (OJ L 55, 28.2.2011, p. 13).	<u>implementing powers (OJ L 55, 28.2.2011, p. 13).</u>	
Recital 67		
(67) The Commission should adopt immediately applicable implementing acts determining whether a national measure taken in respect of compliant products within the scope of this Regulation that poses a risk is justified or not where, in duly justified cases relating to the protection of the health or safety of persons, imperative grounds of urgency so require.	<u>(67) The Commission should adopt immediately applicable implementing acts determining whether a national measure taken in respect of compliant products within the scope of this Regulation that poses a risk is justified or not where, in duly justified cases relating to the protection of the health or safety of persons, imperative grounds of urgency so require.</u>	
Recital 68		
(68) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.	<u>(68) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.</u>	
Recital 69		
(69) When matters relating to this Regulation, other than its implementation or infringements, are being examined in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.	<u>(69) When matters relating to this Regulation, other than its implementation or infringements, are being examined in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.</u>	
Recital 70		
(70) The Commission should, by means of implementing acts and, given their special nature, acting without the	<u>(70) The Commission should, by means of implementing acts and, given their special nature, acting without the</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant products within the scope of this Regulation are justified or not.	<u>application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant products within the scope of this Regulation are justified or not.</u>	
Recital 71		
(71) The traceability of machinery data required for the technical file and for market surveillance purposes, must comply with confidentiality rules to protect manufacturers.	<u>(71) The traceability of machinery data required for the technical file and for market surveillance purposes, must comply with confidentiality rules to protect manufacturers.</u>	
Recital 72		
(72) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.	<del>(72)</del> Member States should <u>lay down rules on</u> <del>provide for</del> penalties applicable to infringements of <del>the provisions of</del> this Regulation and ensure that those rules are enforced. <del>The Directive. Those</del> penalties <u>provided for</u> should be effective, proportionate and dissuasive.	(26) Member States should provide for penalties applicable to infringements of the provisions of this Directive. Those penalties should be effective, proportionate and dissuasive.
Recital 73		
(73) Since the objective of this Regulation, namely to ensure that products within the scope of this Regulation placed on the market fulfils the requirements providing for a high level of protection of health and safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment, while guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of the need for harmonisation , be better achieved at	<del>(73)</del> Since the objective of this Regulation <del>Directive</del> , namely; to <u>ensure that products within</u> <del>lay down the scope</del> <del>essential health and safety requirements in relation to design and manufacture in order to improve the safety of this Regulation</del> <del>machinery</del> placed on the market <u>fulfils the requirements providing for a high level of protection of health and safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment, while guaranteeing the functioning of the internal market, cannot</u>	(28) Since the objective of this Directive, namely, to lay down the essential health and safety requirements in relation to design and manufacture in order to improve the safety of machinery placed on the market, cannot be sufficiently achieved by the Member States and can be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Union level, the Union may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.</p>	<p>be sufficiently achieved by the Member States, <del>but and</del> can rather, by reason of the need for harmonisation, be better achieved at <u>UnionCommunity</u> level, the <u>UnionCommunity</u> may adopt measures, in accordance with the principle of subsidiarity <del>as</del> set out in Article 5 of the Treaty <u>on European Union.</u> In accordance with the principle of proportionality, as set out in that Article, this <u>RegulationDirective</u> does not go beyond what is necessary in order to achieve that objective.</p>	<p>what is necessary in order to achieve that objective.</p>
<p>Recital 74</p>		
<p>(74) Council Directive 73/361/EEC1 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire-ropes, chains and hooks should be repealed as Directive 2006/42/EC took over its scope by including machinery or lifting accessories and chains and ropes.</p>	<p><u>(74) Council Directive 73/361/EEC1 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire-ropes, chains and hooks should be repealed as Directive 2006/42/EC took over its scope by including machinery or lifting accessories and chains and ropes.</u></p>	
<p>1. Council Directive 73/361/EEC of 19 November 1973 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire-ropes, chains and hooks (OJ L 335, 5.12.1973, p. 51–55).</p>	<p><u>1. Council Directive 73/361/EEC of 19 November 1973 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire-ropes, chains and hooks (OJ L 335, 5.12.1973, p. 51–55).</u></p>	
<p>Recital 75</p>		
<p>(75) Directive 2006/42/EC has been amended several times. Since further</p>	<p><u>(75) Directive 2006/42/EC has been amended several times. Since further</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>substantial amendments are needed, and in order to ensure a uniform implementation of the rules on products within the scope of this Regulation throughout the Union, Directive 2006/42/EC should be repealed.</p>	<p><u>substantial amendments are needed, and in order to ensure a uniform implementation of the rules on products within the scope of this Regulation throughout the Union, Directive 2006/42/EC should be repealed.</u></p>	
<p>Recital 76</p>		
<p>(76) It is necessary to provide for sufficient time for economic operators to comply with their obligations under this Regulation, and for Member States to set up the administrative infrastructure necessary for its application. The application of this Regulation should therefore be deferred,</p>	<p><u>(76) It is necessary to provide for sufficient time for economic operators to comply with their obligations under this Regulation, and for Member States to set up the administrative infrastructure necessary for its application. The application of this Regulation should therefore be deferred,</u></p>	
	<p><del>(5) The Member States' mandatory provisions governing construction site hoists intended for lifting persons or persons and goods, which are often supplemented by de facto compulsory technical specifications and/or by voluntary standards, do not necessarily lead to different levels of health and safety but, because of their disparities, do nevertheless constitute barriers to trade within the Community. Moreover, the national systems for the conformity assessment and certification of these machines diverge considerably. It is therefore desirable not to exclude from the scope of this Directive construction site hoists intended for lifting persons or persons and goods.</del></p>	<p>(5) The Member States' mandatory provisions governing construction site hoists intended for lifting persons or persons and goods, which are often supplemented by de facto compulsory technical specifications and/or by voluntary standards, do not necessarily lead to different levels of health and safety but, because of their disparities, do nevertheless constitute barriers to trade within the Community. Moreover, the national systems for the conformity assessment and certification of these machines diverge considerably. It is therefore desirable not to exclude from the scope of this Directive construction site hoists intended for lifting persons or persons and goods.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>(7) This Directive does not apply to the lifting of persons by means of machines not designed for the lifting of persons. However, this does not affect the right of Member States to take national measures, in accordance with the Treaty, with respect to such machines, with a view to implementing Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).</del></p>	<p>(7) This Directive does not apply to the lifting of persons by means of machines not designed for the lifting of persons. However, this does not affect the right of Member States to take national measures, in accordance with the Treaty, with respect to such machines, with a view to implementing Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC).</p>
	<p><del>(8) In relation to agricultural and forestry tractors, the provisions of this Directive concerning the risks currently not covered by Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units should no longer apply when such risks are covered by Directive 2003/37/EC.</del></p>	<p>(8) In relation to agricultural and forestry tractors, the provisions of this Directive concerning the risks currently not covered by Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units should no longer apply when such risks are covered by Directive 2003/37/EC.</p>
	<p><del>(12) The putting into service of machinery within the meaning of this Directive can relate only to the use of the machinery itself for its intended purpose or for a purpose which can reasonably be foreseen. This does not preclude the laying down of conditions of use external to the machinery, provided that it is not</del></p>	<p>(12) The putting into service of machinery within the meaning of this Directive can relate only to the use of the machinery itself for its intended purpose or for a purpose which can reasonably be foreseen. This does not preclude the laying down of conditions of use external to the machinery, provided that it is not</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>thereby modified in a way not specified in this Directive.</del></p>	<p>thereby modified in a way not specified in this Directive.</p>
	<p><del>(13) It is also necessary to provide for an adequate mechanism allowing for the adoption of specific measures at Community level requiring Member States to prohibit or restrict the placing on the market of certain types of machinery presenting the same risks to the health and safety of persons either due to shortcomings in the relevant harmonised standard(s) or by virtue of their technical characteristics, or to make such machinery subject to special conditions. In order to ensure the appropriate assessment of the need for such measures, they should be taken by the Commission, assisted by a committee, in the light of consultations with the Member States and other interested parties. Since such measures are not directly applicable to economic operators, Member States should take all necessary measures for their implementation.</del></p>	<p>(13) It is also necessary to provide for an adequate mechanism allowing for the adoption of specific measures at Community level requiring Member States to prohibit or restrict the placing on the market of certain types of machinery presenting the same risks to the health and safety of persons either due to shortcomings in the relevant harmonised standard(s) or by virtue of their technical characteristics, or to make such machinery subject to special conditions. In order to ensure the appropriate assessment of the need for such measures, they should be taken by the Commission, assisted by a committee, in the light of consultations with the Member States and other interested parties. Since such measures are not directly applicable to economic operators, Member States should take all necessary measures for their implementation.</p>
	<p><del>(18) This Directive defines only the essential health and safety requirements of general application, supplemented by a number of more specific requirements for certain categories of machinery. In order to help manufacturers to prove conformity to these essential requirements, and to allow inspection of conformity to the essential requirements,</del></p>	<p>(18) This Directive defines only the essential health and safety requirements of general application, supplemented by a number of more specific requirements for certain categories of machinery. In order to help manufacturers to prove conformity to these essential requirements, and to allow inspection of conformity to the essential requirements,</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>it is desirable to have standards that are harmonised at Community level for the prevention of risks arising out of the design and construction of machinery. These standards are drawn up by private-law bodies and should retain their non-binding status.</del></p>	<p>it is desirable to have standards that are harmonised at Community level for the prevention of risks arising out of the design and construction of machinery. These standards are drawn up by private-law bodies and should retain their non-binding status.</p>
	<p><del>(22) In order to ensure the same quality for the CE marking and the manufacturer's mark, it is important that they be affixed according to the same techniques. In order to avoid confusion between any CE markings which might appear on certain components and the CE marking corresponding to the machinery, it is important that the latter marking be affixed alongside the name of the person who has taken responsibility for it, namely the manufacturer or his authorised representative.</del></p>	<p>(22) In order to ensure the same quality for the CE marking and the manufacturer's mark, it is important that they be affixed according to the same techniques. In order to avoid confusion between any CE markings which might appear on certain components and the CE marking corresponding to the machinery, it is important that the latter marking be affixed alongside the name of the person who has taken responsibility for it, namely the manufacturer or his authorised representative.</p>
	<p><del>(25) The addressees of any decision taken under this Directive should be informed of the reasons for such a decision and of the legal remedies open to them.</del></p>	<p>(25) The addressees of any decision taken under this Directive should be informed of the reasons for such a decision and of the legal remedies open to them.</p>
	<p><del>(10) Member States are responsible for ensuring that this Directive is effectively enforced on their territory and that the safety of the machinery concerned is, as far as possible, improved in accordance with its provisions. Member States should ensure their capacity to carry out effective market surveillance, taking account of guidelines developed by the</del></p>	<p>(10) Member States are responsible for ensuring that this Directive is effectively enforced on their territory and that the safety of the machinery concerned is, as far as possible, improved in accordance with its provisions. Member States should ensure their capacity to carry out effective market surveillance, taking account of guidelines developed by the</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>Commission, in order to achieve the proper and uniform application of this Directive.</del>	Commission, in order to achieve the proper and uniform application of this Directive.
	<del>(27) The application of this Directive to a number of machines intended for lifting persons requires a better delimitation of the products covered by this Directive with respect to those covered by Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts. A redefinition of the scope of the latter Directive is thus deemed necessary. Directive 95/16/EC should therefore be amended accordingly.</del>	(27) The application of this Directive to a number of machines intended for lifting persons requires a better delimitation of the products covered by this Directive with respect to those covered by Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts. A redefinition of the scope of the latter Directive is thus deemed necessary. Directive 95/16/EC should therefore be amended accordingly.
	<del>(29) In accordance with point 34 of the Interinstitutional Agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.</del>	(29) In accordance with point 34 of the Interinstitutional Agreement on better law-making, Member States are encouraged to draw up, for themselves and in the interests of the Community, their own tables illustrating, as far as possible, the correlation between this Directive and the transposition measures, and to make them public.
	<del>(30) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission</del>	(30) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission
Formula		
HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	

## Chapter 1: General Provisions

DRAFT Machinery Regulation	Comparison	Machinery Directive
CHAPTER I		
GENERAL PROVISIONS	<u>GENERAL PROVISIONS</u>	
Article 1		
Article 1	Article 1	
Subject matter	<u>Subject matter</u>	
Article 1, first paragraph		
This Regulation lays down health and safety requirements for the design and construction of machinery, related products and partly completed machinery to allow their making available on the market or putting into service while ensuring a high level of protection of the health and safety of persons, in particular consumers and professional users, and, where appropriate, domestic animals and property and, where applicable, the environment. It also establishes rules on the free movement of these products in the Union.	<u>This Regulation lays down health and safety requirements for the design and construction of machinery, related products and partly completed machinery to allow their making available on the market or putting into service while ensuring a high level of protection of the health and safety of persons, in particular consumers and professional users, and, where appropriate, domestic animals and property and, where applicable, the environment. It also establishes rules on the free movement of these products in the Union.</u>	
Article 2		Article 1
Article 2	Article <del>2</del> 4	Article 1
Scope	Scope	Scope
Article 2(1), introductory part		Article 1(1), introductory part
(1) This Regulation applies to machinery and the following related products	<u>(1)- This Regulation</u> <del>Directive</del> applies to <u>machinery and the following related products</u> :	1. This Directive applies to the following products:
Article 2(1), introductory part		Article 2, first paragraph, introductory part
(1) This Regulation applies to machinery and the following related products	<u>(1) This Regulation applies to machinery and the following related products</u> <del>For the purposes of this Directive, 'machinery'</del>	For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f).

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>designates the products listed in Article 1(1)(a) to (f).</del>	
Article 2(1), point (a)		Article 1(1), point (a)
(a) deleted	(a) <del>deleted</del> <del>machinery</del> ;	(a) machinery;
Article 2(1), point (b)		Article 1(1), point (b)
(b) interchangeable equipment;	(b) interchangeable equipment;	(b) interchangeable equipment;
Article 2(1), point (c)		Article 1(1), point (c)
(c) safety components;	(c) safety components;	(c) safety components;
Article 2(1), point (d)		Article 1(1), point (d)
(d) lifting accessories;	(d) lifting accessories;	(d) lifting accessories;
Article 2(1), point (e)		Article 1(1), point (e)
(e) chains, ropes and webbing;	(e) chains, ropes and webbing;	(e) chains, ropes and webbing;
Article 2(1), point (f)		Article 1(1), point (f)
(f) removable mechanical transmission devices;	(f) removable mechanical transmission devices;	(f) removable mechanical transmission devices;
Article 2(1), unnumbered paragraph		Article 1(1), point (g)
This Regulation also applies to partly completed machinery.	<u>This Regulation also applies to</u> <del>(g)</del> partly completed machinery.	(g) partly completed machinery.
Article 2(2), introductory part		Article 1(2), introductory part
(2) This Regulation does not apply to:	<u>(2) This Regulation does not apply to:</u> <del>The following are excluded from the scope of this Directive:</del>	The following are excluded from the scope of this Directive:
Article 2(2), point (a)		Article 1(2), point (a)
(a) safety components that are intended to be used as spare parts to replace identical components and are supplied by the manufacturer of the original machinery, related product or partly completed machinery;	(a) safety components <u>that are</u> intended to be used as spare parts to replace identical components and <u>are</u> supplied by the manufacturer of the original machinery, <u>related product or partly completed machinery</u> ;	(a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;
Article 2(2), point (b)		Article 1(2), point (b)
(b) specific equipment for use in fairgrounds or amusement parks;	(b) specific equipment for use in fairgrounds <del>and</del> /or amusement parks;	(b) specific equipment for use in fairgrounds and/or amusement parks;
Article 2(2), point (c)		Article 1(2), point (c)

DRAFT Machinery Regulation	Comparison	Machinery Directive
(c) machinery and related products specially designed for use within or used in a nuclear installation and whose conformity with this Regulation may undermine the nuclear safety;	(c) machinery <u>and related products specially designed or put into service for use within or used in a nuclear installation and whose conformity with this Regulation</u> <del>purposes which, in the event of failure,</del> may <u>undermine the nuclear safety</u> <del>result in an emission of radioactivity;</del>	(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;
Article 2(2), point (d)		Article 1(2), point (d)
(d) weapons, including firearms;	(d) weapons, including firearms;	(d) weapons, including firearms;
Article 2(2), point (e)		Article 1(2), point (e), dash 5
(e) means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport;	<del>(e)</del> <u>(e) the following means of transport:</u> — means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport;	(e) the following means of transport: — means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport
Article 2(2), point (ea)		
(ea) aeronautical products, parts and equipment that fall within the scope of application of Regulation (EU) 2018/1139 and the definition of machinery under this Regulation, as far as in as much as Regulation (EU) 2018/1139 covers the relevant health and safety requirements set out in this Regulation;	<u>(ea) aeronautical products, parts and equipment that fall within the scope of application of Regulation (EU) 2018/1139 and the definition of machinery under this Regulation, as far as in as much as Regulation (EU) 2018/1139 covers the relevant health and safety requirements set out in this Regulation;</u>	
Article 2(2), point (ea)		Article 1(2), point (e), dash 2
(eb) motor vehicles and their trailers, as well as systems, components and separate technical units, parts and equipment designed and constructed for such vehicles, which fall within the scope of application of Regulation (EU) 2018/858, except for machinery mounted on those vehicles;	<del>(eb)</del> <u>(e) the following means of transport:</u> — motor vehicles and their trailers, <u>as well as systems, components and separate technical units, parts and equipment designed and constructed for such</u> <del>covered by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member</del>	(e) the following means of transport: — motor vehicles and their trailers covered by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers, with the exclusion of machinery mounted on these vehicles,

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>States relating to the type approval of motor vehicles, which fall within the scope of application of Regulation (EU) 2018/858, except for and their trailers, with the exclusion of machinery mounted on those these vehicles;</del></p>	
Article 2(2), point (f)		Article 1(2), point (e), dash 3
<p>(f) two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, that fall within the scope of application of Regulation (EU) No 168/2013, except for machinery mounted on those vehicles;</p>	<p><del>(f) e) the following means of transport: — vehicles covered by Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type approval of two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such motor vehicles, that fall within the scope of application of Regulation (EU) No 168/2013, except for with the exclusion of machinery mounted on those these vehicles;</del></p>	<p>(e) the following means of transport: — vehicles covered by Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles, with the exclusion of machinery mounted on these vehicles,</p>
Article 2(2), point (g)		Article 1(2), point (e), dash 1
<p>(g) agricultural and forestry tractors, as well as systems, components, separate technical units, parts and equipment designed and constructed for such tractors, that fall within the scope of application of Regulation (EU) No 167/2013 with the exception of machinery mounted on those tractors;</p>	<p><del>(g) e) the following means of transport: — agricultural and forestry tractors, as well as systems, components, separate technical units, parts and equipment designed and constructed for such tractors, that fall within the scope of application of Regulation (EU) No 167/2013 with the exception exclusion of machinery mounted on those tractors; vehicles</del></p>	<p>(e) the following means of transport: — agricultural and forestry tractors, with the exclusion of machinery mounted on those vehicles</p>
Article 2(2), point (ga)		Article 1(2), point (e), dash 4

DRAFT Machinery Regulation	Comparison	Machinery Directive
(ga) motor vehicles exclusively intended for competition;	<del>(ga)</del> <del>e) the following means of transport:</del> — motor vehicles exclusively intended for competition;	(e) the following means of transport: — motor vehicles exclusively intended for competition
Article 2(2), point (h)		Article 1(2), point (f)
(h) seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;	<del>(hf)</del> seagoing vessels and mobile offshore units and machinery installed on board such vessels <del>and/or</del> units;	(f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;
Article 2(2), point (i)		Article 1(2), point (g)
(i) machinery or related products specially designed and constructed for military or police purposes;	<del>(ig)</del> machinery <del>or related products</del> specially designed and constructed for military or police purposes;	(g) machinery specially designed and constructed for military or police purposes;
Article 2(2), point (j)		Article 1(2), point (h)
(j) machinery or related products specially designed and constructed for research purposes for temporary use in laboratories;	<del>(jh)</del> machinery <del>or related products</del> specially designed and constructed for research purposes for temporary use in laboratories;	(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;
Article 2(2), point (k)		Article 1(2), point (i)
(k) mine winding gear;	<del>(ki)</del> mine winding gear;	(i) mine winding gear;
Article 2(2), point (l)		Article 1(2), point (j)
(l) machinery or related products intended to move performers during artistic performances;	<del>(lj)</del> machinery <del>or related products</del> intended to move performers during artistic performances;	(j) machinery intended to move performers during artistic performances;
Article 2(2), point (m), introductory part		Article 1(2), point (k)
(m) the following electrical and electronic products, insofar as they fall within the scope of application of Directive 2014/35/EU or Directive 2014/53/EU :	<del>(m) the following <del>k)</del> electrical and electronic products <del>falling within the following areas</del>, insofar as they <del>fall within the scope of application of <del>are covered by Council</del> Directive 2014/35/EU or Directive 2014/53/EU :73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits</del></del>	(k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 2(2), point (m)(i) (i) household appliances intended for domestic use which are not electrically operated furniture;	<u>(i)</u> — household appliances intended for domestic use <u>which are not electrically operated furniture</u> ;	Article 1(2), point (k), dash 1 — household appliances intended for domestic use
Article 2(2), point (m)(ii) (ii) audio and video equipment;	<u>(ii)</u> — audio and video equipment;	Article 1(2), point (k), dash 2 — audio and video equipment
Article 2(2), point (m)(iii) (iii) information technology equipment;	<u>(iii)</u> — information technology equipment;	Article 1(2), point (k), dash 3 — information technology equipment
Article 2(2), point (m)(iv) (iv) ordinary office machinery, except additive printing machinery for producing three-dimensional products;	<u>(iv)</u> — ordinary office machinery, <u>except additive printing machinery for producing three-dimensional products</u> ;	Article 1(2), point (k), dash 4 — ordinary office machinery
Article 2(2), point (m)(v) (v) low-voltage switchgear and control gear;	<u>(v)</u> — low-voltage switchgear and control gear;	Article 1(2), point (k), dash 5 — low-voltage switchgear and control gear
Article 2(2), point (m)(vi) (vi) electric motors;	<u>(vi)</u> — electric motors;	Article 1(2), point (k), dash 6 — electric motors
Article 2(2), point (n), introductory part (n) the following high-voltage electrical products:	<u>(n)</u> the following <del>types of</del> high-voltage electrical <u>products</u> <del>equipment</del> :	Article 1(2), point (l) (l) the following types of high-voltage electrical equipment:
Article 2(2), point (n)(i) (i) switch gear and control gear;	<u>(i)</u> — switch gear and control gear; <del>;</del>	Article 1(2), point (l), dash 1 — switch gear and control gear,
Article 2(2), point (n)(ii) (ii) transformers.	<u>(ii)</u> — transformers.	Article 1(2), point (l), dash 2 — transformers.
Article 3 Article 3	Article <del>3</del> Article 3 <del>2</del>	Article 2 Article 2
Definitions	Definitions	Definitions
Article 3, first paragraph, introductory part For the purposes of this Regulation, the following definitions shall apply:	<u>For the purposes of this Regulation,</u> <del>the</del> <u>The</u> following definitions shall apply:	Article 2, second paragraph, introductory part The following definitions shall apply:
Article 3, first paragraph, point (1), introductory part		Article 3, point (a)

DRAFT Machinery Regulation	Comparison	Machinery Directive
(1) 'machinery' means:	(1a) 'machinery' means:	(a) 'machinery' means:
Article 3, first paragraph, point (1)(a)		Article 3, point (a), dash 1
(a) an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application;	(a)— an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application; <del>;</del>	— an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application,
Article 3, first paragraph, point (1)(b)		Article 3, point (a), dash 2
(b) an assembly referred to in point (a), missing only the components to connect it on site or to sources of energy and motion;	(b)— an assembly referred to in <u>point (a)</u> , <del>the first indent,</del> missing only the components to connect it on site or to sources of energy and motion; <del>;</del>	— an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,
Article 3, first paragraph, point (1)(c)		Article 3, point (a), dash 3
(c) an assembly referred to points (a) and (b), ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure;	(c)— an assembly referred to <u>points (a) in the first and (b), second indents,</u> ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure; <del>;</del>	— an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,
Article 3, first paragraph, point (1)(d)		Article 3, point (a), dash 4
(d) assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point (10) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;	(d)— assemblies of machinery referred to in <u>points (a), (b), (c) the first, second and third indents</u> or partly completed machinery referred to in point (10 <del>g</del> ) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole; <del>;</del>	— assemblies of machinery referred to in the first, second and third indents or partly completed machinery referred to in point (g) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole,
Article 3, first paragraph, point (1)(e)		Article 3, point (a), dash 5
(e) an assembly of linked parts or components, at least one of which moves and which are joined together, intended	(e)— an assembly of linked parts or components, at least one of which moves and which are joined together, intended	— an assembly of linked parts or components, at least one of which moves and which are joined together, intended

DRAFT Machinery Regulation	Comparison	Machinery Directive
for lifting loads and whose only power source is directly applied human effort;	for lifting loads and whose only power source is directly applied human effort;	for lifting loads and whose only power source is directly applied human effort;
Article 3, first paragraph, point (1)(f) (f) an assembly as referred to in points (a), (b), (c), (d) and (e) missing only the upload of a software intended for the specific application foreseen by the manufacturer.	<u>(f) an assembly as referred to in points (a), (b), (c), (d) and (e) missing only the upload of a software intended for the specific application foreseen by the manufacturer.</u>	
Article 3, first paragraph, point (2)		Article 3, point (b)
(2) 'interchangeable equipment' means a device which, after the putting into service of a machinery or an agricultural or forestry tractor, is assembled with that machinery or agricultural or forestry tractor by the operator in order to change its function or attribute to it a new function, in so far as that equipment is not a tool;	<u>(2b)</u> 'interchangeable equipment' means a device which, after the putting into service of <u>a machinery or an agricultural or forestry</u> <del>of a</del> tractor, is assembled with that machinery or <u>agricultural or forestry</u> tractor by the operator <del>himself</del> in order to change its function or attribute <u>to it</u> a new function, in so far as <del>that</del> <u>this</u> equipment is not a tool;	(b) 'interchangeable equipment' means a device which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool;
Article 3, first paragraph, point (3)		Article 3, point (c)
(3) 'safety component' means a physical or digital component, including software, of products within the scope of this Regulation, which is designed or intended to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endangers the safety of persons but which is not necessary in order for the products within the scope of this Regulation to function or may be substituted by normal components in order for those products to function;	<u>(3e)</u> 'safety component' means a <u>physical or digital component, including software, of products within the scope of this Regulation,:</u> <del>— which is designed or intended</del> <u> serves</u> to fulfil a safety function <del>and;</del> <del>— which is independently placed on the market,</del> <del>— the failure and/or malfunction of which endangers the safety of persons</del> <del>but,</del> <del>and</del> <del>— which is not necessary in order for the products within the scope of this Regulation</del> <del>machinery</del> to function; <del>or for which normal components may be substituted</del> <u>by normal components</u> in	(c) 'safety component' means a component: — which serves to fulfil a safety function, — which is independently placed on the market, — the failure and/or malfunction of which endangers the safety of persons, and — which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

DRAFT Machinery Regulation	Comparison	Machinery Directive
	order for <u>those products</u> <del>the machinery</del> to function; <del>;</del>	
Article 3, first paragraph, point (3a)		
(3a) 'safety function' means a function that serves to fulfil a protective measure, designed to eliminate, or, if that is not possible, to reduce, a risk and where its failure can result in an increase of the risk;	<u>(3a) 'safety function' means a function that serves to fulfil a protective measure, designed to eliminate, or, if that is not possible, to reduce, a risk and where its failure can result in an increase of the risk;</u>	
Article 3, first paragraph, point (4)		Article 3, point (d)
(4) 'lifting accessory' means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market, including slings and their components;	<del>(4)</del> 'lifting accessory' means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market, <u>including</u> ; slings and their components <del>are also regarded as lifting accessories;</del>	(d) 'lifting accessory' means a component or equipment not attached to the lifting machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market; slings and their components are also regarded as lifting accessories;
Article 3, first paragraph, point (5)		Article 3, point (e)
(5) 'chains' means chains designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;	<u>(5) 'chains'</u> <del>e) 'chains, ropes and webbing'</del> means chains, <del>ropes and webbing</del> designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;	(e) 'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;
Article 3, first paragraph, point (6)		Article 3, point (e)
(6) 'ropes' means ropes designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;	<u>(6) 'ropes'</u> <del>e) 'chains, ropes and webbing'</del> means <del>chains, ropes and webbing</del> designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;	(e) 'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;
Article 3, first paragraph, point (7)		
(7) deleted	<u>(7) deleted</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Article 3, first paragraph, point (8)</p> <p>(8) 'webbing' means webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;</p>	<p>(8) <del>'e) 'chains, ropes and</del> webbing' means <del>chains, ropes and</del> webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;</p>	<p>Article 3, point (e)</p> <p>(e) 'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;</p>
<p>Article 3, first paragraph, point (9)</p> <p>(9) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another machinery by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one item;</p>	<p>(9f) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another <u>machinery</u> <del>machine</del> by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one <del>item</del> <u>product</u>;</p>	<p>Article 3, point (f)</p> <p>(f) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one product;</p>
<p>Article 3, first paragraph, point (10)</p> <p>(10) 'partly completed machinery' means an assembly which is not yet machinery as it cannot in itself function so as to perform a specific application and which is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming a machinery;</p>	<p>(10g) 'partly completed machinery' means an assembly which is <del>not yet</del> <u>almost</u> machinery <del>as it</del> <u>but which</u> cannot in itself <u>function so as to</u> perform a specific application <u>and which</u>. <del>A drive system is partly completed machinery. Partly completed machinery</del> is only intended to be incorporated into or assembled with <del>other</del> machinery or other partly completed machinery or equipment, thereby forming <u>a machinery</u> <del>to which this Directive applies</del>;</p>	<p>Article 3, point (g)</p> <p>(g) 'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies;</p>
<p>Article 3, first paragraph, point (11)</p> <p>(11) 'making available on the market' means any supply of a product within the scope of this Regulation a for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;</p>	<p>(11) <u>'making available on the market' means any supply of a product within the scope of this Regulation a for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Article 3, first paragraph, point (12)</p> <p>(12) 'placing on the market' means the first making available of a product within the scope of this Regulation on the Union market;</p>	<p><del>(12h)</del> 'placing on the market' means <u>the first making available of a product within for the first time in the scope of this Regulation on the Union market</u><del>Community machinery or partly completed machinery with a view to distribution or use, whether for reward or free of charge;</del></p>	<p>Article 3, point (h)</p> <p>(h) 'placing on the market' means making available for the first time in the Community machinery or partly completed machinery with a view to distribution or use, whether for reward or free of charge;</p>
<p>Article 3, first paragraph, point (13)</p> <p>(13) 'putting into service' means the first use, for its intended purpose, in the Union, of machinery or related products;</p>	<p><del>(13k)</del> 'putting into service' means the first use, for its intended purpose, in the <u>UnionCommunity</u>, of machinery <u>or related products covered by this Directive</u>;</p>	<p>Article 3, point (k)</p> <p>(k) 'putting into service' means the first use, for its intended purpose, in the Community, of machinery covered by this Directive;</p>
<p>Article 3, first paragraph, point (13a)</p> <p>(13a) 'essential health and safety requirements' means mandatory provisions relating to the design and construction of the products within the scope of this Regulation to ensure a high level of protection of the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment, as set out in Annex III;</p>	<p><del>(13am)</del> 'essential health and safety requirements' means mandatory provisions relating to the design and construction of the products <u>within the scope of subject to this RegulationDirective</u> to ensure a high level of protection of the health and safety of persons <del>and</del>, where appropriate, <del>of</del> domestic animals and property and, where applicable, <del>of</del> the environment, <u>as set out in Annex III;</u></p>	<p>Article 3, point (m)</p> <p>(m) 'essential health and safety requirements' means mandatory provisions relating to the design and construction of the products subject to this Directive to ensure a high level of protection of the health and safety of persons and, where appropriate, of domestic animals and property and, where applicable, of the environment.</p>
	<p><del>The essential health and safety requirements are set out in Annex I. Essential health and safety requirements for the protection of the environment are applicable only to the machinery referred to in section 2.4 of that Annex.</del></p>	<p>Article 2, point (m), second paragraph</p> <p>The essential health and safety requirements are set out in Annex I. Essential health and safety requirements for the protection of the environment are applicable only to the machinery referred to in section 2.4 of that Annex.</p>
<p>Article 3, first paragraph, point (14)</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(14) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;	<u>(14) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;</u>	
Article 3, first paragraph, point (15)		
(15) deleted	<u>(15) deleted</u>	
Article 3, first paragraph, point (16)		
(16) 'substantial modification' means a modification of a machinery or related product, by physical or digital means after that machinery or related product has been placed on the market or put into service, which is not foreseen or planned by the manufacturer, and which affects the safety of that machinery or related product, by creating a new hazard or by increasing an existing risk, which requires:	<u>(16) 'substantial modification' means a modification of a machinery or related product, by physical or digital means after that machinery or related product has been placed on the market or put into service, which is not foreseen or planned by the manufacturer, and which affects the safety of that machinery or related product, by creating a new hazard or by increasing an existing risk, which requires:</u>	
Article 3, first paragraph, point (16)(i)		
(i) the addition of guards or protective devices to that machinery or related product whose processing modifies the existing safety control system, or	<u>(i) the addition of guards or protective devices to that machinery or related product whose processing modifies the existing safety control system, or</u>	
Article 3, first paragraph, point (16)(ii)		
(ii) the adoption of additional protective measures to ensure the stability or mechanical strength of that machinery or related product;	<u>(ii) the adoption of additional protective measures to ensure the stability or mechanical strength of that machinery or related product;</u>	
Article 3, first paragraph, point (17)		Article 3, point (i)
(17) 'manufacturer' means any natural or legal person who (i) manufactures products within the scope of this Regulation or who has those products designed or manufactured, and markets	<u>(17i) 'manufacturer' means any natural or legal person who (i) <del>designs and/or manufactures products within machinery or partly completed machinery covered by this Directive and is responsible for</del></u>	(i) 'manufacturer' means any natural or legal person who designs and/or manufactures machinery or partly completed machinery covered by this Directive and is responsible for the

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>those products under his or her name or trademark or (ii) manufactures products within the scope of this Regulation, and puts those products into service for his or her own use;</p>	<p>the <del>scope</del><sup>conformity</sup> of <u>this Regulation or who has those products designed or manufactured, and markets those products</u><del>the machinery or the partly completed machinery with this Directive with a view to its being placed on the market;</del> under his <u>or her own</u> name or trademark or (ii) manufactures products within the scope <del>for his own use. In the absence of this Regulation, and a manufacturer as defined above, any natural or legal person who places on the market or</del> puts <u>those products into service for his or her own use</u><del>machinery or partly completed machinery covered by this Directive shall be considered a manufacturer;</del></p>	<p>conformity of the machinery or the partly completed machinery with this Directive with a view to its being placed on the market, under his own name or trademark or for his own use. In the absence of a manufacturer as defined above, any natural or legal person who places on the market or puts into service machinery or partly completed machinery covered by this Directive shall be considered a manufacturer;</p>
<p>Article 3, first paragraph, point (18)</p>		
<p>(18) 'instructions for use' means the information provided by the manufacturer when the machinery or related product is placed on the market or put into service to inform the user of the machinery or related product of the intended and proper use of that machinery or related product, as well as information on any precautions to be taken when using or installing the machinery or related product, including information on the safety aspects and on how to keep that machinery or related product safe and ensure that it remains "fit for purpose" during its entire lifetime;</p>	<p><u>(18) 'instructions for use' means the information provided by the manufacturer when the machinery or related product is placed on the market or put into service to inform the user of the machinery or related product of the intended and proper use of that machinery or related product, as well as information on any precautions to be taken when using or installing the machinery or related product, including information on the safety aspects and on how to keep that machinery or related product safe and ensure that it remains "fit for purpose" during its entire lifetime;</u></p>	
<p>Article 3, first paragraph, point (19)</p>		<p>Article 3, point (j)</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
(19) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks;	(19j) 'authorised representative' means any natural or legal person established <u>within</u> in the <u>Union</u> Community who has received a written mandate from <u>a</u> the manufacturer to <u>act</u> perform on his <u>or her</u> behalf <u>in relation to specified tasks</u> <del>all or part of the obligations and formalities connected with this Directive</del> ;	(j) 'authorised representative' means any natural or legal person established in the Community who has received a written mandate from the manufacturer to perform on his behalf all or part of the obligations and formalities connected with this Directive;
Article 3, first paragraph, point (20)		
(20) 'importer' means any natural or legal person established within the Union who places a product within the scope of this Regulation from a third country on the Union market;	<u>(20) 'importer' means any natural or legal person established within the Union who places a product within the scope of this Regulation from a third country on the Union market;</u>	
Article 3, first paragraph, point (21)		
(21) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product within the scope of this Regulation available on the market;	<u>(21) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product within the scope of this Regulation available on the market;</u>	
Article 3, first paragraph, point (22)		
(22) 'economic operator' means the manufacturer, the authorised representative, the importer and the distributor;	<u>(22) 'economic operator' means the manufacturer, the authorised representative, the importer and the distributor;</u>	
Article 3, first paragraph, point (23)		
(23) 'technical specification' means a document that prescribes technical requirements to be fulfilled by products within the scope of this Regulation;	<u>(23) 'technical specification' means a document that prescribes technical requirements to be fulfilled by products within the scope of this Regulation;</u>	
Article 3, first paragraph, point (24)		Article 3, point (l)
(24) 'harmonised standard' means a harmonised standard as defined in Article	<u>(24) 'harmonised standard' means a harmonised standard as defined in Article 2(1), point (c) of Regulation (EU) No</u>	(l) 'harmonised standard' means a non-binding technical specification adopted by a standardisation body, namely the

DRAFT Machinery Regulation	Comparison	Machinery Directive
2(1), point (c) of Regulation (EU) No 1025/2012;	<del>1025/2012; (1) 'harmonised standard' means a non-binding technical specification adopted by a standardisation body, namely the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services ( 4 );</del>	European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services ( 4 );
Article 3, first paragraph, point (25)		
(25) 'CE marking' means a marking by which the manufacturer indicates that a machinery or related product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;	<u>(25) 'CE marking' means a marking by which the manufacturer indicates that a machinery or related product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;</u>	
Article 3, first paragraph, point (26)		
(26) 'accreditation' means accreditation as defined in Article 2, point (10) of Regulation (EC) No 765/2008;	<u>(26) 'accreditation' means accreditation as defined in Article 2, point (10) of Regulation (EC) No 765/2008;</u>	
Article 3, first paragraph, point (27)		
(27) 'national accreditation body' means a national accreditation body as defined in	<u>(27) 'national accreditation body' means a national accreditation body as defined in</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 2 point (11) of Regulation (EC) No 765/2008;	<u>Article 2 point (11) of Regulation (EC) No 765/2008;</u>	
Article 3, first paragraph, point (28)		
(28) 'conformity assessment' means the process demonstrating whether the applicable essential health and safety requirements of this Regulation relating to machinery or related products have been fulfilled;	<u>(28) 'conformity assessment' means the process demonstrating whether the applicable essential health and safety requirements of this Regulation relating to machinery or related products have been fulfilled;</u>	
Article 3, first paragraph, point (29)		
(29) 'conformity assessment body' means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;	<u>(29) 'conformity assessment body' means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;</u>	
Article 3, first paragraph, point (30)		
(30) 'notified body' means a conformity assessment body notified in accordance with Article 28 of this Regulation;	<u>(30) 'notified body' means a conformity assessment body notified in accordance with Article 28 of this Regulation;</u>	
Article 3, first paragraph, point (31)		
(31) 'market surveillance authority' means a market surveillance authority as defined in Article 3, point (4) of Regulation (EU) 2019/1020;	<u>(31) 'market surveillance authority' means a market surveillance authority as defined in Article 3, point (4) of Regulation (EU) 2019/1020;</u>	
Article 3, first paragraph, point (32)		
(32) 'recall' means any measure aimed at achieving the return of a product within the scope of this Regulation that has already been made available to the user;	<u>(32) 'recall' means any measure aimed at achieving the return of a product within the scope of this Regulation that has already been made available to the user;</u>	
Article 3, first paragraph, point (33)		
(33) 'withdrawal' means any measure aimed at preventing a product within the scope of this Regulation in the supply	<u>(33) 'withdrawal' means any measure aimed at preventing a product within the scope of this Regulation in the supply</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
chain from being made available on the market.	<u>chain from being made available on the market.</u>	
Article 3, first paragraph, point (33a)		
(33a) 'lifetime' means the period from the moment that a machinery or related product is placed on the market or put into service until the moment that it is discarded, including the effective time when the machinery or related product is capable of being used and the phases of transport, assembly, dismantling, disabling, scrapping or other physical or digital modifications foreseen by the manufacturer;	<u>(33a) 'lifetime' means the period from the moment that a machinery or related product is placed on the market or put into service until the moment that it is discarded, including the effective time when the machinery or related product is capable of being used and the phases of transport, assembly, dismantling, disabling, scrapping or other physical or digital modifications foreseen by the manufacturer;</u>	
Article 3, first paragraph, point (33b)		
(33b) 'source code' means the currently installed version of the software of a product within the scope of this Regulation, written in a programming language so that it is unambiguous, understandable to humans;	<u>(33b) 'source code' means the currently installed version of the software of a product within the scope of this Regulation, written in a programming language so that it is unambiguous, understandable to humans;</u>	
Article 3, first paragraph, point (33b)		
(33c) 'professional user' means a natural person who uses or operates a machinery or related product in the course of his or her professional activity or work.	<u>(33c) 'professional user' means a natural person who uses or operates a machinery or related product in the course of his or her professional activity or work.</u>	
Article 4		Article 6
Article 4	Article <del>4</del> 6	Article 6
Free movement	<del>Free</del> Freedom of movement	Freedom of movement
Article 4(1)		Article 6(1)
1. Member States shall not impede, for reasons relating to the aspects covered by this Regulation, the making available on the market of products within the	1. -Member States shall not <del>prohibit, restrict or</del> impede, for reasons relating to the <u>aspects covered by this Regulation,</u> the making available <del>placing</del> on the	1. Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service in their

DRAFT Machinery Regulation	Comparison	Machinery Directive
scope of this Regulation or the putting into service of machinery or related products which comply with this Regulation.	market <u>of products within the scope of this Regulation or the</u> <del>and/or</del> putting into service <u>in their territory</u> of machinery <u>or related products</u> which <u>comply</u> <del>complies</del> with this <u>Regulation</u> <del>Directive</del> .	territory of machinery which complies with this Directive.
		Article 6(2)
	<del>2. Member States shall not prohibit, restrict or impede the placing on the market of partly completed machinery where the manufacturer or his authorised representative makes a declaration of incorporation, referred to in Annex II, part 1, Section B, stating that it is to be incorporated into machinery or assembled with other partly completed machinery to form machinery.</del>	2. Member States shall not prohibit, restrict or impede the placing on the market of partly completed machinery where the manufacturer or his authorised representative makes a declaration of incorporation, referred to in Annex II, part 1, Section B, stating that it is to be incorporated into machinery or assembled with other partly completed machinery to form machinery.
Article 4(2), introductory part		Article 6(3), first sentence
2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the display of a product within the scope of this Regulation which does not comply with this Regulation, provided that a visible sign clearly indicates that it does not comply with this Regulation and will not be available on the market until it has been brought into conformity.	<del>2.3-</del> At trade fairs, exhibitions <u>and</u> , demonstrations <u>or similar events</u> , <del>and such like</del> , Member States shall not prevent the <u>display</u> <del>showing</del> of <u>a product within the scope of this Regulation</u> <del>machinery or partly completed machinery</del> which does not <u>comply with</u> <del>conform to</del> this <u>Regulation</u> <del>Directive</del> , provided that a visible sign clearly indicates that it does not <u>comply with this Regulation</u> <del>conform</del> and <del>that it</del> will not be <u>made</u> <del>available</del> <u>on the market</u> until it has been brought into conformity.	3. At trade fairs, exhibitions, demonstrations, and such like, Member States shall not prevent the showing of machinery or partly completed machinery which does not conform to this Directive, provided that a visible sign clearly indicates that it does not conform and that it will not be made available until it has been brought into conformity.
Article 4(2), first paragraph		Article 6(3), second sentence
During demonstrations, adequate measures shall be taken to ensure the protection of persons.	<u>During</u> <del>Furthermore, during</del> demonstrations <del>of such non-conforming machinery or partly completed</del>	Furthermore, during demonstrations of such non-conforming machinery or partly completed machinery, adequate safety

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>machinery</del> , adequate <del>safety</del> measures shall be taken to ensure the protection of persons.	measures shall be taken to ensure the protection of persons.
Article 4a (ex-article 23)		Article 15
Article 4a (ex-23)	Article <del>4a (ex-23)</del> <sup>15</sup>	Article 15
Protection of persons during installation or use of machinery or related products	<u>Protection of persons during installation or</u> <del>Installation and</del> use of machinery <u>or related products</u>	Installation and use of machinery
Article 4a (ex-article 23), first paragraph		Article 15
Member States may lay down requirements to ensure that persons, including workers, are protected when installing or using machinery or related products, provided that such rules do not allow for modification of a machinery or related product in a way that is not compatible with this Regulation.	<del>This Directive shall not affect Member States may</del> <u>States' entitlement to lay down</u> , <del>in due observance of Community law, such</del> requirements <del>as they may deem necessary</del> to ensure that persons, <u>including</u> <del>and in particular</del> workers, are protected when <u>installing or using machinery or related products</u> , provided that <u>such rules do not allow for modification of a</u> <del>this does not mean that such</del> machinery <u>or related products</u> <del>is modified</del> in a way <u>that is not compatible with</u> <del>specified in</del> this <u>Regulation</u> <del>Directive</del> .	This Directive shall not affect Member States' entitlement to lay down, in due observance of Community law, such requirements as they may deem necessary to ensure that persons, and in particular workers, are protected when using machinery, provided that this does not mean that such machinery is modified in a way not specified in this Directive.
Article 5		
Article 5	Article 5	
Categories of machinery and related products listed in Annex I subject to relevant conformity assessment procedures set out in Article 21	<u>Categories of machinery and related products listed in Annex I subject to relevant conformity assessment procedures set out in Article 21</u>	
Article 5(1)		
1. Machinery and related products that fall within the categories listed in Annex I, part A, shall be subject to the specific conformity assessment procedures, as referred to in Article 21(2), and those in	<u>1. Machinery and related products that fall within the categories listed in Annex I, part A, shall be subject to the specific conformity assessment procedures, as referred to in Article 21(2), and those in</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
part B may be subject to the specific conformity assessment procedures, as referred to in Article 21 (2a).	<u>part B may be subject to the specific conformity assessment procedures, as referred to in Article 21 (2a).</u>	
Article 5(2)		
2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I, after consulting the stakeholders concerned, in view of technical progress and knowledge or new scientific evidence by adding to the list of categories of machinery and related products in Annex I a new category of machinery or related product or withdrawing an existing category of machinery or related product from that list, pursuant to the criteria and the procedure laid down in paragraphs 3, 4 and 6.	<u>2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I, after consulting the stakeholders concerned, in view of technical progress and knowledge or new scientific evidence by adding to the list of categories of machinery and related products in Annex I a new category of machinery or related product or withdrawing an existing category of machinery or related product from that list, pursuant to the criteria and the procedure laid down in paragraphs 3, 4 and 6.</u>	
Article 5(2a)		
2a Before adopting a delegated act, the Commission shall gather the views of experts in the relevant expert groups in accordance with article 45(3).	<u>2a Before adopting a delegated act, the Commission shall gather the views of experts in the relevant expert groups in accordance with article 45(3).</u>	
Article 5(3), introductory part		
3. The Commission shall assess the seriousness of the inherent potential risk for the purpose of adding a category of machinery or related product to Annex I or withdrawing a category of machinery or related product from Annex I. That assessment shall be established based on the combination of the probability of occurrence of harm and the severity of that harm.	<u>3. The Commission shall assess the seriousness of the inherent potential risk for the purpose of adding a category of machinery or related product to Annex I or withdrawing a category of machinery or related product from Annex I. That assessment shall be established based on the combination of the probability of occurrence of harm and the severity of that harm.</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 5(3), first paragraph, introductory part		
In determining the probability and severity of harm, the following criteria shall be taken into account, where relevant:	<u>In determining the probability and severity of harm, the following criteria shall be taken into account, where relevant:</u>	
Article 5(3), first paragraph, point (-a')		
(a) the nature of the hazard inherent to the function of the machinery or related product category, taking into account the intended use and reasonably foreseeable misuse;	<u>(a) the nature of the hazard inherent to the function of the machinery or related product category, taking into account the intended use and reasonably foreseeable misuse;</u>	
Article 5(3), first paragraph, point (a)		
(b) the severity of harm by which a person would be affected, including the degree of reversibility of such harm;	<u>(b) the severity of harm by which a person would be affected, including the degree of reversibility of such harm;</u>	
Article 5(3), first paragraph, point (b)		
(c) the number of persons potentially affected by the harm;	<u>(c) the number of persons potentially affected by the harm;</u>	
Article 5(3), first paragraph, point (c)		
(d) the frequency and the duration of the exposure to the hazard that a person would be exposed to in course of the intended use or reasonably foreseeable misuse of the category of machinery or related product;	<u>(d) the frequency and the duration of the exposure to the hazard that a person would be exposed to in course of the intended use or reasonably foreseeable misuse of the category of machinery or related product;</u>	
Article 5(3), first paragraph, point (d)		
(e) the possibilities of avoiding or limiting harm;	<u>(e) the possibilities of avoiding or limiting harm;</u>	
Article 5(3), first paragraph, point (e)		
DELETED	<u>DELETED</u>	
Article 5(3), first paragraph, point (f)		
DELETED	<u>DELETED</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 5(3), first paragraph, point (g)		
DELETED	<u>DELETED</u>	
Article 5(3), first paragraph, point (h)		
(f) in case of safety components, the likelihood of serious consequences for the safety of the persons exposed in the event of failure.	<u>(f) in case of safety components, the likelihood of serious consequences for the safety of the persons exposed in the event of failure.</u>	
Article 5(4), introductory part		
4. When conducting the assessment referred in the previous paragraph, the Commission shall consider the following elements:	<u>4. When conducting the assessment referred in the previous paragraph, the Commission shall consider the following elements:</u>	
Article 5(4), point (a)		
(a) indications of harm that have been caused in the past by machinery or related products which have been used for its intended use or following any reasonably foreseeable misuse ;	<u>(a) indications of harm that have been caused in the past by machinery or related products which have been used for its intended use or following any reasonably foreseeable misuse ;</u>	
Article 5(4), point (b)		
DELETED	<u>DELETED</u>	
Article 5(4), point (ba)		
(b) information about safety defects detected in the course of market surveillance, and possible available material in the information systems administered by the Commission;	<u>(b) information about safety defects detected in the course of market surveillance, and possible available material in the information systems administered by the Commission;</u>	
Article 5(4), point (c)		
DELETED	<u>DELETED</u>	
Article 5(4), point (ca)		
(c) known accidents and serious close calls, including characteristics of these accidents or close call;	<u>(c) known accidents and serious close calls, including characteristics of these accidents or close call;</u>	
Article 5(4), point (d)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>(d) data on accidents or damage to the health caused by the machinery or related product at least for the preceding four years. In particular information obtained, among others, from the Information and Communication System for Market Surveillance (ICSMS), safeguard clauses, Rapid Alert System (RAPEX), the European Injury Database (EU-IDB), the Eurostat European Statistics on Accidents at Work (ESAW) and the Machinery Administrative Cooperation Group (AdCo).</p>	<p><u>(d) data on accidents or damage to the health caused by the machinery or related product at least for the preceding four years. In particular information obtained, among others, from the Information and Communication System for Market Surveillance (ICSMS), safeguard clauses, Rapid Alert System (RAPEX), the European Injury Database (EU-IDB), the Eurostat European Statistics on Accidents at Work (ESAW) and the Machinery Administrative Cooperation Group (AdCo).</u></p>	
<p>Article 5(4), subparagraph 1 (new)</p>		
<p>In addition to points (a) to (d), the Commission shall take into account any other available information relevant for the assessment referred to in paragraph 3.</p>	<p><u>In addition to points (a) to (d), the Commission shall take into account any other available information relevant for the assessment referred to in paragraph 3.</u></p>	
<p>5. The data and information referred to in the previous paragraph a) to d) shall be provided by Member States in accordance with paragraph 8.</p>	<p><u>5. The data and information referred to in the previous paragraph a) to d) shall be provided by Member States in accordance with paragraph 8.</u></p>	
<p>Article 5(4a)</p>		
<p>6. When the seriousness of its inherent potential risk is established according to the assessment referred to in paragraph 3 taking into account the available information, including the data referred to in paragraph 4, a category of machinery or related product shall be included in Annex I, Part A provided that at least one of the following conditions is fulfilled:</p>	<p><u>6. When the seriousness of its inherent potential risk is established according to the assessment referred to in paragraph 3 taking into account the available information, including the data referred to in paragraph 4, a category of machinery or related product shall be included in Annex I, Part A provided that at least one of the following conditions is fulfilled:</u></p>	
<p>Article 5(4a), point (i)</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(i) Lack of harmonised standards or common specifications covering the relevant essential health and safety requirements;	<u>(i) Lack of harmonised standards or common specifications covering the relevant essential health and safety requirements;</u>	
Article 5(4a), point (ii)		
(ii) Existence of residual risks including those which could be reduced by particular training or personal protective equipment according to the manufacturer and for which data and information set out in § 4 demonstrate the recurrence of similar serious or fatal accidents or damage to health in relation with these residual risks;	<u>(ii) Existence of residual risks including those which could be reduced by particular training or personal protective equipment according to the manufacturer and for which data and information set out in § 4 demonstrate the recurrence of similar serious or fatal accidents or damage to health in relation with these residual risks;</u>	
Article 5(4a), point (iii)		
(iii) data and information which according to the Commission demonstrate recurring wrongful application of the relevant harmonised standards or common specifications and for which conducted market surveillance activities have not lead to major improvements of the market situation, in a reasonable period of time;	<u>(iii) data and information which according to the Commission demonstrate recurring wrongful application of the relevant harmonised standards or common specifications and for which conducted market surveillance activities have not lead to major improvements of the market situation, in a reasonable period of time;</u>	
Article 5(4a), point (iv)		
(iv) The existence of a degree of uncertainty of the existing risk assessment methods related to new categories of machinery or technologies.	<u>(iv) The existence of a degree of uncertainty of the existing risk assessment methods related to new categories of machinery or technologies.</u>	
Article 5, (4a) unnumbered part		
Any other category of machinery or related product for which the seriousness of its inherent potential risk is established according to the assessment referred to	<u>Any other category of machinery or related product for which the seriousness of its inherent potential risk is established according to the assessment referred to</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
in paragraph 3 shall be included in Annex I, Part B.	<u>in paragraph 3 shall be included in Annex I, Part B.</u>	
Article 5(4h)		
7. A Member State which has concerns about a category of machinery or related product being listed or not in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof.	<u>7. A Member State which has concerns about a category of machinery or related product being listed or not in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof.</u>	
The Commission shall conduct the assessment referred to in paragraph 3 immediately after having been informed by a Member State.	<u>The Commission shall conduct the assessment referred to in paragraph 3 immediately after having been informed by a Member State.</u>	
After that assessment the Commission may initiate the procedure laid down in paragraph 2.	<u>After that assessment the Commission may initiate the procedure laid down in paragraph 2.</u>	
Article 5(5)		
8. By 24 months after the date of the entry into force of this Regulation, and every 5 years thereafter, Member States shall provide the data and information referred to in paragraph 4, including information that no event referred to in paragraph 4 occurred, for any category of machinery or related products which is included in Annex I or for which a Member State has concerns about not being included in Annex I	<u>8. By 24 months after the date of the entry into force of this Regulation, and every 5 years thereafter, Member States shall provide the data and information referred to in paragraph 4, including information that no event referred to in paragraph 4 occurred, for any category of machinery or related products which is included in Annex I or for which a Member State has concerns about not being included in Annex I</u>	
Article 5(6)		
9. The Commission shall adopt implementing acts setting out and, where necessary in view of technological and market development, updating a template concerning the collection of the data and	<u>9. The Commission shall adopt implementing acts setting out and, where necessary in view of technological and market development, updating a template concerning the collection of the data and</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
the information by the Member States referred to in paragraph 4(a) to (d).	<u>the information by the Member States referred to in paragraph 4(a) to (d).</u>	
When adopting the implementing acts, the Commission shall adopt guidance to Member States on the collection and transmission of comparable, high-quality data and information.	<u>When adopting the implementing acts, the Commission shall adopt guidance to Member States on the collection and transmission of comparable, high-quality data and information.</u>	
Those implementing acts shall be adopted in accordance with the [examination] procedure referred to in Article 46(3).	<u>Those implementing acts shall be adopted in accordance with the [examination] procedure referred to in Article 46(3).</u>	
The first such implementing act shall be adopted not later than 12 months after the entry into force of this Regulation	<u>The first such implementing act shall be adopted not later than 12 months after the entry into force of this Regulation</u>	
Article 5(5b)		
10. The Commission shall, if necessary after the Commission report referred to in Article 51(2a), adopt delegated acts to supplement paragraph 4 of this Article by specifying Member States' obligation to provide data and information required pursuant to this Article through the establishment of a common methodology on the data and information to be collected, including the relevant definitions, methods for their collection and compilation, and the procedures for its transmission, in order to ensure that sufficient and comparable data is available for the Commission to carry out the assessment referred to in paragraph 3.	<u>10. The Commission shall, if necessary after the Commission report referred to in Article 51(2a), adopt delegated acts to supplement paragraph 4 of this Article by specifying Member States' obligation to provide data and information required pursuant to this Article through the establishment of a common methodology on the data and information to be collected, including the relevant definitions, methods for their collection and compilation, and the procedures for its transmission, in order to ensure that sufficient and comparable data is available for the Commission to carry out the assessment referred to in paragraph 3.</u>	
Those delegated acts shall be adopted in accordance with Article 45.	<u>Those delegated acts shall be adopted in accordance with Article 45.</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 6		
Article 6	<u>Article 6</u>	
Safety components	<u>Safety components</u>	
Article 6(1)		Article 2 (c), second paragraph
1. An indicative list of safety components is set out in Annex II.	1. An indicative list of safety components is set out in Annex <del>II</del> <u>V</u> ;	An indicative list of safety components is set out in Annex V;
Article 6(2)		Article 8(1)
2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex II in view of technical progress and knowledge or new scientific evidence by including a new safety component in the indicative list of safety components or withdrawing an existing safety component from that list.	<del>2.1.</del> The Commission is empowered to adopt delegated acts in accordance with Article <del>45 to amend</del> <u>21a amending</u> Annex II <u>in view of technical progress and knowledge or new scientific evidence by including a new safety component in</u> <del>V to update</del> the indicative list of safety components <u>or withdrawing an existing safety component from that list.</u>	1. The Commission is empowered to adopt delegated acts in accordance with Article 21a amending Annex V to update the indicative list of safety components.
		Article 8(2)
	<del>2. The Commission, acting in accordance with the advisory procedure referred to in Article 22(2), may take any appropriate measure connected with the practical application of this Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission, as provided for in Article 19(1).</del>	2. The Commission, acting in accordance with the advisory procedure referred to in Article 22(2), may take any appropriate measure connected with the practical application of this Directive, including measures necessary to ensure cooperation of Member States with each other and with the Commission, as provided for in Article 19(1).
Article 6(3)		
3. DELETED	<u>3. DELETED</u>	
Article 6(4)		
4. A Member State which has concerns about a safety component being listed or not listed in Annex II shall immediately	<u>4. A Member State which has concerns about a safety component being listed or not listed in Annex II shall immediately</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
inform the Commission of its concerns and provide reasons in support thereof.	<u>inform the Commission of its concerns and provide reasons in support thereof.</u>	
Article 7		
Article 7	<u>Article 7</u>	
Essential health and safety requirements for products within the scope of this Regulation	<u>Essential health and safety requirements for products within the scope of this Regulation</u>	
Article 7, first paragraph		
Machinery or related products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended use or under conditions which can reasonably be foreseen, they meet the essential health and safety requirements set out in Annex III.	<u>Machinery or related products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended use or under conditions which can reasonably be foreseen, they meet the essential health and safety requirements set out in Annex III.</u>	
Article 7, paragraph 1 a (new)		
Partly completed machinery shall only be made available on the market if they meet the relevant essential health and safety requirements set out in Annex III.	<u>Partly completed machinery shall only be made available on the market if they meet the relevant essential health and safety requirements set out in Annex III.</u>	
Article 8		Article 3
Article 8	Article <del>8</del> 3	Article 3
Specific Union harmonisation legislation	Specific <u>Union harmonisation legislation</u> <del>Directives</del>	Specific Directives
Article 8, first paragraph		Article 3, first paragraph
Where, for a certain product within the scope of this Regulation, the risks addressed by the essential health and safety requirements set out in Annex III are wholly or partly covered by other more specific Union harmonisation legislation, this Regulation shall not apply	Where, for a <u>certain product within machinery</u> , the <u>scope of this Regulation, the risks addressed by the essential health and safety requirements set out</u> <del>hazards referred to in Annex III</del> are wholly or partly covered <del>more</del> <u>specifically</u> by other <u>more specific Union</u>	Where, for machinery, the hazards referred to in Annex I are wholly or partly covered more specifically by other Community Directives, this Directive shall not apply, or shall cease to apply, to that machinery in respect of such hazards

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>to that product within the scope of this Regulation to the extent that that specific Union legislation covers such risks.</p>	<p><u>harmonisation legislation, this Regulation</u><del>Community Directives, this Directive</del> shall not apply,<del>or shall cease to apply,</del> to that <u>product within the scope of this Regulation to the extent that that specific Union legislation covers machinery in respect of such risks</u><del>hazards from the date of implementation of those other Directives.</del></p>	<p>from the date of implementation of those other Directives.</p>
<p>Article 9</p>		
<p>Article 9</p>	<p><u>Article 9</u></p>	
<p>deleted</p>	<p><u>deleted</u></p>	

## Chapter 2: Obligations of economic operators

DRAFT Machinery Regulation	Comparison	Machinery Directive
CHAPTER II		
OBLIGATIONS OF ECONOMIC OPERATORS	<u>OBLIGATIONS OF ECONOMIC OPERATORS</u>	
Article 10		Article 5
Article 10	Article <del>10</del> <sup>5</sup>	Article 5
Obligations of manufacturers of machinery and related products	<u>Obligations of manufacturers of machinery and related products</u> <del>Placing on the market and putting into service</del>	Placing on the market and putting into service
Article 10(1)		Article 5, point (1)(a)
1. When placing a machinery or a related product on the market or putting it into service, manufacturers shall ensure that it has been designed and constructed in accordance with the essential health and safety requirements set out in Annex III.	1. <del>When</del> <sup>Before</sup> placing <u>a machinery or a related product</u> on the market <del>and/or</del> putting it into service, <del>manufacturers</del> <sup>the manufacturer or his authorised representative</sup> shall: <del>(a)</del> ensure that it <u>has been designed and constructed in accordance with the</u> <del>satisfies the relevant</del> essential health and safety requirements set out in Annex III. <del>;</del>	1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall: (a) ensure that it satisfies the relevant essential health and safety requirements set out in Annex I;
Article 10(2), introductory part		Article 5, point (1)(b)+(d)
2. Before placing a machinery or related product on the market or putting it into service, manufacturers shall draw up the technical documentation set out in part A of Annex IV and carry out the relevant conformity assessment procedure referred to in Article 21 or have it carried out.	<del>2.</del> <sup>4.</sup> Before placing <u>a machinery or related product</u> on the market <del>and/or</del> putting it into service, <del>manufacturers</del> <sup>the manufacturer or his authorised representative</sup> shall <u>draw up:</u> <del>(b)</del> <del>ensure that</del> the technical <u>documentation set out in</u> <del>file referred to in Annex VII,</del> part A <u>of Annex IV and is</u> available; <del>(d)</del> carry out the <u>relevant</u> <del>appropriate</del> <u>procedures for assessing</u> conformity assessment procedure referred to in <del>in</del>	1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall: (b) ensure that the technical file referred to in Annex VII, part A is available; (d) carry out the appropriate procedures for assessing conformity in accordance with Article 12;

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>accordance with Article 21 or have it carried out. 12;</del>	
Article 10(2), first paragraph		Article 5, point (1)(e)+(f)
<p>Where compliance of a machinery or related product with the essential health and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity in accordance with Article 18 and affix the CE marking in accordance with Article 20.</p>	<p><del>Where compliance of a</del> <u>1. Before placing machinery or related product with</u> <del>on the essential health</del> <u>market and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers/</u> <del>or putting it into service, the manufacturer or his authorised representative shall:</del>  <del>(e)</del> draw up the <u>EU</u> <del>EG</del> declaration of conformity in accordance with <u>Article 18</u> <del>Annex II, part 1, Section A</del> and <u>ensure that it accompanies the machinery;</u>  <del>(f)</del> affix the CE marking in accordance with <u>Article 20</u> <del>16</del>.</p>	<p>1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:            (e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery;            (f) affix the CE marking in accordance with Article 16.</p>
		Article 5, point (3)
	<p><del>3. For the purposes of the procedures referred to in Article 12, the manufacturer or his authorised representative shall have, or shall have access to, the necessary means of ensuring that the machinery satisfies the essential health and safety requirements set out in Annex I.</del></p>	<p>3. For the purposes of the procedures referred to in Article 12, the manufacturer or his authorised representative shall have, or shall have access to, the necessary means of ensuring that the machinery satisfies the essential health and safety requirements set out in Annex I.</p>
		Article 5, point (4)
	<p><del>4. Where machinery is also the subject of other Directives relating to other aspects and providing for the affixing of the CE marking, the marking shall indicate that the machinery also conforms to the provisions of those other Directives.</del></p>	<p>4. Where machinery is also the subject of other Directives relating to other aspects and providing for the affixing of the CE marking, the marking shall indicate that the machinery also conforms to the provisions of those other Directives.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>However, where one or more of those Directives allow the manufacturer or his authorised representative to choose, during a transitional period, the system to be applied, the CE marking shall indicate conformity only to the provisions of those Directives applied by the manufacturer or his authorised representative. Particulars of the Directives applied, as published in the Official Journal of the European Union, shall be given on the EC declaration of conformity.</del></p>	<p>However, where one or more of those Directives allow the manufacturer or his authorised representative to choose, during a transitional period, the system to be applied, the CE marking shall indicate conformity only to the provisions of those Directives applied by the manufacturer or his authorised representative. Particulars of the Directives applied, as published in the Official Journal of the European Union, shall be given on the EC declaration of conformity.</p>
<p>Article 10(3)</p>		<p>Annex VII, A, (2), first paragraph</p>
<p>3. Manufacturers shall keep the technical documentation and the EU declaration of conformity at the disposal of the market surveillance authorities for ten years after the machinery or the related product has been placed on the market or put into service. Where relevant, the source code or programming logic included in the technical documentation shall be made available upon a reasoned request from the competent national authorities provided that it is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.</p>	<p><u>3. Manufacturers shall keep the technical documentation and the EU declaration of conformity at the disposal of the market surveillance authorities for ten years after the machinery or the related product has been placed on the market or put into service. Where relevant, the source code or programming logic included in the technical documentation shall be made available upon a reasoned request from the competent national authorities provided that it is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.</u>  <del>2. The technical file referred to in point 1 must be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of the machinery or, in the</del></p>	<p>2. The technical file referred to in point 1 must be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>ease of series manufacture, of the last unit produced.</del>	
		Annex VII, A, (2), second paragraph
	<del>The technical file does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC declaration of conformity.</del>	The technical file does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. However, it must be capable of being assembled and made available within a period of time commensurate with its complexity by the person designated in the EC declaration of conformity.
		Annex VII, A, (2), third paragraph
	<del>The technical file does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.</del>	The technical file does not have to include detailed plans or any other specific information as regards the sub-assemblies used for the manufacture of the machinery unless a knowledge of them is essential for verification of conformity with the essential health and safety requirements.
		Annex VII, A, (1)(a), dash 10
	<del>— a copy of the EC declaration of conformity;</del>	— a copy of the EC declaration of conformity;
		Annex II, 2, first paragraph
	<del>The manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery.</del>	The manufacturer of machinery or his authorised representative shall keep the original EC declaration of conformity for a period of at least 10 years from the last date of manufacture of the machinery.
Article 10(4), introductory part		Annex VII A(1)(b), first paragraph
4. Manufacturers shall ensure that procedures are in place for machinery or related products that are part of a series	<u>4. Manufacturers shall ensure that procedures are in place for machinery or related products that are part of a series</u>	(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>production to remain in conformity with this Regulation. Changes in the production process or in the design or characteristics of the machinery or related product and changes in the harmonised standards or other technical specifications or in the common specifications referred to in Article 17 by reference to which the conformity of the machinery or related product is declared shall be adequately taken into account.</p>	<p><u>production to remain in conformity with this Regulation. Changes in the production process or in the design or characteristics of the machinery or related product and changes in the harmonised standards or other technical specifications or in the common specifications referred to in Article 17 by reference to which the conformity of the machinery or related product is declared shall be adequately taken into account.</u> <del>(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive.</del></p>	<p>conformity with the provisions of this Directive.</p>
<p>Article 10(4), first paragraph</p>		
<p>When deemed appropriate with regard to the risks presented by machinery or related products, manufacturers shall, in order to protect the health and safety of users, carry out sample testing of machinery or related products made available on the market and investigate their results. If necessary, manufacturers shall keep a register of complaints, of non-conforming machinery or related products and machinery or related products recalls, and shall keep distributors informed of any such monitoring.</p>	<p><u>When deemed appropriate with regard to the risks presented by machinery or related products, manufacturers shall, in order to protect the health and safety of users, carry out sample testing of machinery or related products made available on the market and investigate their results. If necessary, manufacturers shall keep a register of complaints, of non-conforming machinery or related products and machinery or related products recalls, and shall keep distributors informed of any such monitoring.</u></p>	
<p>Article 10(5)</p>		<p>Annex I, 1, point (1.7)(1.7.3), first paragraph</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>5. Manufacturers shall ensure that the machinery or related product which they place on the market or put into service bears at least a designation of the machinery, series or type, the year of construction, that is the year in which the manufacturing process is completed, and, if any, batch or serial number or other element allowing its identification, or, where the size or nature of the machinery or related product does not allow it, that the required information is provided on the packaging or in a document accompanying the machinery or related product.</p>	<p><u>5. Manufacturers shall ensure that the All machinery or related product which they place on</u><del>must be marked visibly, legibly and indelibly with the following minimum particulars:</del></p> <ul style="list-style-type: none"> <li><del>— the market or put into service bears at least a</del><u>business name and full address of the manufacturer and, where applicable, his authorised representative,</u></li> <li><del>— designation of the machinery,</del></li> <li><del>— the CE Marking (see Annex III),</del></li> <li><del>— designation of series or type,</del></li> <li><del>— serial number, if any,</del></li> <li><del>— the year of construction, that is the year in which the manufacturing process is completed, and, if any, batch or serial number or other element allowing its identification, or, where the size or nature of the machinery or related product does not allow it, that the required information is provided on the packaging or in a document accompanying the machinery or related product.</del></li> </ul>	<p>All machinery must be marked visibly, legibly and indelibly with the following minimum particulars:</p> <ul style="list-style-type: none"> <li>— the business name and full address of the manufacturer and, where applicable, his authorised representative,</li> <li>— designation of the machinery,</li> <li>— the CE Marking (see Annex III),</li> <li>— designation of series or type,</li> <li>— serial number, if any,</li> <li>— the year of construction, that is the year in which the manufacturing process is completed.</li> </ul>
Article 10(6)		
<p>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and the website, e-mail address or other digital contact at which they can be contacted on the machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related products. The address shall indicate a</p>	<p><u>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and the website, e-mail address or other digital contact at which they can be contacted on the machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related products. The address shall indicate a</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by users and market surveillance authorities.	<u>single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by users and market surveillance authorities.</u>	
Article 10(7)		Article 5, point (1)(c)
7. Manufacturers shall ensure that the machinery or related products are accompanied by the instructions for use and information set out in Annex III. The instructions may be provided in a digital format.	7. Manufacturers shall ensure that the <u>machinery or related products are accompanied by the instructions for use and information set out in Annex III. The instructions may be provided in a digital format.</u> <del>1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall: (c) provide, in particular, the necessary information, such as instructions;</del>	1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall: (c) provide, in particular, the necessary information, such as instructions;
Such instructions and information shall clearly describe the product model to which they correspond.	<u>Such instructions and information shall clearly describe the product model to which they correspond.</u>	
Article 10(7), introductory part		
When the instructions for use are provided in digital format, the manufacturer shall:	<u>When the instructions for use are provided in digital format, the manufacturer shall:</u>	
Article 10(7), point (a)		
(a) mark on the machinery or related product or on the packaging and in an accompanying document how to access the digital instructions;	<u>(a) mark on the machinery or related product or on the packaging and in an accompanying document how to access the digital instructions;</u>	
Article 10(7), point (b)		
(b) present them in a format that makes it possible for the user to print and download the instructions for use and save them on an electronic device so that	<u>(b) present them in a format that makes it possible for the user to print and download the instructions for use and save them on an electronic device so that</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>he or she can access them at all times, in particular during a breakdown of the machinery or related product. This requirement also applies where the instructions for use are embedded in the software of the machinery or related product;</p>	<p><u>he or she can access them at all times, in particular during a breakdown of the machinery or related product. This requirement also applies where the instructions for use are embedded in the software of the machinery or related product;</u></p>	
<p>Article 10(7), point (c)</p>		
<p>(c) make them accessible online during the expected lifetime of the machinery or related product and not less than 10 years after the placing on the market of the machinery or related product.</p>	<p><u>(c) make them accessible online during the expected lifetime of the machinery or related product and not less than 10 years after the placing on the market of the machinery or related product.</u></p>	
<p>Article 10(7), unnumbered paragraph 1</p>		
<p>However, upon request of the user at the time of the purchase, the manufacturer shall provide the instructions for use in paper format free of charge within one month.</p>	<p><u>However, upon request of the user at the time of the purchase, the manufacturer shall provide the instructions for use in paper format free of charge within one month.</u></p>	
<p>Article 10(7), unnumbered paragraph 2</p>		
<p>In the case of a machinery or related product intended for non-professional users or which can, under reasonably foreseeable conditions, be used by non-professional users even if not intended for them, the manufacturer shall provide in paper format the safety information that are essential for putting the machinery or related product into service and for using it in a safe way.</p>	<p><u>In the case of a machinery or related product intended for non-professional users or which can, under reasonably foreseeable conditions, be used by non-professional users even if not intended for them, the manufacturer shall provide in paper format the safety information that are essential for putting the machinery or related product into service and for using it in a safe way.</u></p>	
<p>Article 10(7), unnumbered paragraph 3</p>		<p>Annex I, (1.7.4), first paragraph</p>
<p>The instructions for use and information shall be in a language which can be easily understood by users, as determined by</p>	<p><del>The</del> <u>All machinery must be accompanied by instructions for use and information shall be in</u> <del>the official Community</del></p>	<p>All machinery must be accompanied by instructions in the official Community language or languages of the Member</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>the Member State concerned and shall be clear, understandable, intelligible and legible.</p>	<p>language <u>which can be easily understood by users, as determined by</u> <del>or languages of</del> the Member State <u>concerned and shall be clear, understandable, intelligible and legible</u> <del>in which it is placed on the market and/or put into service.</del></p>	<p>State in which it is placed on the market and/or put into service.</p>
	<p><del>(a) The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative.</del></p>	<p>Annex I, (1.7.4.1)(a) (a) The instructions must be drafted in one or more official Community languages. The words 'Original instructions' must appear on the language version(s) verified by the manufacturer or his authorised representative.</p>
<p>Article 10(8)</p>		<p>Article 5, point (1)(e)</p>
<p>8. Manufacturers shall ensure that the machinery or related products is accompanied by the EU declaration of conformity set out in Part A of Annex V or shall provide the internet address at which it can be accessed in the instructions for use and information set out in section 1.7 of Annex III.</p>	<p><del>8. Manufacturers shall ensure that the 1. Before placing machinery or related products is accompanied by</del> <u>on the market and/or putting it into service</u>; the <del>EU manufacturer or his authorised representative shall:</del> <u>(e) draw up the EC declaration of conformity set out in Part A of</u> <del>accordance with Annex V or shall provide the internet address at which it can be accessed in</del> <u>part 1, Section A and ensure that it accompanies the instructions for use and information set out in section 1.7 of Annex III.</u> <del>machinery;</del></p>	<p>1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall: (e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery;</p>
<p>Article 10(8), unnumbered point</p>		
<p>Digital EU declarations of conformity shall be made accessible online for the expected lifetime of the machinery or related product and not less than 10 years after placing on the market or</p>	<p><u>Digital EU declarations of conformity shall be made accessible online for the expected lifetime of the machinery or related product and not less than 10 years after placing on the market or</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>putting into service of the machinery or related product.</p>	<p><u>putting into service of the machinery or related product.</u></p>	
<p>Article 10(9)</p>		
<p>9. Manufacturers who consider or have reason to believe that a machinery or related product, which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that machinery or related product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the machinery or related product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the machinery or related product available on the market or put into service to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.</p>	<p><u>9. Manufacturers who consider or have reason to believe that a machinery or related product, which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that machinery or related product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the machinery or related product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the machinery or related product available on the market or put into service to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.</u></p>	
<p>Article 10(10)</p>		<p>Annex VII, A, (3)</p>
<p>10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery or related products with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate</p>	<p><u>10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery or related products with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate</u></p>	<p>3. Failure to present the technical file in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
the risks presented by the machinery or related products, which they have placed on the market or put into service.	<u>the risks presented by the machinery or related products, which they have placed on the market or put into service.</u> <del>3. Failure to present the technical file in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the machinery in question with the essential health and safety requirements.</del>	
Article 10a		
Article 10a	Article 10a	
Obligations of manufacturers of partly completed machinery	<u>Obligations of manufacturers of partly completed machinery</u>	
		Article 5, point (2)
	<del>2. Before placing partly completed machinery on the market, the manufacturer or his authorised representative shall ensure that the procedure referred to in Article 13 has been completed.</del>	2. Before placing partly completed machinery on the market, the manufacturer or his authorised representative shall ensure that the procedure referred to in Article 13 has been completed.
		Article 13(1)
	<del>1. The manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that:</del>	1. The manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that:
Article 10a(1), introductory part		
1. When placing a partly completed machinery on the market, manufacturers shall ensure that it has been designed and constructed in accordance with the relevant essential health and safety requirements set out in Annex III .	<u>1. When placing a partly completed machinery on the market, manufacturers shall ensure that it has been designed and constructed in accordance with the relevant essential health and safety requirements set out in Annex III .</u>	
Article 10a(2)		Article 13(1)(a)

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>2. Before placing a partly completed machinery on the market, manufacturers shall draw up the technical documentation set out in part B of Annex IV</p>	<p><u>2. Before placing a partly completed machinery on the market, manufacturers shall draw up the relevant technical documentation set out described in Annex VII, part B of Annex IV is prepared;</u></p>	<p>(a) the relevant technical documentation described in Annex VII, part B is prepared;</p>
<p>Where compliance of a partly completed machinery with the relevant essential health and safety requirements laid down in Annex III has been demonstrated in the technical documentation set out in Part B of Annex IV, manufacturers shall draw up the EU declaration of incorporation in accordance with Article 18a.</p>	<p><u>Where compliance of a partly completed machinery with the relevant essential health and safety requirements laid down in Annex III has been demonstrated in the technical documentation set out in Part B of Annex IV, manufacturers shall draw up the EU declaration of incorporation in accordance with Article 18a.</u> <del>(c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up.</del></p>	<p>Article 13(1)(c)  (c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up.</p>
<p>Article 10a(3)</p>		<p>Annex VII, B, fourth paragraph</p>
<p>3. Manufacturers shall keep the technical documentation and the EU declaration of incorporation at the disposal of the market surveillance authorities for ten years after the partly completed machinery has been placed on the market.</p>	<p><u>3. Manufacturers shall keep the technical documentation and the EU declaration of incorporation at the disposal of the market surveillance authorities for ten years after the partly completed machinery has been placed on the market.</u> <del>The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does</del></p>	<p>The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.</del></p>	
		Annex II, 2, second paragraph
	<p><del>The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.</del></p>	<p>The manufacturer of partly completed machinery or his authorised representative shall keep the original declaration of incorporation for a period of at least 10 years from the last date of manufacture of the partly completed machinery.</p>
Article 10a(4)		Annex VII B(b), first paragraph
<p>4. Manufacturers shall ensure that procedures are in place for partly completed machinery that are part of a series production to remain in conformity with this Regulation. Changes in the production process or in the design or characteristics of the partly completed machinery and changes in the harmonised standards or other technical specifications or in the common specifications referred to in Article 17 by reference to which the conformity of the partly completed machinery is declared or by application of which its conformity is verified shall be adequately taken into account.</p>	<p><u>4. Manufacturers shall ensure that procedures are in place for partly completed machinery that are part of a series production to remain in conformity with this Regulation. Changes in the production process or in the design or characteristics of the partly completed machinery and changes in the harmonised standards or other technical specifications or in the common specifications referred to in Article 17 by reference to which the conformity of the partly completed machinery is declared or by application of which its conformity is verified shall be adequately taken into account.</u>  <del>(b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in</del></p>	<p>(b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>conformity with the essential health and safety requirements applied.</del></p>	
Article 10a(5)		
<p>5. Manufacturers shall ensure that the partly completed machinery which they place on the market bears at least the designation of the the partly completed machinery, the year of construction, that is the year in which the manufacturing process is completed, model and series or type and, if any, batch or serial number or other element allowing its identification, or, where the size or nature of the partly completed machinery does not allow it, that the required information is provided on the packaging or in a document accompanying the partly completed machinery.</p>	<p><u>5. Manufacturers shall ensure that the partly completed machinery which they place on the market bears at least the designation of the the partly completed machinery, the year of construction, that is the year in which the manufacturing process is completed, model and series or type and, if any, batch or serial number or other element allowing its identification, or, where the size or nature of the partly completed machinery does not allow it, that the required information is provided on the packaging or in a document accompanying the partly completed machinery.</u></p>	
Article 10a(6)		
<p>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and website, email address or other digital contact at which they can be contacted on the partly completed machinery or, where that is not possible, on its packaging or in a document accompanying the partly completed machinery. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by the person who incorporates the partly completed machinery into a</p>	<p><u>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and website, email address or other digital contact at which they can be contacted on the partly completed machinery or, where that is not possible, on its packaging or in a document accompanying the partly completed machinery. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by the person who incorporates the partly completed machinery into a</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
machinery and market surveillance authorities.	<u>machinery and market surveillance authorities.</u>	
Article 10a(7)		Article 13(1)(b)
7. Manufacturers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Annex X.	<u>7. Manufacturers shall ensure that the partly completed machinery is accompanied by the</u> <del>(b)</del> <u> assembly instructions set out</u> <del>described</del> <u> in Annex X.</u> <del>VI are prepared;</del>	(b) assembly instructions described in Annex VI are prepared;
		Article 13(2)
	<del>2. The assembly instructions and the declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall then form part of the technical file for that machinery.</del>	2. The assembly instructions and the declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the final machinery and shall then form part of the technical file for that machinery.
The assembly instructions may be provided by the manufacturer in digital format.	<u>The assembly instructions may be provided by the manufacturer in digital format.</u>	
When the assembly instructions are provided in digital format, the manufacturer shall:	<u>When the assembly instructions are provided in digital format, the manufacturer shall:</u>	
Article 10a(7), point (a)		
(a) mark on the partly completed machinery, and on the packaging or in an accompanying document how to access the digital assembly instructions;	<u>(a) mark on the partly completed machinery, and on the packaging or in an accompanying document how to access the digital assembly instructions;</u>	
Article 10a(7), point (b)		
(b) present them in a format that makes it possible for the person who incorporates the partly completed machinery to print and download the assembly instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of	<u>(b) present them in a format that makes it possible for the person who incorporates the partly completed machinery to print and download the assembly instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
the partly completed machinery. This requirement also applies where the assembly instructions are embedded in the software of the partly completed machinery;	<u>the partly completed machinery. This requirement also applies where the assembly instructions are embedded in the software of the partly completed machinery;</u>	
Article 10a(7), point (c)		
(c) make them accessible online for not less than 10 years after the placing on the market of the partly completed machinery.	<u>(c) make them accessible online for not less than 10 years after the placing on the market of the partly completed machinery.</u>	
Article 10a(7), unnumbered paragraph 1		
However, at the time of purchase upon request of the person who incorporates the partly completed machinery, the manufacturer shall provide the assembly instructions in paper format free of charge within one month.	<u>However, at the time of purchase upon request of the person who incorporates the partly completed machinery, the manufacturer shall provide the assembly instructions in paper format free of charge within one month.</u>	
Article 10a(7), unnumbered paragraph 2		Annex VI, second paragraph
The assembly instructions shall be in a language which can be easily understood by the person who incorporates the partly completed machinery, as determined by the Member State concerned and shall be clear, understandable, intelligible and legible.	The assembly instructions <del>shall</del> <b>must</b> be <del>written in an official Community language which can be easily understood by acceptable to the person who incorporates</del> <u>manufacturer of the machinery in which the</u> partly completed machinery, <del>as determined by the Member State concerned and shall be clear, understandable, intelligible and legible</del> <u>will be assembled, or to his authorised representative.</u>	The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.
Article 10a(8), first subparagraph		Article 13(2)
8. Manufacturers shall ensure that the partly completed machinery is accompanied by the EU declaration of incorporation set out in Part B of Annex V	<u>8. Manufacturers</u> <del>2. The assembly instructions and the declaration of incorporation shall ensure that</del> <u>accompany</u> the partly completed machinery <del>until it is</del>	2. The assembly instructions and the declaration of incorporation shall accompany the partly completed machinery until it is incorporated into the

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>or shall provide the internet address at which it can be accessed in the assembly instructions set out in Annex X.</p>	<p><u>accompanied by the EU declaration of incorporation set out in Part B of Annex V</u> <del>or incorporated into the final machinery</del> <u>and shall provide the internet address at which it can be accessed in the assembly instructions set out in Annex X</u> <del>then form part of the technical file for that machinery.</del></p>	<p>final machinery and shall then form part of the technical file for that machinery.</p>
<p>Article 10a(8), second subparagraph</p>		
<p>Digital EU declarations of incorporation shall be made accessible online for at least 10 years after placing on the market of the partly completed machinery.</p>	<p><u>Digital EU declarations of incorporation shall be made accessible online for at least 10 years after placing on the market of the partly completed machinery.</u></p>	
<p>Article 10a(9)</p>		
<p>9. Manufacturers who consider or have reason to believe that a partly completed machinery which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk as regards the essential health and safety requirements, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.</p>	<p><u>9. Manufacturers who consider or have reason to believe that a partly completed machinery which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk as regards the essential health and safety requirements, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.</u></p>	
<p>Article 10a(10)</p>		<p>Annex VII, B, fifth paragraph</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the partly completed machinery with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks as regards the essential health and safety requirements presented by the partly completed machinery, which they have placed on the market.</p>	<p><u>10. Manufacturers shall, further</u><del>Failure to present the relevant technical documentation in response to a duly</del> reasoned request <u>from a</u><del>by the</del> competent national <u>authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate</u><del>authorities may constitute sufficient grounds for doubting</del> the conformity of the partly completed machinery with <u>this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks as regards</u> the essential health and safety requirements <u>presented by the partly completed machinery, which they have placed on the market</u><del>applied and attested.</del></p>	<p>Failure to present the relevant technical documentation in response to a duly reasoned request by the competent national authorities may constitute sufficient grounds for doubting the conformity of the partly completed machinery with the essential health and safety requirements applied and attested.</p>
Article 11		
Article 11	<u>Article 11</u>	
Authorised representatives	<u>Authorised representatives</u>	
Article 11(1), introductory part		
<p>1. A manufacturer of a product within the scope of this Regulation may, by a written mandate, appoint an authorised representative.</p>	<p><u>1. A manufacturer of a product within the scope of this Regulation may, by a written mandate, appoint an authorised representative.</u></p>	
Article 11(1), first paragraph		
<p>The obligations laid down in Article 10(1) and Article 10a(1) and the obligation to draw up the technical documentation set</p>	<p><u>The obligations laid down in Article 10(1) and Article 10a(1) and the obligation to draw up the technical documentation set</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
out in Annex IV shall not form part of the authorised representative's mandate.	<u>out in Annex IV shall not form part of the authorised representative's mandate.</u>	
Article 11(2), introductory part		
2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:	<u>2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:</u>	
Article 11(2), point (a)		
(a) keep the technical documentation and the EU declaration of conformity of machinery and related products or the EU declaration of incorporation of partly completed machinery at the disposal of the national market surveillance authorities for the expected lifetime of the machinery or related product and not less than ten years after the product has been placed on the market;	<u>(a) keep the technical documentation and the EU declaration of conformity of machinery and related products or the EU declaration of incorporation of partly completed machinery at the disposal of the national market surveillance authorities for the expected lifetime of the machinery or related product and not less than ten years after the product has been placed on the market;</u>	
Article 11(2), point (b)		
(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the product within the scope of this Regulation. It could be either in paper or digital format;	<u>(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the product within the scope of this Regulation. It could be either in paper or digital format;</u>	
Article 11(2), point (c)		
(c) cooperate with the competent national authorities, at their request, on any actions taken to eliminate the risks presented by a product within the scope	<u>(c) cooperate with the competent national authorities, at their request, on any actions taken to eliminate the risks presented by a product within the scope</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
of this Regulation covered by the authorised representative's mandate.	<u>of this Regulation covered by the authorised representative's mandate.</u>	
Article 12		
Article 12	<u>Article 12</u>	
Obligations of importers of machinery and related products	<u>Obligations of importers of machinery and related products</u>	
Article 12(1)		
1. Importers shall place only compliant machinery or related products on the market .	<u>1. Importers shall place only compliant machinery or related products on the market .</u>	
Article 12(2), introductory part		
2. Before placing a machinery or related product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 21 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation set out in Part A of Annex IV, that the machinery or related product bears the CE marking referred to in Article 19 and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 10(5) and (6).	<u>2. Before placing a machinery or related product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 21 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation set out in Part A of Annex IV, that the machinery or related product bears the CE marking referred to in Article 19 and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 10(5) and (6).</u>	
Article 12(2), first paragraph		
Where an importer considers or has reason to believe that a machinery or related product is not in conformity with this Regulation, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the machinery or related product	<u>Where an importer considers or has reason to believe that a machinery or related product is not in conformity with this Regulation, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the machinery or related product</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>presents a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.</p>	<p><u>presents a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.</u></p>	
Article 12(3)		
<p>3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and website, email address or other digital contact at which they can be contacted on the machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related product. The contact details shall be in a language easily understood by users and market surveillance authorities.</p>	<p><u>3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and website, email address or other digital contact at which they can be contacted on the machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related product. The contact details shall be in a language easily understood by users and market surveillance authorities.</u></p>	
Article 12(4)		
<p>4. Importers shall ensure that the machinery or related product is accompanied by the instructions for use and information set out in Article 10(7).</p>	<p><u>4. Importers shall ensure that the machinery or related product is accompanied by the instructions for use and information set out in Article 10(7).</u></p>	
Article 12(5)		
<p>5. Importers shall ensure that the storage or transport conditions, while the machinery or related product is under their responsibility, do not jeopardise the conformity with the essential health and safety requirements set out in Annex III.</p>	<p><u>5. Importers shall ensure that the storage or transport conditions, while the machinery or related product is under their responsibility, do not jeopardise the conformity with the essential health and safety requirements set out in Annex III.</u></p>	
Article 12(6)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>6. When deemed appropriate with regard to the risks presented by a machinery or related product, importers shall, in order to protect health and safety of persons, and where appropriate, domestic animals and property and, where applicable, the environment carry out sample testing of machinery or related products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery or related products and machinery or related products recalls, and shall keep distributors informed of any such monitoring.</p>	<p><u>6. When deemed appropriate with regard to the risks presented by a machinery or related product, importers shall, in order to protect health and safety of persons, and where appropriate, domestic animals and property and, where applicable, the environment carry out sample testing of machinery or related products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery or related products and machinery or related products recalls, and shall keep distributors informed of any such monitoring.</u></p>	
Article 12(7)		
<p>7. Importers who consider or have reason to believe that a machinery or related product, which they have placed on the market, is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that machinery or related product into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the machinery or related product presents a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, importers shall immediately inform the competent national authorities of the Member States in which they made the machinery or related product available on the market to that effect,</p>	<p><u>7. Importers who consider or have reason to believe that a machinery or related product, which they have placed on the market, is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that machinery or related product into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the machinery or related product presents a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, importers shall immediately inform the competent national authorities of the Member States in which they made the machinery or related product available on the market to that effect,</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
giving details, in particular, of the non-conformity and of any corrective actions taken.	<u>giving details, in particular, of the non-conformity and of any corrective actions taken.</u>	
Article 12(8)		
<p>8. Importers shall, for ten years after the machinery or related product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation set out in Part A of Annex IV can be made available to those authorities upon request. Where relevant, the importer shall arrange with the manufacturer that the source code or programming logic included in the technical documentation be made available upon a reasoned request from competent national authorities provided that it is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.</p>	<p><u>8. Importers shall, for ten years after the machinery or related product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation set out in Part A of Annex IV can be made available to those authorities upon request. Where relevant, the importer shall arrange with the manufacturer that the source code or programming logic included in the technical documentation be made available upon a reasoned request from competent national authorities provided that it is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.</u></p>	
Article 12(9)		
<p>9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery or related products with this Regulation in a language that can be easily understood by that authority. They shall cooperate with that authority, at its</p>	<p><u>9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery or related products with this Regulation in a language that can be easily understood by that authority. They shall cooperate with that authority, at its</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
request, on any actions taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment presented by machinery or related products, which they have placed on the market.	<u>request, on any actions taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment presented by machinery or related products, which they have placed on the market.</u>	
Article 12a		
Article 12a	<u>Article 12a</u>	
Obligations of importers of partly completed machinery	<u>Obligations of importers of partly completed machinery</u>	
Article 12a(1)		
1. Importers shall place only compliant partly completed machinery on the market .	<u>1. Importers shall place only compliant partly completed machinery on the market .</u>	
Article 12a(2), introductory part		
2. Before placing a partly completed machinery on the market, importers shall ensure that the manufacturer has drawn up the technical documentation set out in Part B of Annex IV, that it is accompanied by the required documents and that the manufacturer has complied with the requirements set out in Article 10a (5) and (6).	<u>2. Before placing a partly completed machinery on the market, importers shall ensure that the manufacturer has drawn up the technical documentation set out in Part B of Annex IV, that it is accompanied by the required documents and that the manufacturer has complied with the requirements set out in Article 10a (5) and (6).</u>	
Article 12a(2), first paragraph		
Where an importer considers or has reason to believe that a partly completed machinery is not in conformity with this Regulation, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the partly completed machinery presents a	<u>Where an importer considers or has reason to believe that a partly completed machinery is not in conformity with this Regulation, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the partly completed machinery presents a</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>risk as regards the relevant essential health and safety requirements, the importer shall inform the manufacturer and the market surveillance authorities to that effect.</p>	<p><u>risk as regards the relevant essential health and safety requirements, the importer shall inform the manufacturer and the market surveillance authorities to that effect.</u></p>	
<p>Article 12a(3)</p>		
<p>3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and website, email address or other digital contact at which they can be contacted on the partly completed machinery or, where that is not possible, on its packaging or in a document accompanying the partly completed machinery . The contact details shall be in a language easily understood by the person who incorporates the partly completed machinery and market surveillance authorities.</p>	<p><u>3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and website, email address or other digital contact at which they can be contacted on the partly completed machinery or, where that is not possible, on its packaging or in a document accompanying the partly completed machinery . The contact details shall be in a language easily understood by the person who incorporates the partly completed machinery and market surveillance authorities.</u></p>	
<p>Article 12a(4)</p>		
<p>4. Importers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Article 10a(7).</p>	<p><u>4. Importers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Article 10a(7).</u></p>	
<p>Article 12a(5)</p>		
<p>5. Importers shall ensure that the storage or transport conditions of partly completed machinery, while it is under their responsibility, do not jeopardise the conformity with the relevant essential health and safety requirements set out in Annex III.</p>	<p><u>5. Importers shall ensure that the storage or transport conditions of partly completed machinery, while it is under their responsibility, do not jeopardise the conformity with the relevant essential health and safety requirements set out in Annex III.</u></p>	
<p>Article 12a(7)</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>7. Importers who consider or have reason to believe that a partly completed machinery , which they have placed on the market, is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk as regards essential health and safety requirements, importers shall immediately inform the competent national authorities of the Member States in which they made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.</p>	<p><u>7. Importers who consider or have reason to believe that a partly completed machinery , which they have placed on the market, is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk as regards essential health and safety requirements, importers shall immediately inform the competent national authorities of the Member States in which they made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.</u></p>	
<p>Article 12a(8)</p>		
<p>8. Importers shall, for ten years after the partly completed machinery has been placed on the market, keep a copy of the EU declaration of incorporation at the disposal of the market surveillance authorities and ensure that the technical documentation set out in Part B of Annex IV can be made available to those authorities upon request in digital or paper format.</p>	<p><u>8. Importers shall, for ten years after the partly completed machinery has been placed on the market, keep a copy of the EU declaration of incorporation at the disposal of the market surveillance authorities and ensure that the technical documentation set out in Part B of Annex IV can be made available to those authorities upon request in digital or paper format.</u></p>	
<p>Article 12a(9)</p>		
<p>9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the</p>	<p><u>9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>information and documentation, in paper or digital format, necessary to demonstrate the conformity of the partly completed machinery with this Regulation in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks presented by a partly completed machinery, which they have placed on the market.</p>	<p><u>information and documentation, in paper or digital format, necessary to demonstrate the conformity of the partly completed machinery with this Regulation in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks presented by a partly completed machinery, which they have placed on the market.</u></p>	
Article 13		
Article 13	<u>Article 13</u>	
Obligations of distributors of machinery and related product	<u>Obligations of distributors of machinery and related product</u>	
Article 13(1)		
<p>1. When making a machinery or related product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.</p>	<p><u>1. When making a machinery or related product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.</u></p>	
Article 13(2), introductory part		
<p>2. Before making a machinery or related product available on the market, distributors shall verify that:</p>	<p><u>2. Before making a machinery or related product available on the market, distributors shall verify that:</u></p>	
Article 13(2), point (a)		
<p>(a) the machinery or related product bears the CE marking;</p>	<p><u>(a) the machinery or related product bears the CE marking;</u></p>	
Article 13(2), point (b)		
<p>(b) the machinery or related product is accompanied by the EU declaration of conformity set out in Part A of Annex V</p>	<p><u>(b) the machinery or related product is accompanied by the EU declaration of conformity set out in Part A of Annex V</u></p>	
Article 13(2), point (ba)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(ba) the machinery or related product is accompanied by the instructions for use and information set out in Article 10(7), and that they are in a language which can be easily understood by users as determined by the Member State in which the machinery or related product is to be made available on the market.	<u>(ba) the machinery or related product is accompanied by the instructions for use and information set out in Article 10(7), and that they are in a language which can be easily understood by users as determined by the Member State in which the machinery or related product is to be made available on the market.</u>	
Article 13(2), point (c)		
(c) the manufacturer and the importer have complied with the requirements set out in Article 10(5) and (6) and Article 12(3) respectively.	<u>(c) the manufacturer and the importer have complied with the requirements set out in Article 10(5) and (6) and Article 12(3) respectively.</u>	
Article 13(3)		
3. Where a distributor considers or has reason to believe that a machinery or related product is not in conformity with this Regulation, the distributor shall not make the machinery or related product available on the market until it has been brought into conformity. Furthermore, where the machinery or related product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.	<u>3. Where a distributor considers or has reason to believe that a machinery or related product is not in conformity with this Regulation, the distributor shall not make the machinery or related product available on the market until it has been brought into conformity. Furthermore, where the machinery or related product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.</u>	
Article 13(4)		
4. Distributors shall ensure that the storage or transport conditions, while a machinery or related product is under their responsibility, do not jeopardise the	<u>4. Distributors shall ensure that the storage or transport conditions, while a machinery or related product is under their responsibility, do not jeopardise the</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>conformity with the essential health and safety requirements set out in Annex III.</p>	<p><u>conformity with the essential health and safety requirements set out in Annex III.</u></p>	
<p>Article 13(5)</p>		
<p>5. Distributors who consider or have reason to believe that a machinery or related product, which they have made available on the market, is not in conformity with this Regulation shall make sure that the corrective actions necessary to bring that machinery or related product into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the machinery or related product presents a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, distributors shall immediately inform the competent national authorities of the Member States in which they have made the machinery or related product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.</p>	<p><u>5. Distributors who consider or have reason to believe that a machinery or related product, which they have made available on the market, is not in conformity with this Regulation shall make sure that the corrective actions necessary to bring that machinery or related product into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the machinery or related product presents a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, distributors shall immediately inform the competent national authorities of the Member States in which they have made the machinery or related product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.</u></p>	
<p>Article 13(6)</p>		
<p>6. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or digital format, necessary to demonstrate the conformity of the machinery or related product with this Regulation in a language that can be</p>	<p><u>6. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or digital format, necessary to demonstrate the conformity of the machinery or related product with this Regulation in a language that can be</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, presented by a machinery or related product, which they have made available on the market.</p>	<p><u>easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, presented by a machinery or related product, which they have made available on the market.</u></p>	
Article 13a		
Article 13a	Article 13a	
Obligations of distributors of partly completed machinery	<u>Obligations of distributors of partly completed machinery</u>	
Article 13a(1)		
<p>1. When making a partly completed machinery available on the market, distributors shall act with due care in relation to the requirements of this Regulation.</p>	<p><u>1. When making a partly completed machinery available on the market, distributors shall act with due care in relation to the requirements of this Regulation.</u></p>	
Article 13a(2), introductory part		
<p>2. Before making a partly completed machinery available on the market, distributors shall verify that:</p>	<p><u>2. Before making a partly completed machinery available on the market, distributors shall verify that:</u></p>	
Article 13a(2), point (a), introductory part		
<p>(a) the partly completed machinery is accompanied by the by the EU declaration of incorporation set out in part B of Annex V</p>	<p><u>(a) the partly completed machinery is accompanied by the by the EU declaration of incorporation set out in part B of Annex V</u></p>	
Article 13a(2), point (aa)		
<p>(aa) the partly completed machinery is accompanied by the assembly instructions set out in Article 10a(7), and that they are in a language which can be</p>	<p><u>(aa) the partly completed machinery is accompanied by the assembly instructions set out in Article 10a(7), and that they are in a language which can be</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>easily understood by the person who incorporates the partly completed machinery as determined by the Member State in which the partly completed machinery is to be made available on the market.</p>	<p><u>easily understood by the person who incorporates the partly completed machinery as determined by the Member State in which the partly completed machinery is to be made available on the market.</u></p>	
Article 13a(2), point (b)		
<p>(b) the manufacturer and the importer have complied with the requirements set out in Article 10a (5) and (6) and Article 12a (3) respectively.</p>	<p><u>(b) the manufacturer and the importer have complied with the requirements set out in Article 10a (5) and (6) and Article 12a (3) respectively.</u></p>	
Article 13a(3)		
<p>3. Where a distributor considers or has reason to believe that a partly completed machinery is not in conformity with this Regulation, the distributor shall not make the partly completed machinery available on the market until it has been brought into conformity. Furthermore, where the partly completed machinery presents a risk as regards relevant essential health and safety requirements, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.</p>	<p><u>3. Where a distributor considers or has reason to believe that a partly completed machinery is not in conformity with this Regulation, the distributor shall not make the partly completed machinery available on the market until it has been brought into conformity. Furthermore, where the partly completed machinery presents a risk as regards relevant essential health and safety requirements, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.</u></p>	
Article 13a(4)		
<p>4. Distributors shall ensure that the storage or transport conditions, while a partly completed machinery is under their responsibility, do not jeopardise the conformity with the relevant essential health and safety requirements set out in Annex III.</p>	<p><u>4. Distributors shall ensure that the storage or transport conditions, while a partly completed machinery is under their responsibility, do not jeopardise the conformity with the relevant essential health and safety requirements set out in Annex III.</u></p>	
Article 13a(5)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>5. Distributors who consider or have reason to believe that a partly completed machinery which they have made available on the market, is not in conformity with this Regulation shall make sure that the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the partly completed machinery presents a risk as regards applicable essential health and safety requirements distributors shall immediately inform the competent national authorities of the Member States in which they have made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.</p>	<p><u>5. Distributors who consider or have reason to believe that a partly completed machinery which they have made available on the market, is not in conformity with this Regulation shall make sure that the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the partly completed machinery presents a risk as regards applicable essential health and safety requirements distributors shall immediately inform the competent national authorities of the Member States in which they have made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.</u></p>	
<p>Article 13a(6)</p>		
<p>6. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or digital format, necessary to demonstrate the conformity of the partly completed machinery with this Regulation. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks as regards the essential health and safety requirements presented by a partly</p>	<p><u>6. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or digital format, necessary to demonstrate the conformity of the partly completed machinery with this Regulation. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks as regards the essential health and safety requirements presented by a partly</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
completed machinery, which they have made available on the market.	<u>completed machinery, which they have made available on the market.</u>	
Article 14		
Article 14	<u>Article 14</u>	
Cases in which obligations of manufacturers apply to importers and distributors	<u>Cases in which obligations of manufacturers apply to importers and distributors</u>	
Article 14, first paragraph		
An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 and 10a where that importer or distributor places a product within the scope of this Regulation on the market under his or her name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.	<u>An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 and 10a where that importer or distributor places a product within the scope of this Regulation on the market under his or her name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.</u>	
Article 15		
Article 15	<u>Article 15</u>	
Other cases in which obligations of manufacturers apply	<u>Other cases in which obligations of manufacturers apply</u>	
Article 15, first paragraph		
A natural or legal person, that carries out a substantial modification of a machinery or related product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for that machinery or related product or, if the substantial modification has only an impact on the safety of a part	<u>A natural or legal person, that carries out a substantial modification of a machinery or related product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for that machinery or related product or, if the substantial modification has only an impact on the safety of a part</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
of an assembly of machinery, for the affected machinery of this assembly as demonstrated in the risk assessment.	<u>of an assembly of machinery, for the affected machinery of this assembly as demonstrated in the risk assessment.</u>	
Article 15, first paragraph a		
The person who carries out the substantial modification shall in particular and without prejudice to other obligations set out in Article 10, ensure and declare on its sole responsibility that the machinery or related product concerned is in conformity with the applicable requirements of this Regulation and shall apply the relevant conformity assessment procedure as provided in Article 21(2), (2a) and (3) of this Regulation.	<u>The person who carries out the substantial modification shall in particular and without prejudice to other obligations set out in Article 10, ensure and declare on its sole responsibility that the machinery or related product concerned is in conformity with the applicable requirements of this Regulation and shall apply the relevant conformity assessment procedure as provided in Article 21(2), (2a) and (3) of this Regulation.</u>	
Article 15, first paragraph b		
A non-professional user who carries out a substantial modification on his or her own machinery or related product for his or her own use shall not be considered a manufacturer for the purposes of this Regulation and shall not be subject to the obligations of the manufacturer set out in Article 10.	<u>A non-professional user who carries out a substantial modification on his or her own machinery or related product for his or her own use shall not be considered a manufacturer for the purposes of this Regulation and shall not be subject to the obligations of the manufacturer set out in Article 10.</u>	
Article 16		
Article 16	<u>Article 16</u>	
Identification of economic operators	<u>Identification of economic operators</u>	
Article 16(1), introductory part		
1. Economic operators shall, on request, identify the following to the market surveillance authorities:	<u>1. Economic operators shall, on request, identify the following to the market surveillance authorities:</u>	
Article 16(1), point (a)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(a) any economic operator who has supplied them with a product within the scope of this Regulation;	<u>(a) any economic operator who has supplied them with a product within the scope of this Regulation;</u>	
Article 16(1), point (b)		
(b) any economic operator to whom they have supplied a product within the scope of this Regulation.	<u>(b) any economic operator to whom they have supplied a product within the scope of this Regulation.</u>	
Article 16(2)		
2. Economic operators shall be able to present the information referred to in paragraph 1 for ten years after they have been supplied with the product within the scope of this Regulation and for ten years after they have supplied the product within the scope of this Regulation.	<u>2. Economic operators shall be able to present the information referred to in paragraph 1 for ten years after they have been supplied with the product within the scope of this Regulation and for ten years after they have supplied the product within the scope of this Regulation.</u>	

### Chapter 3: Conformity of products within the scope of this regulation

DRAFT Machinery Regulation	Comparison	Machinery Directive
CHAPTER III		
CONFORMITY OF PRODUCTS WITHIN THE SCOPE OF THIS REGULATION	<u>CONFORMITY OF PRODUCTS WITHIN THE SCOPE OF THIS REGULATION</u>	
Article 17		Article 7
Article 17	Article <del>17</del> <sup>7</sup>	Article 7
Presumption of conformity of products within the scope of this Regulation	Presumption of conformity <u>of products within the scope of this Regulation</u> <del>and harmonised standards</del>	Presumption of conformity and harmonised standards
		Article 7(1)
	<del>1. Member States shall regard machinery bearing the CE marking and accompanied by the EC declaration of conformity, the content of which is set out in Annex II, part 1, Section A, as complying with the provisions of this Directive.</del>	1. Member States shall regard machinery bearing the CE marking and accompanied by the EC declaration of conformity, the content of which is set out in Annex II, part 1, Section A, as complying with the provisions of this Directive.
Article 17(1)		Article 7(2)
1. A product within the scope of this Regulation which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those standards or parts thereof.	<u>1. A product within the scope of this Regulation which is</u> <del>2. Machinery manufactured</del> in conformity with a harmonised <u>standards or parts thereof</u> <del>standard</del> , the references <u>of</u> <del>to</del> which have been published in the Official Journal of the European Union, shall be presumed to <u>be in conformity</u> <del>comply</del> with the essential health and safety requirements <u>set out in Annex III</u> covered by <u>those standards or parts thereof</u> <del>such a harmonised standard</del> .	2. Machinery manufactured in conformity with a harmonised standard, the references to which have been published in the Official Journal of the European Union, shall be presumed to comply with the essential health and safety requirements covered by such a harmonised standard.
		Article 7(3)
	<del>3. The Commission shall publish in the Official Journal of the European Union the references of the harmonised standards.</del>	3. The Commission shall publish in the Official Journal of the European Union the references of the harmonised standards.

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>4. Member States shall take the appropriate measures to enable the social partners to have an influence at national level on the process of preparing and monitoring the harmonised standards.</del></p>	<p>Article 7(4) 4. Member States shall take the appropriate measures to enable the social partners to have an influence at national level on the process of preparing and monitoring the harmonised standards.</p>
Article 17(2)		
<p>2. The Commission shall, as provided in Article 10(1) of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential health and safety requirements set out in Annex III.</p>	<p><u>2. The Commission shall, as provided in Article 10(1) of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential health and safety requirements set out in Annex III.</u></p>	
Article 17(3), first subparagraph, introductory part		
<p>3. The Commission is empowered to adopt implementing acts establishing common specifications that cover technical requirements providing a means to comply with the essential health and safety requirements set out in Annex III for products within the scope of this Regulation where the following conditions have been fulfilled:</p>	<p><u>3. The Commission is empowered to adopt implementing acts establishing common specifications that cover technical requirements providing a means to comply with the essential health and safety requirements set out in Annex III for products within the scope of this Regulation where the following conditions have been fulfilled:</u></p>	
Article 17(3), first subparagraph, point (a)		
<p>(a) the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements set out in Annex III and the request has not been</p>	<p><u>(a) the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements set out in Annex III and the request has not been</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>accepted or the European standardisation deliverables addressing that request is not delivered within the deadline set in accordance with Article 10(1) of Regulation 1025/2012 or European standardisation deliverables does not comply with the request; and</p>	<p><u>accepted or the European standardisation deliverables addressing that request is not delivered within the deadline set in accordance with Article 10(1) of Regulation 1025/2012 or European standardisation deliverables does not comply with the request; and</u></p>	
<p>Article 17(3), first subparagraph, point (b)</p>		
<p>(b) no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.</p>	<p><u>(b) no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and no such reference is expected to be published within a reasonable period.</u></p>	
<p>Article 17(3), second subparagraph</p>		
<p>Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).</p>	<p><u>Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).</u></p>	
<p>Article 17(3a)</p>		
<p>3a. Before preparing a draft implementing act, the Commission shall inform the committee referred to in Article 22 of Regulation EU (No) 1025/2012 that it considers that the conditions in paragraph 3 are fulfilled.</p>	<p><u>3a. Before preparing a draft implementing act, the Commission shall inform the committee referred to in Article 22 of Regulation EU (No) 1025/2012 that it considers that the conditions in paragraph 3 are fulfilled.</u></p>	
<p>Article 17(3b)</p>		
<p>3b. When preparing the draft implementing act establishing the common specification, the Commission shall take into account the views of relevant bodies or the expert group and</p>	<p><u>3b. When preparing the draft implementing act establishing the common specification, the Commission shall take into account the views of relevant bodies or the expert group and</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
shall duly consult all relevant stakeholders.	<u>shall duly consult all relevant stakeholders.</u>	
Article 17(4)		
4. A product within the scope of this Regulation which is in conformity with the common specifications established by one or more implementing acts referred to in paragraph 3 or parts thereof shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those common specifications or parts thereof.	<u>4. A product within the scope of this Regulation which is in conformity with the common specifications established by one or more implementing acts referred to in paragraph 3 or parts thereof shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those common specifications or parts thereof.</u>	
Article 17(4a)		
4a. Where a harmonised standard is adopted by an European standardisation organisation and proposed to the Commission for the publication of its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal implementing acts referred to in paragraph 3, or parts thereof which cover the same essential health and safety requirements set out in Annex III.	<u>4a. Where a harmonised standard is adopted by an European standardisation organisation and proposed to the Commission for the publication of its reference in the Official Journal of the European Union, the Commission shall assess the harmonised standard in accordance with Regulation (EU) 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal implementing acts referred to in paragraph 3, or parts thereof which cover the same essential health and safety requirements set out in Annex III.</u>	
Article 17(4b)		
4b. When a Member State considers that a common specification does not entirely satisfy the essential health and safety requirements set out in Annex III, it shall	<u>4b. When a Member State considers that a common specification does not entirely satisfy the essential health and safety requirements set out in Annex III, it shall</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, may amend the implementing act establishing the common specification in question.</p>	<p><u>inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, may amend the implementing act establishing the common specification in question.</u></p>	
<p>Article 11 of Regulation (EU) No 1025/2012 "Formal objections to harmonised standards"</p>	<p><u>Article 11 of Regulation (EU) No 1025/2012</u> <u>"Formal objections to harmonised standards"</u> <del>Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee set up by Directive 98/34/EC, setting out the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.</del></p>	<p>Article 10 Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee set up by Directive 98/34/EC, setting out the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.</p>
<p>Article 17(5)</p>		
<p>5. Machinery and related products that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme adopted in accordance with Regulation (EU)</p>	<p><u>5. Machinery and related products that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme adopted in accordance with Regulation (EU)</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>2019/881 and the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III, sections 1.1.9 and 1.2.1, as regards protection against corruption and safety and reliability of control systems in so far as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.</p>	<p><u>2019/881 and the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III, sections 1.1.9 and 1.2.1, as regards protection against corruption and safety and reliability of control systems in so far as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.</u></p>	
<p>Article 18</p>		
<p>Article 18</p>	<p><u>Article 18</u></p>	
<p>EU declaration of conformity of machinery and related products</p>	<p><u>EU declaration of conformity of machinery and related products</u></p>	
<p>Article 18(1)</p>		
<p>1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex III has been demonstrated.</p>	<p><u>1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex III has been demonstrated.</u></p>	
<p>Article 18(2)</p>		
<p>2. The EU declaration of conformity shall have the model structure set out in part A of Annex V, and shall contain the elements specified in the relevant modules set out in Annexes VI, VIII, IX, and IXa and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the machinery or related product is placed on the market,</p>	<p><u>2. The EU declaration of conformity shall have the model structure set out in part A of Annex V, and shall contain the elements specified in the relevant modules set out in Annexes VI, VIII, IX, and IXa and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the machinery or related product is placed on the market,</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
is made available on the market or put into service.	<u>is made available on the market or put into service.</u>	
Article 18(3)		
3. Where a machinery or related product is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.	<u>3. Where a machinery or related product is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.</u>	
Article 18(4)		
4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the machinery or related product with the requirements laid down in this Regulation.	<u>4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the machinery or related product with the requirements laid down in this Regulation.</u>	
Article 18a		
EU declaration of incorporation of partly completed machinery	<u>EU declaration of incorporation of partly completed machinery</u>	
Article 18a(1)		
1. The EU declaration of incorporation shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex III has been demonstrated.	<u>1. The EU declaration of incorporation shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex III has been demonstrated.</u>	
Article 18a(2)		
2. The EU declaration of incorporation shall have the model structure set out in part B of Annex V. It shall be translated into the language or languages required by the Member State in which the partly	<u>2. The EU declaration of incorporation shall have the model structure set out in part B of Annex V. It shall be translated into the language or languages required by the Member State in which the partly</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
completed machinery is placed on the market or is made available on the market.	<u>completed machinery is placed on the market or is made available on the market.</u>	
Article 18a(3)		
3. Where a partly completed machinery is subject to more than one Union act requiring an EU declaration of conformity, the EU declaration of incorporation shall include a sentence declaring the conformity with such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.	<u>3. Where a partly completed machinery is subject to more than one Union act requiring an EU declaration of conformity, the EU declaration of incorporation shall include a sentence declaring the conformity with such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.</u>	
Article 18a(4)		
4. By drawing up the EU declaration of incorporation, the manufacturer shall assume responsibility for the compliance of the partly completed machinery with the requirements laid down in this Regulation.	<u>4. By drawing up the EU declaration of incorporation, the manufacturer shall assume responsibility for the compliance of the partly completed machinery with the requirements laid down in this Regulation.</u>	
Article 19		Article 16
Article 19	Article <del>19</del> <sup>16</sup>	Article 16
General principles of the CE marking	<u>General principles of the CE marking</u>	CE marking
Article 19, first paragraph		Article 16
The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	<del>1. The CE conformity marking shall consist of the initials 'CE' as shown in Annex III.</del> <del>2. The CE marking shall be subject</del> <u>affixed</u> to the <u>general principles set out in Article 30 of Regulation (EC) No 765/2008</u> <del>machinery visibly, legibly and indelibly in accordance with Annex III.</del> <del>3. The affixing on machinery of markings, signs and inscriptions which are likely to</del>	1. The CE conformity marking shall consist of the initials 'CE' as shown in Annex III. 2. The CE marking shall be affixed to the machinery visibly, legibly and indelibly in accordance with Annex III. 3. The affixing on machinery of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both, shall be

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>mislead third parties as to the meaning or form of the CE marking, or both, shall be prohibited. Any other marking may be affixed to the machinery provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.</del></p>	<p>prohibited. Any other marking may be affixed to the machinery provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.</p>
Annex II of Regulation (EC) No 765/2008	Annex <u>II</u> of Regulation (EC) No 765/2008 <del>III</del>	Annex III
Article 20		
Article 20	<u>Article 20</u>	
Rules for affixing the CE marking to machinery and related products	<u>Rules for affixing the CE marking to machinery and related products</u>	
Article 20(1)		
1. The CE marking shall be affixed visibly, legibly and indelibly to the machinery or related product. Where that is not possible or not warranted on account of the nature of the machinery or related product, it shall be affixed to the packaging and to the documents accompanying the machinery or related product.	<p><u>1. The CE marking shall be affixed visibly, legibly and indelibly to the machinery or related product. Where that is not possible or not warranted on account of the nature of the machinery or related product, it shall be affixed to the packaging and to the documents accompanying the machinery or related product.</u></p>	
Article 20(2)		Article 5, point (1)(f)
2. The CE marking shall be affixed before the machinery or related product is placed on the market or put into service.	<p><u>2. The CE marking shall be affixed before</u>  <del>1. Before placing</del> machinery or related product is placed on the market <del>and/or</del> <del>put</del> <del>putting it</del> into service, <del>the manufacturer or his authorised representative shall:</del>  <del>(f) affix the CE marking in accordance with Article 16.</del></p>	<p>1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:                      (f) affix the CE marking in accordance with Article 16.</p>
Article 20(3), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>3. Where the conformity of machinery or related products is assessed in accordance with the conformity assessment procedure referred to in Article 21 (2) points a) and b) and c) and in article 21 (2a) points b) and c) and d) , the CE marking shall be followed by the identification number of the notified body involved in that procedure.</p>	<p><u>3. Where the conformity of machinery or related products is assessed in accordance with the conformity assessment procedure referred to in Article 21 (2) points a) and b) and c) and in article 21 (2a) points b) and c) and d) , the CE marking shall be followed by the identification number of the notified body involved in that procedure.</u></p>	
Article 20(3), first paragraph		
<p>The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.</p>	<p><u>The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.</u></p>	
Article 20(4)		
<p>4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or any other marking indicating a special risk or use.</p>	<p><u>4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or any other marking indicating a special risk or use.</u></p>	
Article 20(5)		
<p>5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.</p>	<p><u>5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.</u></p>	

## Chapter 4: Conformity assessment

DRAFT Machinery Regulation	Comparison	Machinery Directive
CHAPTER IV		
CONFORMITY ASSESSMENT	<u>CONFORMITY ASSESSMENT</u>	
Article 21		Article 12
Article 21	Article 21 <del>12</del>	Article 12
Conformity assessment procedures for machinery and related products	<u>Conformity assessment procedures</u> <del>Procedures</del> for <del>assessing the conformity of</del> machinery <u>and related products</u>	Procedures for assessing the conformity of machinery
Article 21(1)		Article 12(1)
1. The manufacturer or the natural or legal person referred to in Article 15 shall apply one of the procedures for assessment of conformity referred to in paragraphs 2, 2a and 3.	1. -The manufacturer or <u>the natural or legal person referred to in Article 15</u> <del>his authorised representative shall, in order to certify the conformity of machinery with the provisions of this Directive,</del> apply one of the procedures for assessment of conformity <u>referred to</u> <del>described</del> in paragraphs 2, <del>2a</del> <u>3</u> and <del>3</del> <u>4</u> .	1. The manufacturer or his authorised representative shall, in order to certify the conformity of machinery with the provisions of this Directive, apply one of the procedures for assessment of conformity described in paragraphs 2, 3 and 4.
Article 21(2), introductory part		
2. Where the category of machinery or related product is listed in Annex I, part A, the manufacturer or the natural or legal person referred to in Article 15 shall apply one of the following procedures:	<u>2. Where the category of machinery or related product is listed in Annex I, part A, the manufacturer or the natural or legal person referred to in Article 15 shall apply one of the following procedures:</u>	
Article 21(2), point (a)		
(a) EU type-examination procedure (module B) set out in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;	<u>(a) EU type-examination procedure (module B) set out in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;</u>	
Article 21(2), point (b)		
(b) Conformity based on full quality assurance (module H) set out in Annex IX.	<u>(b) Conformity based on full quality assurance (module H) set out in Annex IX.</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 21(2), point (c) (c) Conformity based on unit verification (module G) set out in Annex IXa.	<u>(c) Conformity based on unit verification (module G) set out in Annex IXa.</u>	
Article 21(2a) 2a. Where the machinery or related product is listed in Annex I, part B, the manufacturer as defined in Article 3(17) and referred to in Article 15 shall apply one of the following procedures:	<del>2a.3-</del> Where the machinery <u>or related product is listed</u> <del>referred to</del> in Annex I, <u>part B, the manufacturer as defined in Article 3(17)</u> <del>IV</del> and <del>manufactured in accordance with the harmonised standards referred to in Article 15</del> <u>7(2)</u> , <del>and provided that those standards cover all of the relevant essential health and safety requirements, the manufacturer or his authorised representative</del> shall apply one of the following procedures:	Article 12(3) 3. Where the machinery is referred to in Annex IV and manufactured in accordance with the harmonised standards referred to in Article 7(2), and provided that those standards cover all of the relevant essential health and safety requirements, the manufacturer or his authorised representative shall apply one of the following procedures:
Article 21(2a)(a)		Article 12(3)(a)
(a) the internal production control procedure (module A) set out in Annex VI;	(a) the <u>internal production control procedure (module A) set out</u> <del>for assessment of conformity with internal checks on the manufacture of machinery, provided for</del> in Annex <del>VI</del> <u>VIII</u> ;	(a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII;
Article 21(2a)(b)		Article 12(3)(b)
(b) the EU type-examination procedure (module B) provided for in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;	(b) the <del>EU</del> <u>EC</u> type-examination procedure <u>(module B) provided for in Annex VII, followed by conformity to type based on IX, plus the internal production control (module C) set out</u> <del>checks on the manufacture of machinery provided for in Annex VIII, point 3;</del>	(b) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;
Article 21(2a)(c)		Article 12(3)(c)
(c) conformity based on full quality assurance procedure (module H) set out in Annex IX;	(c) <u>conformity based on</u> <del>the</del> full quality assurance procedure <u>(module H) set out</u> <del>provided for</del> in Annex <del>IX</del> <u>X</u> .	(c) the full quality assurance procedure provided for in Annex X.
Article 21(2a)(d)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(d) conformity based on unit verification procedure (module G) set out in Annex IXa.	<u>(d) conformity based on unit verification procedure (module G) set out in Annex IXa.</u>	
Article 21(2a) unnumbered paragraph 1		
If a manufacturer applies the internal production control procedure referred to in point (a), he or she shall have designed and constructed the machinery or related product in accordance with the harmonised standards or common specifications specific for that category of machinery or related product covering all the relevant essential health and safety requirements.	<u>If a manufacturer applies the internal production control procedure referred to in point (a), he or she shall have designed and constructed the machinery or related product in accordance with the harmonised standards or common specifications specific for that category of machinery or related product covering all the relevant essential health and safety requirements.</u>	
Article 21(2a) unnumbered paragraph 2		Article 12(4)
Where the machinery or related product is listed in Annex I part B and has not been manufactured in accordance with the harmonized standards or common specifications covering all the relevant essential health and safety requirements for that category of machinery or related product, the manufacturer shall apply one of the procedures referred to in paragraph 2a(b), (c) or (d).	<del>4.</del> Where the machinery <u>or related product is listed</u> <del>referred to</del> in Annex I <u>part B</u> <del>IV</del> and has not been manufactured in accordance with the <del>harmonized</del> <u>harmonised</u> standards <del>referred to in Article 7(2), or only partly in accordance with such standards,</del> or <u>common specifications covering</u> <del>if the harmonised standards do not cover</del> all the relevant essential health and safety requirements <del>for that category of</del> <del>or if no harmonised standards exist for the machinery or related product</del> <u>in question,</u> the manufacturer <del>or his authorised representative</del> shall apply one of the <del>following</del> <u>procedures referred to in paragraph 2a(b), (c) or (d).</u> <del>;</del>	4. Where the machinery is referred to in Annex IV and has not been manufactured in accordance with the harmonised standards referred to in Article 7(2), or only partly in accordance with such standards, or if the harmonised standards do not cover all the relevant essential health and safety requirements or if no harmonised standards exist for the machinery in question, the manufacturer or his authorised representative shall apply one of the following procedures:
		Article 12(4)(a)

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>(a) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;</del>	(a) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;
		Article 12(4)(b)
	<del>(b) the full quality assurance procedure provided for in Annex X.</del>	(b) the full quality assurance procedure provided for in Annex X.
Article 21(3)		Article 12(2)
3. Where the machinery or related product is not listed in Annex I, the manufacturer or the natural or legal person referred to in Article 15 shall apply the internal production control procedure (module A) set out in Annex VI.	<del>3.2-</del> Where the machinery or related product is not listed referred to in Annex IV, the manufacturer or the natural or legal person referred to in Article 15 his authorised representative shall apply the internal production control procedure (module A) set out for assessment of conformity with internal checks on the manufacture of machinery provided for in Annex VI/VIII.	2. Where the machinery is not referred to in Annex IV, the manufacturer or his authorised representative shall apply the procedure for assessment of conformity with internal checks on the manufacture of machinery provided for in Annex VIII.
Article 21(4)		
4. Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment.	<u>4. Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment.</u>	
Article 22		
Article 22 (moved to Art.10a)	<u>Article 22 (moved to Art.10a)</u>	
Article 23, moved to article 4a, Council Mandate (row 166a)		
Article 23	<u>Article 23</u>	
deleted	<u>deleted</u>	

## Chapter 5: Notification of conformity assessment bodies

DRAFT Machinery Regulation	Comparison	Machinery Directive
CHAPTER V		Article 14
NOTIFICATION OF CONFORMITY ASSESSMENT BODIES	<u>NOTIFICATION OF CONFORMITY ASSESSMENT BODIES</u> <del>Notified bodies</del>	Notified bodies
Article 24		
Article 24	<u>Article 24</u>	
Notification	<u>Notification</u>	
Article 24, first paragraph		Article 14(1)
Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks in accordance with this Regulation.	<del>1.</del> Member States shall notify the Commission and the other Member States of <del>the</del> <u>bodies authorised</u> <del>which they have appointed</del> to carry out <u>third-party</u> <del>the assessment of</del> conformity <u>assessment tasks</u> <del>for placing on the market referred to in</del> <u>accordance</u> <del>Article 12(3) and (4), together</del> with this <u>Regulation</u> <del>the specific conformity assessment procedures and categories of machinery for which these bodies have been appointed and the identification numbers assigned to them beforehand by the Commission. Member States shall notify the Commission and other Member States of any subsequent amendment.</del>	1. Member States shall notify the Commission and the other Member States of the bodies which they have appointed to carry out the assessment of conformity for placing on the market referred to in Article 12(3) and (4), together with the specific conformity assessment procedures and categories of machinery for which these bodies have been appointed and the identification numbers assigned to them beforehand by the Commission. Member States shall notify the Commission and other Member States of any subsequent amendment.
Article 25		
Article 25	<u>Article 25</u>	
Notifying authorities	<u>Notifying authorities</u>	
Article 25(1)		Article 14(2)
1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of	<del>1.2.</del> <del>The</del> Member States shall <u>designate a notifying authority</u> <del>ensure</del> that <u>shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of</u>	2. The Member States shall ensure that the notified bodies are monitored regularly to check that they comply at all times with the criteria set out in Annex XI. The notified body shall provide all

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 30.</p>	<p><u>conformity assessment bodies and the monitoring of notified bodies</u> <del>are monitored regularly to check that they comply at all times with the criteria set out in Annex XI. The notified body shall provide all relevant information on request, including compliance with Article 30</del> <u>budgetary documents, to enable the Member States to ensure that the requirements of Annex XI are met.</u></p>	<p>relevant information on request, including budgetary documents, to enable the Member States to ensure that the requirements of Annex XI are met.</p>
<p>Article 25(2)</p>		
<p>2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.</p>	<p><u>2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.</u></p>	
<p>Article 25(3)</p>		
<p>3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body, which is not a governmental entity that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 26. In addition, that body shall have arrangements to cover liabilities arising out of its activities.</p>	<p><u>3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body, which is not a governmental entity that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 26. In addition, that body shall have arrangements to cover liabilities arising out of its activities.</u></p>	
<p>Article 25(4)</p>		
<p>4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.</p>	<p><u>4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.</u></p>	
<p>Article 26</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 26	<u>Article 26</u>	
Requirements relating to notifying authorities	<u>Requirements relating to notifying authorities</u>	
Article 26(1)		
1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.	<u>1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.</u>	
Article 26(2)		
2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.	<u>2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.</u>	
Article 26(3)		
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.	<u>3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.</u>	
Article 26(4)		
4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy services on a commercial or competitive basis.	<u>4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy services on a commercial or competitive basis.</u>	
Article 26(5)		
5. A notifying authority shall safeguard the confidentiality of the information it obtains.	<u>5. A notifying authority shall safeguard the confidentiality of the information it obtains.</u>	
Article 26(6)		
6. A notifying authority shall have a sufficient number of competent	<u>6. A notifying authority shall have a sufficient number of competent</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
personnel at its disposal for the proper performance of its tasks.	<u>personnel at its disposal for the proper performance of its tasks.</u>	
Article 27		
Article 27	<u>Article 27</u>	
Information obligation on notifying authorities	<u>Information obligation on notifying authorities</u>	
Article 27, first paragraph		
Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.	<u>Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.</u>	
Article 27, second paragraph		
The Commission shall make that information publicly available.	<u>The Commission shall make that information publicly available.</u>	
Article 28		
Article 28	<u>Article 28</u>	
Requirements relating to notified bodies	<u>Requirements relating to notified bodies</u>	
Article 28(1)		Article 14(3)
1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.	<u>1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.</u> <del>3. Member States shall apply the criteria set out in Annex XI in assessing the bodies to be notified and the bodies already notified.</del>	3. Member States shall apply the criteria set out in Annex XI in assessing the bodies to be notified and the bodies already notified.
Article 28(2)		
2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.	<u>2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.</u>	
Article 28(3), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>3. A conformity assessment body shall be a third-party body independent of the organisation or the machinery or related product it assesses.</p>	<p><u>3. A conformity assessment body shall be a third-party body independent of the organisation or the machinery or related product it assesses.</u></p>	
<p>Article 28(3), first paragraph</p>		
<p>A body belonging to a business association or professional federation representing undertakings involved in the design, manufacture, provision, assembly, use or maintenance of machinery or related products which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a conformity assessment body.</p>	<p><u>A body belonging to a business association or professional federation representing undertakings involved in the design, manufacture, provision, assembly, use or maintenance of machinery or related products which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a conformity assessment body.</u></p>	
<p>Article 28(4), first subparagraph</p>		<p>Annex XI, (1), first sentence</p>
<p>4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, importer, distributor, installer, purchaser, owner, user or maintainer of machinery or related products, that they assess, nor fulfil any of those roles in relation to partly completed machinery that has been incorporated into the assessed product or be the representative of any of those parties. This shall not preclude the use of assessed machinery or related products that are necessary for the operations of the conformity assessment</p>	<p><u>4. A conformity assessment</u><del>1. The</del> body, its <u>top-level management</u><del>director</del> and the <u>personnel</u><del>staff</del> responsible for carrying out the <u>conformity assessment tasks</u><del>verification tests</del> shall not be the designer, manufacturer, supplier, <u>importer, distributor, -or- installer, purchaser, owner, user or maintainer of machinery or related products,</u> <del>that machines which they assess inspect,</del> nor fulfil any of those roles in relation to partly completed machinery that has been incorporated into the assessed product or be the <del>authorised</del> representative of any of <u>those</u><del>these</del> parties. <u>This shall not preclude the use of assessed machinery or related products</u></p>	<p>1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of machines which they inspect, nor the authorised representative of any of these parties.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
body or the use of machinery or related products for personal purposes.	<u>that are necessary for the operations of the conformity assessment body or the use of machinery or related products for personal purposes.</u>	
Article 28(4), second subparagraph		Annex XI, (1), second sentence
A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, import, distribution, manufacture, marketing, installation, use or maintenance of those machinery or related products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.	<u>A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, import, distribution, manufacture, marketing, installation, use or maintenance of those machinery or related products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.</u> <del>They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines.</del>	They shall not become involved, either directly or as authorised representatives, in the design, construction, marketing or maintenance of the machines.
		Annex XI, (1), third sentence
	<del>This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.</del>	This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.
Article 28(4), third subparagraph		
A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or	<u>A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
impartiality of its conformity assessment activities.	<u>impartiality of its conformity assessment activities.</u>	
Article 28(5)		Annex XI, (2)
5. A conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence its judgement or the results of its conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.	<u>5. A conformity assessment</u> <del>2. The</del> body and its <del>personnel</del> <u>staff</u> shall carry out the <u>conformity assessment activities</u> <del>verification tests</del> with the highest degree of professional integrity and <u>the requisite technical competence in the specific field</u> and shall be free from all pressures and inducements, particularly financial, which might influence <del>its</del> <u>their</u> judgement or the results of <u>its conformity assessment activities</u> <del>the inspection</del> , especially <u>as regards</u> <del>from</del> persons or groups of persons with an interest in the <u>results</u> <del>result</del> of those <u>activities</u> <del>verifications</del> .	2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.
Article 28(6), first subparagraph		
6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes VII, IX and IXa and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.	<u>6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes VII, IX and IXa and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.</u>	
Article 28(6), second subparagraph, introductory part		
At all times, and for each conformity assessment procedure and each kind of machinery or related products for which it has been notified, a conformity	<u>At all times, and for each conformity assessment procedure and each kind of machinery or related products for which it has been notified, a conformity</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
assessment body shall have at its disposal the necessary:	<u>assessment body shall have at its disposal the necessary:</u>	
Article 28(6), second subparagraph, point (a)		
(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;	<u>(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;</u>	
Article 28(6), second subparagraph, point (b)		
(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;	<u>(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;</u>	
Article 28(6), second subparagraph, point (c)		
(c) appropriate policies and procedures to distinguish between tasks that it carries out as a notified body and other activities;	<u>(c) appropriate policies and procedures to distinguish between tasks that it carries out as a notified body and other activities;</u>	
Article 28(6), second subparagraph, point (d)		
(d) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the machinery technology in question and the mass or serial nature of the production process.	<u>(d) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the machinery technology in question and the mass or serial nature of the production process.</u>	
Article 28(6), third subparagraph		
A conformity assessment body shall have the means necessary to perform the	<u>A conformity assessment body shall have the means necessary to perform the</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.</p>	<p><u>technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.</u></p>	
<p>Article 28(7), introductory part</p>		<p>Annex XI, (4)</p>
<p>7. The personnel responsible for carrying out conformity assessment tasks shall have the following:</p>	<p><u>7</u>4. The <del>personnel</del><u>staff</u> responsible for <u>carrying out conformity assessment tasks</u><del>inspection</del> shall have the following:</p>	<p>4. The staff responsible for inspection shall have:</p>
<p>Article 28(7), point (a)</p>		<p>Annex XI, (4), dash 1</p>
<p>(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;</p>	<p><u>(a)</u>— sound technical and vocational training <u>covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;</u></p>	<p>— sound technical and vocational training,</p>
<p>Article 28(7), point (b)</p>		<p>Annex XI, (4), dash 2</p>
<p>(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;</p>	<p><u>(b)</u>— satisfactory knowledge of the requirements of the <u>assessments</u><del>tests</del> they carry out and adequate <u>authority to carry out those assessments;</u><del>experience of such tests;</del></p>	<p>— satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,</p>
<p>Article 28(7), point (c)</p>		
<p>(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex III, of the applicable harmonised standards and common specifications referred to in Article 17, and of the relevant provisions of Union harmonisation legislation and of national legislation;</p>	<p><u>(c)</u> <u>appropriate knowledge and understanding of the essential health and safety requirements set out in Annex III, of the applicable harmonised standards and common specifications referred to in Article 17, and of the relevant provisions of Union harmonisation legislation and of national legislation;</u></p>	
<p>Article 28(7), point (d)</p>		<p>Annex XI, (4), dash 3</p>
<p>(d) the ability to draw up certificates, records and reports demonstrating that</p>	<p><u>(d)</u>— the ability to draw up <del>the</del> certificates, records and reports <u>demonstrating that conformity</u></p>	<p>— the ability to draw up the certificates, records and reports required to</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
conformity assessments have been carried out.	<u>assessments have been carried out</u> <del>required to authenticate the performance of the tests.</del>	authenticate the performance of the tests.
Article 28(8), introductory part		Annex XI, (5), first sentence
8. The impartiality of a conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.	<del>8</del> 5. The impartiality of a <u>conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks</u> <del>inspection staff</del> shall be guaranteed.	5. The impartiality of inspection staff shall be guaranteed.
Article 28(8), first paragraph		Annex XI, (5), second sentence
The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not depend on the number of conformity assessments carried out or on the results of those assessments.	<del>The</del> <u>Their</u> remuneration <u>of the top-level management and the personnel responsible for carrying out the conformity assessment tasks</u> shall not depend on the number of <u>conformity assessments</u> <del>tests</del> carried out or on the results of <u>those assessments</u> <del>such tests</del> .	Their remuneration shall not depend on the number of tests carried out or on the results of such tests.
Article 28(9)		Annex XI, (6)
9. A conformity assessment body shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.	<u>9. A conformity assessment</u> <del>6. The</del> body shall take out liability insurance unless <del>its</del> liability is assumed by the <u>Member State</u> in accordance with national law, or the Member State itself is directly responsible for the <u>conformity assessment</u> <del>tests</del> .	6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.
Article 28(10)		Annex XI, (7)
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment tasks in accordance with Annexes VII, IX and IXa, except in relation to the competent	<del>10</del> 7. The <u>personnel</u> <del>staff</del> of a <u>conformity assessment</u> <del>the body shall be bound to</del> observe professional secrecy with regard to all information obtained in carrying out <u>the conformity assessment tasks in accordance with Annexes VII, IX and IXa,</u> <del>its tasks (except in relation to</del> <u>vis-à-vis</u>	7. The staff of the body shall be bound to observe professional secrecy with regard to all information obtained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>authorities of the Member State in which its tasks are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected.</p>	<p>the competent <del>administrative</del> authorities of the <u>Member State</u> in which its <del>tasks</del><u>activities</u> are carried out. <u>Proprietary rights, intellectual property rights and trade secrets shall be protected</u>) <del>under this Directive or any provision of national law giving effect to it.</del></p>	<p>this Directive or any provision of national law giving effect to it.</p>
<p>Article 28(11)</p>		<p>Annex XI, (8)</p>
<p>11. A conformity assessment body shall participate in, or ensure that its personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 40 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.</p>	<p><u>11. A conformity assessment body shall participate in, or ensure that its personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 40 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.</u><del>8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.</del></p>	<p>8. Notified bodies shall participate in coordination activities. They shall also take part directly or be represented in European standardisation, or ensure that they know the situation in respect of relevant standards.</p>
		<p>Annex XI, (9)</p>
	<p><del>9. Member States may take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the files of its customers are sent to another body or are made available to the Member State which has notified it.</del></p>	<p>9. Member States may take all necessary measures they regard as necessary in order to ensure that, in the event of cessation of the activities of a notified body, the files of its customers are sent to another body or are made available to the Member State which has notified it.</p>
<p>Article 29</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Presumption of conformity of notified bodies	<u>Presumption of conformity of notified bodies</u>	
Article 29, first paragraph		Article 14(5)
Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article 28 in so far as the applicable harmonised standards cover those requirements.	<del>Where a conformity 5. Bodies meeting the assessment body demonstrates its conformity with the</del> criteria laid down in the relevant harmonised standards <del>or parts thereof</del> ; the references of which <del>have been shall be</del> published in the Official Journal of the European Union, <del>it shall be presumed to comply with fulfil</del> the <u>requirements set out in Article 28 in so far as the applicable harmonised standards cover those requirements relevant criteria.</u>	5. Bodies meeting the assessment criteria laid down in the relevant harmonised standards, the references of which shall be published in the Official Journal of the European Union, shall be presumed to fulfil the relevant criteria.
Article 30		
Article 30	<u>Article 30</u>	
Subsidiaries of and subcontracting by notified bodies	<u>Subsidiaries of and subcontracting by notified bodies</u>	
Article 30(1)		
1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 28 and shall inform the notifying authority accordingly.	<u>1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 28 and shall inform the notifying authority accordingly.</u>	
Article 30(2)		
2. A notified body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever those are established.	<u>2. A notified body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever those are established.</u>	
Article 30(3)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.	<u>3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.</u>	
Article 30(4)		
4. A notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes VII, IX and IXa.	<u>4. A notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes VII, IX and IXa.</u>	
Article 31		
Article 31	Article 31	
Application for notification	Application for notification	
Article 31(1)		
1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.	<u>1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.</u>	
Article 31(2)		
2. The application for notification shall be accompanied by a description of the conformity assessment activities, of the conformity assessment procedures set out in Annexes VII, IX and IXa and of the kinds or categories of machinery or related products for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 28.	<u>2. The application for notification shall be accompanied by a description of the conformity assessment activities, of the conformity assessment procedures set out in Annexes VII, IX and IXa and of the kinds or categories of machinery or related products for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 28.</u>	
Article 31(3)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>3. Where the conformity assessment body concerned cannot provide an accreditation certificate as referred to in paragraph 2, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 28.</p>	<p><u>3. Where the conformity assessment body concerned cannot provide an accreditation certificate as referred to in paragraph 2, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 28.</u></p>	
Article 32		
Article 32	<u>Article 32</u>	
Notification procedure	<u>Notification procedure</u>	
Article 32(1)		
<p>1. A notifying authority shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 28.</p>	<p><u>1. A notifying authority shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 28.</u></p>	
Article 32(2)		
<p>2. The notifying authority shall send a notification to the Commission and the other Member States , using the electronic notification tool developed and managed by the Commission.</p>	<p><u>2. The notifying authority shall send a notification to the Commission and the other Member States , using the electronic notification tool developed and managed by the Commission.</u></p>	
Article 32(3), introductory part		
<p>3. The notification referred to in paragraph 2 shall include the following:</p>	<p><u>3. The notification referred to in paragraph 2 shall include the following:</u></p>	
Article 32(3), point (a)		
<p>(a) full details of the conformity assessment activities to be performed;</p>	<p><u>(a) full details of the conformity assessment activities to be performed;</u></p>	
Article 32(3), point (b)		
<p>(b) an indication of the conformity assessment module or modules and the</p>	<p><u>(b) an indication of the conformity assessment module or modules and the</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
kinds of machinery or related products concerned;	<u>kinds of machinery or related products concerned;</u>	
Article 32(3), point (c)		
(c) the relevant attestation of competence.	<u>(c) the relevant attestation of competence.</u>	
Article 32(4)		
4. Where a notification is not based on an accreditation certificate referred to in Article 31(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 28.	<u>4. Where a notification is not based on an accreditation certificate referred to in Article 31(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 28.</u>	
Article 32(5), introductory part		
5. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it includes documentary evidence referred to in Article 31(3) and in paragraph 4 of this Article.	<u>5. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it includes documentary evidence referred to in Article 31(3) and in paragraph 4 of this Article.</u>	
Article 32(5), first paragraph		
Only such a body shall be considered a notified body for the purposes of this Regulation.	<u>Only such a body shall be considered a notified body for the purposes of this Regulation.</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 32(6)		
6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification referred to in paragraph 2.	<u>6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification referred to in paragraph 2.</u>	
Article 33		
Article 33	Article 33	
Identification numbers and lists of notified bodies	<u>Identification numbers and lists of notified bodies</u>	
Article 33(1), introductory part		
1. The Commission shall assign an identification number to a notified body.	<u>1. The Commission shall assign an identification number to a notified body.</u>	
Article 33(1), first paragraph		
It shall assign a single such number even where the body is notified under several Union acts.	<u>It shall assign a single such number even where the body is notified under several Union acts.</u>	
Article 33(2), introductory part		Article 14(4)
2. The Commission shall make publicly available the list of bodies notified under this Regulation including the identification numbers that have been assigned to them and the conformity assessment activities for which they have been notified.	<del>2.4-</del> The Commission shall <u>make publicly available</u> <del>publish in the Official Journal of the European Union, for information, a list of bodies</del> <u>the notified under this Regulation including the</u> <del>bodies and their</del> <u>identification numbers that have been assigned to them and the conformity assessment activities</u> <del>and the tasks</del> for which they have been notified. <del>The Commission shall ensure that this list is kept up to date.</del>	4. The Commission shall publish in the Official Journal of the European Union, for information, a list of the notified bodies and their identification numbers and the tasks for which they have been notified. The Commission shall ensure that this list is kept up to date.
Article 33(2), first paragraph		
The Commission shall ensure that the list is kept up to date.	<u>The Commission shall ensure that the list is kept up to date.</u>	
Article 34		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 34	<u>Article 34</u>	
Changes to notifications	<u>Changes to notifications</u>	
Article 34(1)		Article 14(8)
<p>1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 28, or that it is failing to fulfil its obligations as set out in Article 36 the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.</p>	<p><u>1. Where a notifying authority</u><del>8. A Member State which</del> <u>has ascertained or has been informed that a notified a body shall immediately withdraw its notification if it finds:</u>  <del>(a) that the</del> body no longer meets the <u>requirements laid down</u><del>criteria set out</del> <u>in Article 28, Annex XI;</u> or  <del>(b) that it is failing</del><u>the body seriously fails to fulfil its obligations as set out in Article 36 the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It</u><del>responsibilities.</del>  <del>The Member State</del> shall immediately inform the Commission and the other Member States accordingly.</p>	<p>8. A Member State which has notified a body shall immediately withdraw its notification if it finds:                      (a) that the body no longer meets the criteria set out in Annex XI; or                      (b) that the body seriously fails to fulfil its responsibilities.                      The Member State shall immediately inform the Commission and the other Member States accordingly.</p>
Article 34(2)		
<p>2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.</p>	<p><u>2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.</u></p>	
Article 35		
Article 35	<u>Article 35</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Challenge of the competence of notified bodies	<u>Challenge of the competence of notified bodies</u>	
Article 35(1)		
1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.	<u>1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.</u>	
Article 35(2)		
2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.	<u>2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.</u>	
Article 35(3)		
3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.	<u>3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.</u>	
Article 35(4), introductory part		
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary.	<u>4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary.</u>	
Article 35(4), first paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 46(2).	<u>That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 46(2).</u>	
Article 36		
Article 36	Article 36	
Operational obligations of notified bodies	<u>Operational obligations of notified bodies</u>	
Article 36(1)		
1. A notified body shall carry out conformity assessments in accordance with the conformity assessment procedures set out in Annexes VII, IX and IXa.	<u>1. A notified body shall carry out conformity assessments in accordance with the conformity assessment procedures set out in Annexes VII, IX and IXa.</u>	
Article 36(2), introductory part		
2. A notified body shall perform its activities in a proportionate manner, avoiding unnecessary burdens for economic operators, and taking due account of the size of an undertaking, the sector in which the undertaking operates, the structure of the undertaking, the degree of complexity of the technology in question and the mass or serial nature of the production process.	<u>2. A notified body shall perform its activities in a proportionate manner, avoiding unnecessary burdens for economic operators, and taking due account of the size of an undertaking, the sector in which the undertaking operates, the structure of the undertaking, the degree of complexity of the technology in question and the mass or serial nature of the production process.</u>	
Article 36(2), first paragraph		
In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the machinery or related product with the requirements of this Regulation.	<u>In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the machinery or related product with the requirements of this Regulation.</u>	
Article 36(3)		Article 14(6), first sentence
3. Where a notified body finds that the essential health and safety requirements set out in Annex III, or corresponding	<u>3. Where <del>6.</del> if a notified body finds that the essential health and safety relevant requirements set out in Annex III, or</u>	6. If a notified body finds that relevant requirements of this Directive have not been met or are no longer met by the

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>harmonised standards or common specifications referred to in Article 17 have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective actions and shall not issue a certificate of conformity or adopt an approval decision.</p>	<p><u>corresponding harmonised standards or common specifications referred to in Article 17 of this Directive</u> have not been met <del>or are no longer met</del> by <u>a the manufacturer</u> <del>or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued</del>, it shall <u>require the manufacturer to take</u>, <del>taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of appropriate corrective actions and shall not issue a certificate of conformity or adopt an approval decision</del> <u>measures by the manufacturer</u>.</p>	<p>manufacturer or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer.</p>
<p>Article 36(4)</p>		<p>Article 14(6), first sentence</p>
<p>4. Where, in the course of the monitoring of conformity following the issue of an approval decision according to Annex IX, a notified body finds that a machinery or related product no longer complies, it shall require the manufacturer to take appropriate corrective actions and shall suspend or withdraw the approval decision, if necessary.</p>	<p><u>4. Where, in the course of the monitoring of conformity following the issue of an approval decision according to Annex IX,</u> <del>6. If a notified body finds that a machinery</del> <u>relevant requirements of this Directive have not been met</u> or <u>related product</u> <del>are</del> no longer <u>complies, it shall require</u> <del>met by the manufacturer to take appropriate corrective actions and shall</del> <del>or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued, it shall, taking account of the principle of proportionality,</del> suspend or withdraw the</p>	<p>6. If a notified body finds that relevant requirements of this Directive have not been met or are no longer met by the manufacturer or that an EC type-examination certificate or the approval of a quality assurance system should not have been issued, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate or the approval issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>certificate or the approval decision, if necessary issued or place restrictions on it, giving detailed reasons, unless compliance with such requirements is ensured by the implementation of appropriate corrective measures by the manufacturer.</del></p>	<p>appropriate corrective measures by the manufacturer.</p>
Article 36(5)		Article 14(6), second+third sentence
<p>5. Where corrective actions are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates or approval decisions, as appropriate.</p>	<p><u>5. Where corrective actions are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates or approval decisions, as appropriate.</u>  <del>In the event of suspension or withdrawal of the certificate or the approval or of any restriction placed on it, or in cases where intervention by the competent authority may prove necessary, the notified body shall inform the competent authority pursuant to Article 4. The Member State shall inform the other Member States and the Commission without delay. An appeal procedure shall be available.</del></p>	<p>In the event of suspension or withdrawal of the certificate or the approval or of any restriction placed on it, or in cases where intervention by the competent authority may prove necessary, the notified body shall inform the competent authority pursuant to Article 4. The Member State shall inform the other Member States and the Commission without delay. An appeal procedure shall be available.</p>
Article 37		
Article 37	<u>Article 37</u>	
Appeals against decisions of notified bodies	<u>Appeals against decisions of notified bodies</u>	
Article 37, first paragraph		
<p>A notified body shall ensure that a transparent and accessible appeals procedure against its decisions is available.</p>	<p><u>A notified body shall ensure that a transparent and accessible appeals procedure against its decisions is available.</u></p>	
Article 38		
Information obligation on notified bodies	<u>Information obligation on notified bodies</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 38(1), introductory part		
1. A notified body shall inform the notifying authority of the following:	<u>1. A notified body shall inform the notifying authority of the following:</u>	
Article 38(1), point (a)		
(a) any refusal, restriction, suspension or withdrawal of a certificate or approval decision;	<u>(a) any refusal, restriction, suspension or withdrawal of a certificate or approval decision;</u>	
Article 38(1), point (b)		
(b) any circumstances affecting the scope of, or the conditions for, its notification;	<u>(b) any circumstances affecting the scope of, or the conditions for, its notification;</u>	
Article 38(1), point (c)		
(c) any request for information which it has received from market surveillance authorities regarding its conformity assessment activities;	<u>(c) any request for information which it has received from market surveillance authorities regarding its conformity assessment activities;</u>	
Article 38(1), point (d)		
(d) on request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.	<u>(d) on request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border activities and subcontracting.</u>	
Article 38(2)		
2. A notified body shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same kinds of machinery or related products with relevant information on issues relating to negative and, on request, positive conformity assessment results.	<u>2. A notified body shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same kinds of machinery or related products with relevant information on issues relating to negative and, on request, positive conformity assessment results.</u>	
Article 39		
Exchange of experience	<u>Exchange of experience</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 39, first paragraph		Article 14(7)
<p>The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.</p>	<p><del>7.—The Commission shall provide for the organisation of an exchange of experience between the Member States' national authorities responsible for appointment, notification policy and monitoring of notified bodies in the Member States, and the notified bodies, in order to coordinate the uniform application of this Directive.</del></p>	<p>7. The Commission shall provide for the organisation of an exchange of experience between the authorities responsible for appointment, notification and monitoring of notified bodies in the Member States, and the notified bodies, in order to coordinate the uniform application of this Directive.</p>
		Article 19(1)
	<p><del>1. Member States shall take the appropriate measures to ensure that the competent authorities referred to in Article 4(3) cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.</del></p>	<p>1. Member States shall take the appropriate measures to ensure that the competent authorities referred to in Article 4(3) cooperate with each other and with the Commission and transmit to each other the information necessary to enable this Directive to be applied uniformly.</p>
		Article 19(2)
	<p><del>2.—The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.</del></p>	<p>2. The Commission shall provide for the organisation of an exchange of experience between the competent authorities responsible for market surveillance in order to coordinate the uniform application of this Directive.</p>
Article 40		
Article 40	Article 40	
Coordination of notified bodies	Coordination of notified bodies	
Article 40, first paragraph		
<p>The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly</p>	<p><u>The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
operated in the form of a sectoral group of notified bodies.	<u>operated in the form of a sectoral group of notified bodies.</u>	
Article 40, second paragraph		
Notified bodies shall participate in the work of that group, directly or by means of designated representatives.	<u>Notified bodies shall participate in the work of that group, directly or by means of designated representatives.</u>	

## Chapter 6: Union market surveillance and Union safeguard procedures

DRAFT Machinery Regulation	Comparison	Machinery Directive
CHAPTER VI		
UNION MARKET SURVEILLANCE AND UNION SAFEGUARD PROCEDURES	<u>UNION MARKET SURVEILLANCE AND UNION SAFEGUARD PROCEDURES</u>	
Article 41		
Procedure at national level for dealing with products presenting a risk	<u>Procedure at national level for dealing with products presenting a risk</u>	
Article 41(1), first subparagraph		Article 11(1)
<p>1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a product within the scope of this Regulation presents a risk to the health or safety of persons, and, where appropriate, domestic animals or to property and, where applicable, the environment, they shall carry out an evaluation in relation to the product concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.</p>	<p>1. <del>-Where the market surveillance authorities of one a-Member State have sufficient reason to believe</del><u>ascertains that a product within the scope of machinery covered by this Regulation presents a risk to</u> <del>Directive, bearing the CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose or under reasonably foreseeable conditions, is liable to endanger</del> the health or safety of persons, <del>and or</del>, where appropriate, domestic animals or <del>to property and or</del>, where applicable, the environment, <del>they</del><u>it shall carry out an evaluation in relation to the product concerned covering</u> <del>take</del> all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary <del>with appropriate measures to withdraw such machinery from the market, to prohibit the placing on</del> the market <del>surveillance authorities for that purpose</del><u>and/or putting into service of</u></p>	<p>1. Where a Member State ascertains that machinery covered by this Directive, bearing the CE marking, accompanied by the EC declaration of conformity and used in accordance with its intended purpose or under reasonably foreseeable conditions, is liable to endanger the health or safety of persons or, where appropriate, domestic animals or property or, where applicable, the environment, it shall take all appropriate measures to withdraw such machinery from the market, to prohibit the placing on the market and/or putting into service of such machinery or to restrict the free movement thereof.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>such machinery or to restrict the free movement thereof.</del>	
Article 41(1), second subparagraph		Article 20
<p>Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the product within the scope of this Regulation does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take appropriate and proportionate corrective action, as provided for in Article 16(3) of Regulation (EU) 2019/1020, to bring the non-compliance to an end or to eliminate hazards or, if that is not possible, minimize the risk they specify within a reasonable period which is commensurate with the nature of the risk referred to in the first subparagraph.</p>	<p><u>Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the product within the scope of this Regulation does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take appropriate and proportionate corrective action, as provided for in Article 16(3) of Regulation (EU) 2019/1020, to bring the non-compliance to an end or to eliminate hazards or, if that is not possible, minimize the risk they specify within a reasonable period which is commensurate with the nature of the risk referred to in the first subparagraph.</u><del>Any measure taken pursuant to this Directive which restricts the placing on the market and/or putting into service of any machinery covered by this Directive shall state the exact grounds on which it is based. Such a measure shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.</del></p>	<p>Any measure taken pursuant to this Directive which restricts the placing on the market and/or putting into service of any machinery covered by this Directive shall state the exact grounds on which it is based. Such a measure shall be notified as soon as possible to the party concerned, who shall at the same time be informed of the legal remedies available to him under the laws in force in the Member State concerned and of the time limits to which such remedies are subject.</p>
Article 41(1), third subparagraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>The market surveillance authorities shall inform the relevant notified body accordingly.</p>	<p><u>The market surveillance authorities shall inform the relevant notified body accordingly.</u></p>	
<p>Article 41(2)</p>		<p>Article 11(2)</p>
<p>2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.</p>	<p><u>2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they</u> <del>The Member State</del> shall immediately inform the Commission and the other Member States of <u>the results</u> <del>any such measure, indicating the reasons for its decision and, in particular, whether the non-conformity is due to:</del>  <del>(a) failure to satisfy the essential requirements referred to in Article 5(1)(a);</del>  <del>(b) incorrect application of the evaluation and of the actions which they have required</del> <u>harmonised standards referred to in Article 7(2);</u>  <del>(c) shortcomings in the economic operator to take.</del> <u>harmonised standards themselves referred to in Article 7(2).</u></p>	<p>2. The Member State shall immediately inform the Commission and the other Member States of any such measure, indicating the reasons for its decision and, in particular, whether the non-conformity is due to:                  (a) failure to satisfy the essential requirements referred to in Article 5(1)(a);                  (b) incorrect application of the harmonised standards referred to in Article 7(2);                  (c) shortcomings in the harmonised standards themselves referred to in Article 7(2).</p>
		<p>Article 11(5)</p>
	<p><del>5. Where machinery does not conform and bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall so inform the Commission. The Commission shall inform the other Member States.</del></p>	<p>5. Where machinery does not conform and bears the CE marking, the competent Member State shall take appropriate action against whomsoever has affixed the marking and shall so inform the Commission. The Commission shall inform the other Member States.</p>
<p>Article 41(3)</p>		
<p>3. The economic operator shall ensure that all appropriate corrective action is taken in respect of the concerned</p>	<p><u>3. The economic operator shall ensure that all appropriate corrective action is taken in respect of the concerned</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>products within the scope of this Regulation that the economic operator has made available on the market throughout the Union.</p>	<p><u>products within the scope of this Regulation that the economic operator has made available on the market throughout the Union.</u></p>	
<p>Article 41(4), introductory part</p>		
<p>4. Where the relevant economic operator does not take corrective action referred to in paragraph 1, second subparagraph, within the specified period or where the non-compliance or the risk referred to in paragraph 1, first subparagraph, persists, the market surveillance authorities shall ensure that the product concerned is withdrawn or recalled, or that making available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly without delay.</p>	<p><u>4. Where the relevant economic operator does not take corrective action referred to in paragraph 1, second subparagraph, within the specified period or where the non-compliance or the risk referred to in paragraph 1, first subparagraph, persists, the market surveillance authorities shall ensure that the product concerned is withdrawn or recalled, or that making available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly without delay.</u></p>	
<p>Article 41(5), introductory part</p>		
<p>5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant product within the scope of this Regulation, the origin of that product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:</p>	<p><u>5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant product within the scope of this Regulation, the origin of that product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 41(5), point (a)		
(a) failure of the product to meet the requirements relating to the essential health and safety requirements set out in Annex III;	<u>(a) failure of the product to meet the requirements relating to the essential health and safety requirements set out in Annex III;</u>	
Article 41(5), point (b)		
(b) shortcomings in the harmonised standards referred to in Article 17(1);	<u>(b) shortcomings in the harmonised standards referred to in Article 17(1);</u>	
Article 41(5), point (c)		
(c) shortcomings in the common specifications referred to in Article 17(4).	<u>(c) shortcomings in the common specifications referred to in Article 17(4).</u>	
Article 41(6)		
6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the concerned product within the scope of this Regulation, and, in the event of disagreement with the adopted national measure, of their objections.	<u>6. Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the concerned product within the scope of this Regulation, and, in the event of disagreement with the adopted national measure, of their objections.</u>	
Article 41(7)		
7. Where, within three months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.	<u>7. Where, within three months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.</u>	
Article 41(8)		
8. Member States shall ensure that appropriate restrictive measures, such as	<u>8. Member States shall ensure that appropriate restrictive measures, such as</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>withdrawal of the product, are taken in respect of the concerned product within the scope of this Regulation without delay.</p>	<p><u>withdrawal of the product, are taken in respect of the concerned product within the scope of this Regulation without delay.</u></p>	
<p>Article 42</p>		
<p>Article 42</p>	<p><u>Article 42</u></p>	
<p>Union safeguard procedure</p>	<p><u>Union safeguard procedure</u></p>	
<p>Article 42(1), first subparagraph</p>		<p>Article 11(3)</p>
<p>1. Where, on completion of the procedure set out in Article 41(4), (6) and (7) objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not.</p>	<p><u>1. Where, on completion of the procedure set out in Article 41(4), (6) and (7) objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not.</u>  <del>3. The Commission shall enter into consultation with the parties concerned without delay. The Commission shall consider, after this consultation, whether or not the measures taken by the Member State are justified, and it shall communicate its decision to the Member State which took the initiative, the other Member States, and the manufacturer or his authorised representative.</del></p>	<p>3. The Commission shall enter into consultation with the parties concerned without delay. The Commission shall consider, after this consultation, whether or not the measures taken by the Member State are justified, and it shall communicate its decision to the Member State which took the initiative, the other Member States, and the manufacturer or his authorised representative.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>2. Any Member State may request the Commission to examine the need for the adoption of the measures referred to in paragraph 1. In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties, indicating the measures it intends to take in order to ensure, at Community level, a high level of protection of the health and safety of persons and, where appropriate, of domestic animals and property and, where applicable, of the environment.</del></p>	<p>Article 9(2), first and second paragraph</p> <p>2. Any Member State may request the Commission to examine the need for the adoption of the measures referred to in paragraph 1. In the cases referred to in paragraph 1, the Commission shall consult the Member States and other interested parties, indicating the measures it intends to take in order to ensure, at Community level, a high level of protection of the health and safety of persons and, where appropriate, of domestic animals and property and, where applicable, of the environment.</p>
<p>Article 42(1), second subparagraph</p> <p>The Commission shall address its decision to all Member States and shall without delay communicate it to them and to the relevant economic operator or operators.</p>	<p><del>6. The Commission shall address its decision to all Member States and shall without delay communicate it to them and to the relevant economic operator or operators.</del> <u>6. The Commission shall ensure that Member States and shall without delay communicate it to them and to the relevant economic operator or operators.</u></p>	<p>Article 11(6)</p> <p>6. The Commission shall ensure that Member States are kept informed of the progress and outcome of the procedure.</p>
<p>Article 42(1), third subparagraph</p> <p>That implementing act shall be adopted in accordance with the examination procedure referred to in Article 46(3).</p>	<p><del>That</del> <u>Taking due account of the results of that consultation, the Commission shall adopt the necessary measures by implementing acts.</u> <del>Those implementing acts</del> shall be adopted in accordance with the examination procedure referred to in Article <del>46</del><u>22</u>(3).</p>	<p>Article 9(2), third paragraph</p> <p>Taking due account of the results of that consultation, the Commission shall adopt the necessary measures by implementing acts. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 22(3).</p>
<p>Article 42(2), introductory part</p> <p>2. If the national measure is considered justified, all Member States shall ensure</p>	<p><u>2. If the national measure is considered justified, all Member States shall ensure</u></p>	<p>Article 9(1), second paragraph</p> <p>When, in accordance with the procedure referred to in Article 11, the Commission</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>that appropriate restrictive measures, such as withdrawal, are taken in respect of the non-compliant product within the scope of this Regulation, and shall inform the Commission accordingly.</p>	<p><u>that appropriate restrictive measures, such as withdrawal, are taken in respect of the non-compliant product within the scope of this Regulation, and shall inform the Commission accordingly.</u><del>When, in accordance with the procedure referred to in Article 11, the Commission considers that a measure taken by a Member State is justified, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery presenting the same risk by virtue of its technical characteristics or to make such machinery subject to special conditions.</del></p>	<p>considers that a measure taken by a Member State is justified, the Commission may, in accordance with paragraph 3 of this Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery presenting the same risk by virtue of its technical characteristics or to make such machinery subject to special conditions.</p>
<p>Article 42(2), first paragraph</p>		
<p>If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.</p>	<p><u>If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.</u></p>	
<p>Article 42(3)</p>		<p>Article 10</p>
<p>3. Where the national measure is considered justified and the non-compliance of the product within the scope of this Regulation is attributed to shortcomings in the harmonised standards or common specifications referred to in Article 41(5), points (b) and (c), of this Regulation, the Commission shall respectively apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 or in Article 17(4b) of this Regulation.</p>	<p><u>3. Where the national measure is considered justified and the non-compliance of the product within the scope of this Regulation is attributed to shortcomings in the harmonised standards or common specifications referred to in Article 41(5), points (b) and (c), of this Regulation, the Commission shall respectively apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012 or in Article 17(4b) of this Regulation.</u><del>Where a Member State or the Commission considers that a</del></p>	<p>Where a Member State or the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee set up by Directive 98/34/EC, setting out the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall decide to publish, not to publish, to</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission or the Member State shall bring the matter before the committee set up by Directive 98/34/EC, setting out the reasons therefor. The committee shall deliver an opinion without delay. In the light of the committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.</del></p>	<p>publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.</p>
		<p>Article 11(4)</p>
	<p><del>4. Where the measures referred to in paragraph 1 are based on a shortcoming in the harmonised standards and if the Member State which instigated the measures maintains its position, the Commission or the Member State shall initiate the procedure referred to in Article 10.</del></p>	<p>4. Where the measures referred to in paragraph 1 are based on a shortcoming in the harmonised standards and if the Member State which instigated the measures maintains its position, the Commission or the Member State shall initiate the procedure referred to in Article 10.</p>
		<p>Article 9(1), first paragraph</p>
	<p><del>1. When, in accordance with the procedure referred to in Article 10, the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission may, in accordance with paragraph 3 of this</del></p>	<p>1. When, in accordance with the procedure referred to in Article 10, the Commission considers that a harmonised standard does not entirely satisfy the essential health and safety requirements which it covers and which are set out in Annex I, the Commission may, in accordance with paragraph 3 of this</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery with technical characteristics presenting risks due to the shortcomings in the standard or to make such machinery subject to special conditions.</del>	Article, take measures requiring Member States to prohibit or restrict the placing on the market of machinery with technical characteristics presenting risks due to the shortcomings in the standard or to make such machinery subject to special conditions.
Article 43		
Compliant products within the scope of this Regulation which present a risk	<u>Compliant products within the scope of this Regulation which present a risk</u>	
Article 43(1)		
1. Where, having carried out an evaluation under Article 41(1), a Member State finds that although a product within the scope of this Regulation is in compliance with the essential health and safety requirements set out in Annex III, it presents a risk to the health and safety of persons and, where appropriate, domestic animals or to property and, where applicable, the environment, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw that product or to recall it within a reasonable period which is commensurate with the nature of the risk.	<u>1. Where, having carried out an evaluation under Article 41(1), a Member State finds that although a product within the scope of this Regulation is in compliance with the essential health and safety requirements set out in Annex III, it presents a risk to the health and safety of persons and, where appropriate, domestic animals or to property and, where applicable, the environment, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw that product or to recall it within a reasonable period which is commensurate with the nature of the risk.</u>	
Article 43(2)		
2. The economic operator shall ensure that corrective action is taken in respect of all the products concerned that the	<u>2. The economic operator shall ensure that corrective action is taken in respect of all the products concerned that the</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
economic operator has made available on the market throughout the Union.	<u>economic operator has made available on the market throughout the Union.</u>	
Article 43(3)		
3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of that product, the nature of the risk involved and the nature and duration of the national measures taken.	<u>3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of that product, the nature of the risk involved and the nature and duration of the national measures taken.</u>	
Article 43(4), first subparagraph		
4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not and, where necessary, order appropriate measures.	<u>4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not and, where necessary, order appropriate measures.</u>	
Article 43(4), second subparagraph		
That implementing act shall be adopted in accordance with the examination procedure referred to in Article 46(3).	<u>That implementing act shall be adopted in accordance with the examination procedure referred to in Article 46(3).</u>	
Article 43(4), third subparagraph		
On duly justified imperative grounds of urgency relating to the protection of the health and safety of persons, the Commission shall adopt an immediately	<u>On duly justified imperative grounds of urgency relating to the protection of the health and safety of persons, the Commission shall adopt an immediately</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
applicable implementing act in accordance with the procedure referred to in Article 46(4).	<u>applicable implementing act in accordance with the procedure referred to in Article 46(4).</u>	
Article 43(5)		
5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator or operators.	<u>5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator or operators.</u>	
Article 44		
Formal non-compliance	<u>Formal non-compliance</u>	
		Article 17
	<del>Non-conformity of marking</del>	Non-conformity of marking
Article 44(1), introductory part		Article 17(2)
1. Without prejudice to Article 41, where a Member State makes one of the following findings with regard to a machinery or related product, it shall require the relevant economic operator to put an end to the non-compliance concerned:	<u>1. Without prejudice to Article 41, where</u> <del>2. Where a Member State makes one</del> <u>ascertains that marking does not conform to the relevant provisions of the following findings with regard to a machinery</u> <del>this Directive, the manufacturer or related his authorised representative shall be obliged to make the product, it shall require the relevant economic operator conform and to put an end to the non-compliance concerned: infringement under conditions fixed by that Member State.</del>	2. Where a Member State ascertains that marking does not conform to the relevant provisions of this Directive, the manufacturer or his authorised representative shall be obliged to make the product conform and to put an end to the infringement under conditions fixed by that Member State.
Article 44(1), point (a)		Article 17(1)(b)
(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 20 of this Regulation;	<del>1. Member States shall consider the following marking not to conform:</del> (a) the <del>affixing of the</del> CE marking <u>has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 20 of</u> <del>pursuant to this Regulation</del> <u>Directive</u>	1. Member States shall consider the following marking not to conform: (a) the affixing of the CE marking pursuant to this Directive on products not covered by this Directive;

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>on products not covered by this Directive;</del>	
		Article 17(1)(c)
	<del>1. Member States shall consider the following marking not to conform: (c) the affixing on machinery of a marking, other than the CE marking, which is prohibited under Article 16(3).</del>	1. Member States shall consider the following marking not to conform: (c) the affixing on machinery of a marking, other than the CE marking, which is prohibited under Article 16(3).
Article 44(1), point (b)		Article 17(1)(b)
(b) the CE marking has not been affixed;	<del>1. Member States shall consider the following marking not to conform: (b) the absence of the CE marking has not been affixed and/or the absence of the EC declaration of conformity for machinery;</del>	1. Member States shall consider the following marking not to conform: (b) the absence of the CE marking and/or the absence of the EC declaration of conformity for machinery;
Article 44(1), point (c)		
(c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 20(3) or has not been affixed;	<u>(c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 20(3) or has not been affixed;</u>	
Article 44(1), point (d)		Article 17(1)(b)
(d) the EU declaration of conformity has not been drawn up or has not been drawn up correctly;	<del>(d)1. Member States shall consider the EU following marking not to conform: (b) the absence of the CE marking and/or the absence of the EC declaration of conformity has not been drawn up or has not been drawn up correctly for machinery;</del>	1. Member States shall consider the following marking not to conform: (b) the absence of the CE marking and/or the absence of the EC declaration of conformity for machinery;
Article 44(1), point (e)		
(e) the technical documentation is either not available or not complete;	<u>(e) the technical documentation is either not available or not complete;</u>	
Article 44(1), point (f)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(f) the information referred to in Article 10(6) or Article 12(3) is absent, false or incomplete;	<u>(f) the information referred to in Article 10(6) or Article 12(3) is absent, false or incomplete;</u>	
Article 44(1), point (g)		
(g) any other administrative requirement provided for in Article 10 or Article 12 is not fulfilled.	<u>(g) any other administrative requirement provided for in Article 10 or Article 12 is not fulfilled.</u>	
Article 44(1a), introductory part		
1a. Without prejudice to Article 41, where a Member State makes one of the following findings with regard to partly completed machinery, it shall require the relevant economic operator to put an end to the non-compliance concerned:	<u>1a. Without prejudice to Article 41, where a Member State makes one of the following findings with regard to partly completed machinery, it shall require the relevant economic operator to put an end to the non-compliance concerned:</u>	
Article 44(1a), point (a)		
(a) the EU declaration of incorporation has not been drawn up or has not been drawn up correctly;	<u>(a) the EU declaration of incorporation has not been drawn up or has not been drawn up correctly;</u>	
Article 44(1a), point (b)		
(b) the technical documentation is either not available or not complete;	<u>(b) the technical documentation is either not available or not complete;</u>	
Article 44(1a), point (c)		
(c) the information referred to in Article 10a(5) or Article 12a(3) is absent, false or incomplete;	<u>(c) the information referred to in Article 10a(5) or Article 12a(3) is absent, false or incomplete;</u>	
Article 44(1a), point (d)		
(d) any other administrative requirement provided for in Article 10a or Article 12a is not fulfilled.	<u>(d) any other administrative requirement provided for in Article 10a or Article 12a is not fulfilled.</u>	
Article 44(2)		Article 17(3)
2. Where the non-compliance referred to in paragraph 1 and 1a persists, the Member State concerned shall take all	<u>2.3-</u> Where <u>the non-compliance referred to in paragraph 1 and 1a</u> <del>conformity</del> persists, the Member State <u>concerned</u>	3. Where non-conformity persists, the Member State shall take all appropriate measures to restrict or prohibit the

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>appropriate measures to restrict or prohibit the concerned product within the scope of this Regulation being made available on the market or ensure that it is recalled or withdrawn from the market.</p>	<p>shall take all appropriate measures to restrict or prohibit the <u>concerned product within the scope of this Regulation being made available</u> <del>placing</del> on the market <del>of the product in question</del> or <del>to</del> ensure that it is <u>recalled or</u> withdrawn from the market <del>in accordance with the procedure laid down in Article 11.</del></p>	<p>placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedure laid down in Article 11.</p>

## Chapter 7: Delegated powers and committee procedure

DRAFT Machinery Regulation	Comparison	Machinery Directive
CHAPTER VII		
DELEGATED POWERS AND COMMITTEE PROCEDURE	<u>DELEGATED POWERS AND COMMITTEE PROCEDURE</u>	
Article 45		Article 21a
Article 45	Article <del>45</del> <sup>21a</sup>	Article 21a
Exercise of the delegation	Exercise of the delegation	Exercise of the delegation
Article 45(1)		Article 21a(1)
1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1.- The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
Article 45(2)		Article 21a(2)
2. The power to adopt delegated acts referred to in Articles 5(2), 5(10) and 6(2) shall be conferred on the Commission for a period of five years from ... [the date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.	2.- The power to adopt delegated acts referred to in <u>Articles 5(2), 5(10) and 6(2)</u> <del>Article 8(1)</del> shall be conferred on the Commission for a period of five years from ... [the date of entry into force of this Regulation]. <del>26 July 2019</del> . The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.	2. The power to adopt delegated acts referred to in Article 8(1) shall be conferred on the Commission for a period of five years from 26 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.
Article 45(3)		Article 21a(4)
3. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down	<del>3.4.</del> Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.</p>	<p>in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.</p>	<p>in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.</p>
<p>Article 45(4)</p>		<p>Article 21a(3)</p>
<p>4. The delegation of powers referred to in Articles 5(2), 5(10) and 6(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.</p>	<p><del>4.3-</del> The delegation of <del>powers</del><del>power</del> referred to in <u>Articles 5(2), 5(10) and 6(2)</u><del>Article 8(1)</del> may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.</p>	<p>3. The delegation of power referred to in Article 8(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.</p>
<p>Article 45(5)</p>		<p>Article 21a(5)</p>
<p>5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.</p>	<p>5.- As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.</p>	<p>5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.</p>
<p>Article 45(6)</p>		<p>Article 21a(6)</p>
<p>6. A delegated act adopted pursuant to Articles 5(2), 5(10) and 6(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two</p>	<p>6.- A delegated act adopted pursuant to <u>Articles 5(2), 5(10) and 6(2)</u><del>Article 8(1)</del> shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of <del>two</del><del>three</del> months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended</p>	<p>6. A delegated act adopted pursuant to Article 8(1) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
months at the initiative of the European Parliament or of the Council.	by two months at the initiative of the European Parliament or of the Council.	by two months at the initiative of the European Parliament or of the Council.
Article 46		
Article 46	Article <del>46</del> <sup>22</sup>	Article 22
Committee procedure	Committee <u>procedure</u>	Committee
Article 46(1)		Article 22(1)
1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1.- The Commission shall be assisted by a committee. <u>That committee shall be a committee within,</u> <del>hereinafter referred to as the meaning of Regulation (EU) No 182/2011</del> <u>'Committee'</u> .	1. The Commission shall be assisted by a committee, hereinafter referred to as the 'Committee'.
Article 46(2)		Article 22(2)
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	2.- Where reference is made to this paragraph, <u>Article 4</u> <del>Articles 3 and 7 of Regulation (EU) No 182/2011</del> <del>Decision 1999/468/EC</del> shall apply, <del>having regard to the provisions of Article 8 thereof.</del>	2. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
Article 46(3)		Article 22(2)
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	3.- Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 <del>of the European Parliament and of the Council ( 6 )</del> shall apply.	3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 of the European Parliament and of the Council ( 6 ) shall apply.
Article 46(3a)		
(3a) Where the committee delivers no opinion regarding the draft implementing act as referred to in Article 17(3), the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.	<u>(3a) Where the committee delivers no opinion regarding the draft implementing act as referred to in Article 17(3), the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.</u>	
Article 46(4)		
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.	<u>4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Article 46(5), introductory part		
5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.	<u>5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.</u>	
Article 46(5), first paragraph		
The committee may furthermore examine any other matter concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.	<u>The committee may furthermore examine any other matter concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.</u>	

## Chapter 8: Confidentiality and penalties

DRAFT Machinery Regulation	Comparison	Machinery Directive
CHAPTER VIII		
CONFIDENTIALITY AND PENALTIES	<u>CONFIDENTIALITY AND PENALTIES</u>	
Article 47		Article 18
Article 47	Article 47 <del>18</del>	Article 18
Confidentiality	Confidentiality	Confidentiality
Article 47(1), introductory part		Article 18(1), first sentence
1. All parties shall respect the confidentiality of the following information and data obtained in carrying out their tasks in accordance with this Regulation:	1. All parties shall respect <del>Without prejudice to existing national provisions and practices in the area of</del> confidentiality of <del>Members States shall ensure that all parties and persons concerned by the following application of this Directive are required to treat as confidential</del> information and data obtained in <del>carrying out the execution of</del> their tasks in accordance with this Regulation:-	1. Without prejudice to existing national provisions and practices in the area of confidentiality, Members States shall ensure that all parties and persons concerned by the application of this Directive are required to treat as confidential information obtained in the execution of their tasks.
Article 47(1), point (a)		
(a) personal data;	<u>(a) personal data;</u>	
Article 47(1), point (b)		Article 18(1), second sentence
(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights, unless disclosure is in the public interest.	<u>(b) commercially</u> <del>More particularly business, professional and trade secrets shall be treated as confidential, unless the divulging of such</del> information and trade secrets of a natural or legal person, including intellectual property rights, unless disclosure is <del>necessary</del> in the public interest <del>order to protect the health and safety of persons.</del>	More particularly business, professional and trade secrets shall be treated as confidential, unless the divulging of such information is necessary in order to protect the health and safety of persons.
Article 47(2)		
2. Without prejudice to paragraph 1, information exchanged on a confidential	<u>2. Without prejudice to paragraph 1, information exchanged on a confidential</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>basis between the competent national authorities and between competent national authorities and the Commission shall not be disclosed without the prior agreement of the originating competent national authority.</p>	<p><u>basis between the competent national authorities and between competent national authorities and the Commission shall not be disclosed without the prior agreement of the originating competent national authority.</u></p>	
Article 47(3)		Article 18(2)
<p>3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.</p>	<p><del>3. Paragraphs 2.</del> <del>The provisions of paragraph 1 and 2</del> shall not affect the <u>rights and obligations of the Commission, Member States and the notified bodies</u> with regard to <del>the mutual</del> exchange of information and the <del>dissemination</del> <u>issuing</u> of warnings, <u>nor the obligations of the persons concerned to provide information under criminal law.</u></p>	<p>2. The provisions of paragraph 1 shall not affect the obligations of the Member States and the notified bodies with regard to mutual exchange of information and the issuing of warnings.</p>
Article 47(4)		
<p>4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements when these agreements and arrangements ensure that any exchange of information is in accordance with applicable Union law.</p>	<p><u>4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements when these agreements and arrangements ensure that any exchange of information is in accordance with applicable Union law.</u></p>	
		Article 18(3)
	<p><del>3. Any decisions taken by the Member States and by the Commission in accordance with Articles 9 and 11 shall be published.</del></p>	<p>3. Any decisions taken by the Member States and by the Commission in accordance with Articles 9 and 11 shall be published.</p>
Article 48		Article 23
Article 48	Article <del>48</del> <sup>23</sup>	Article 23
Penalties	Penalties	Penalties

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Article 48(1)</p> <p>1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive and may include criminal penalties for serious infringements.</p>	<p><u>1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of</u><del>of the national provisions adopted pursuant to</del> this <del>Regulation</del><u>Directive</u> and shall take all measures necessary to ensure that they are implemented. The penalties provided for <del>shall</del><u>must</u> be effective, proportionate and dissuasive <u>and may include criminal penalties for serious infringements.</u></p>	<p>Article 23, first and second sentence</p> <p>Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.</p>
<p>Article 48(2)</p> <p>2. Member States shall, by 39 months following the entry into force of this Regulation, notify the Commission of those rules and of those measures and shall notify it without delay of any subsequent amendment affecting them.</p>	<p><u>2. Member States shall, by 39 months following the entry into force of this Regulation,</u> notify <del>those provisions to</del> the Commission <u>of those rules and of those measures</u><del>by 29 June 2008</del> and shall notify it without delay of any subsequent amendment affecting them.</p>	<p>Article 23, third sentence</p> <p>Member States shall notify those provisions to the Commission by 29 June 2008 and shall notify it without delay of any subsequent amendment affecting them.</p>

## Chapter 9: Transitional and final provisions

DRAFT Machinery Regulation	Comparison	Machinery Directive
CHAPTER IX		
TRANSITIONAL AND FINAL PROVISIONS	<u>TRANSITIONAL AND FINAL PROVISIONS</u>	
Article 49		
Article 49	Article <del>49</del> <sup>25</sup>	Article 25
Repeals	<u>Repeals</u> <del>Repeal</del>	Repeal
Article 49(1), introductory part		
1. Directive 73/361/EEC is repealed.	<u>1. Directive 73/361/EEC is repealed.</u>	
Article 49(1), first paragraph		
References to the repealed Directive 73/361/EEC shall be construed as references to this Regulation.	<u>References to the repealed Directive 73/361/EEC shall be construed as references to this Regulation.</u>	
Article 49(2), introductory part		Article 25, first paragraph
2. Directive 2006/42/EC is repealed with effect from ... [42 months after the date of entry into force of this Regulation].	<u>2. Directive 2006/42</u> <del>98/37</del> /EC is <del>hereby repealed with effect</del> <sup>as</sup> from ... [42 months after the date of entry into force of this Regulation]. <del>29 December 2009.</del>	Directive 98/37/EC is hereby repealed as from 29 December 2009.
Article 49(2), first paragraph		Article 25, second paragraph
References to the repealed Directive 2006/42/EC shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex XI.	References <del>made</del> to the repealed Directive <u>2006/42/EC</u> shall be construed as <u>references being made</u> to this <u>Regulation</u> <del>Directive</del> and <del>shall</del> <sup>should</sup> be read in accordance with the correlation table in Annex <del>XI</del> <sup>XII</sup> .	References made to the repealed Directive shall be construed as being made to this Directive and should be read in accordance with the correlation table in Annex XII.
Article 50		
Transitional provisions	<u>Transitional provisions</u>	
Article 50(1)		
1. Member States shall not impede the making available on the market of products which were placed on the market in conformity with Directive 2006/42/EC before ... [the date of application of this Regulation]. However,	<u>1. Member States shall not impede the making available on the market of products which were placed on the market in conformity with Directive 2006/42/EC before ... [the date of application of this Regulation]. However,</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Chapter VI of this Regulation shall apply, as from ... [the date of application of this Regulation], mutatis mutandis to such products instead of Article 11 of that Directive, including products for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC.	<u>Chapter VI of this Regulation shall apply, as from ... [the date of application of this Regulation], mutatis mutandis to such products instead of Article 11 of that Directive, including products for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC.</u>	
Article 50(2)		
2. EC type-examination certificates and approval decisions issued in accordance with Article 12 of Directive 2006/42/EC shall remain valid until they expire.	<u>2. EC type-examination certificates and approval decisions issued in accordance with Article 12 of Directive 2006/42/EC shall remain valid until they expire.</u>	
		Article 21
	<del>Article 21</del>	Article 21
	<del>Dissemination of information</del>	Dissemination of information
	<del>The Commission shall take the necessary measures for appropriate information concerning the implementation of this Directive to be made available.</del>	The Commission shall take the necessary measures for appropriate information concerning the implementation of this Directive to be made available.
Article 51		
Article 51	<u>Article 51</u>	
Evaluation and review	<u>Evaluation and review</u>	
Article 51(1)		
1. By ... [60 months after the date of entry into force of this Regulation] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.	<u>1. By ... [60 months after the date of entry into force of this Regulation] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.</u>	
Article 51(2), first subparagraph, introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
2. Taking account of technical progress and practical experience gained in Member States as indicated in Article 5, the Commission shall in its report include an evaluation on the following aspects of this Regulation:	<u>2. Taking account of technical progress and practical experience gained in Member States as indicated in Article 5, the Commission shall in its report include an evaluation on the following aspects of this Regulation:</u>	
Article 51(2), first subparagraph, point (a)		
(a) the essential health and safety requirements set out in Annex III;	<u>(a) the essential health and safety requirements set out in Annex III;</u>	
Article 51(2), first subparagraph, point (b)		
(b) the conformity assessment procedure applicable to machinery or related products listed in Annex I.	<u>(b) the conformity assessment procedure applicable to machinery or related products listed in Annex I.</u>	
Article 51(2), second subparagraph		
Where appropriate, the report shall be accompanied by a legislative proposal for amendment of the relevant provisions of this Regulation.	<u>Where appropriate, the report shall be accompanied by a legislative proposal for amendment of the relevant provisions of this Regulation.</u>	
Article 51(2), second subparagraph a		
2a. By 24 months after the date of entry into force of this Regulation] and every four years thereafter, the Commission shall submit a specific report on the assessment of Article 5(4) and (8) of this Regulation to the European Parliament and to the Council. The reports shall be made public.	<u>2a. By 24 months after the date of entry into force of this Regulation] and every four years thereafter, the Commission shall submit a specific report on the assessment of Article 5(4) and (8) of this Regulation to the European Parliament and to the Council. The reports shall be made public.</u>	
Article 51(2), second subparagraph b		
The Commission shall in its reports include the following:	<u>The Commission shall in its reports include the following:</u>	
(a) a summary of data and information provided by Member States in accordance with Article 5(8) during the reporting period;	<u>(a) a summary of data and information provided by Member States in accordance with Article 5(8) during the reporting period;</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
(b) an assessment of the list of categories of machinery or related products in Annex I in view of the criteria set out in Article 5(4).	<u>(b) an assessment of the list of categories of machinery or related products in Annex I in view of the criteria set out in Article 5(4).</u>	
Article 51(2), second subparagraph c		
In the reports, the Commission shall assess the appropriateness and availability of sufficient and comparable data and information, and identify any shortcomings, necessary to ensure effective functioning and enforcement of Article 5.	<u>In the reports, the Commission shall assess the appropriateness and availability of sufficient and comparable data and information, and identify any shortcomings, necessary to ensure effective functioning and enforcement of Article 5.</u>	
Article 52		
Article 52	<u>Article 52</u>	
Entry into force and application	<u>Entry into force and application</u>	
Article 52, first paragraph		Article 28
This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	This <del>Regulation</del> <u>Directive</u> shall enter into force on the <del>twentieth</del> <u>20<sup>th</sup></u> day following <u>that of</u> its publication in the Official Journal of the European Union.	This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.
Article 52, second paragraph		
It shall apply from ... [42 months after the date of entry into force of this Regulation], with the exception of:	<u>It shall apply from ... [42 months after the date of entry into force of this Regulation], with the exception of:</u>	
Article 52, second paragraph a		
a) articles 24 to 40 , which shall apply from [6 months following the entry into force of this Regulation]	<u>a) articles 24 to 40 , which shall apply from [6 months following the entry into force of this Regulation]</u>	
Article 52, second paragraph b		
b) article 48(1) which shall apply from [39 months following the entry into force of this Regulation]	<u>b) article 48(1) which shall apply from [39 months following the entry into force of this Regulation]</u>	
Article 52, second paragraph c		

DRAFT Machinery Regulation	Comparison	Machinery Directive
c) Article 5 (6) and article 46 which shall apply from the date of entry into force of this Regulation]	<u>c) Article 5 (6) and article 46 which shall apply from the date of entry into force of this Regulation]</u>	
Article 52, second paragraph d		
d) Article 5 (2) to (7) and (10) and articles 45 and 51(2a), which shall apply from 12 months following the entry into force of this Regulation]	<u>d) Article 5 (2) to (7) and (10) and articles 45 and 51(2a), which shall apply from 12 months following the entry into force of this Regulation]</u>	
Article 52, third paragraph		Article 29
This Regulation shall be binding in its entirety and directly applicable in all Member States.	This <u>Regulation shall be binding in its entirety and directly applicable in all</u> <del>Directive is addressed to the</del> Member States.	This Directive is addressed to the Member States.
Formula		
Done at Brussels,	<u>Done at Brussels,</u>	
Formula		
For the European Parliament	<u>For the European Parliament</u>	
Formula		
For the Council	<u>For the Council</u>	

**Annex I: Categories of machinery or related products to which ...**

<b>DRAFT Machinery Regulation</b>	<b>Comparison</b>	<b>Machinery Directive</b>
Annex I, first heading -a		Annex IV
ANNEX I	ANNEX <del>IV</del>	ANNEX IV
Annex I, first heading		
CATEGORIES OF MACHINERY OR RELATED PRODUCTS TO WHICH ONE OF THE PROCEDURES REFERRED TO IN ARTICLE 21 (2) AND (2A) SHALL BE APPLIED	<u>CATEGORIES OF MACHINERY OR RELATED PRODUCTS TO WHICH ONE OF THE PROCEDURES REFERRED TO IN ARTICLE 21 (2) AND (2A) SHALL BE APPLIED</u> <del>Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied</del>	Categories of machinery to which one of the procedures referred to in Article 12(3) and (4) must be applied
PART A		
Part A	<u>Part A</u>	
Categories of machinery or related products to which the procedures referred to in Article 21 (2) shall be applied	<u>Categories of machinery or related products to which the procedures referred to in Article 21 (2) shall be applied</u>	
Annex I, point (14)		
14. Removable mechanical transmission devices including their guards.	14. Removable mechanical transmission devices including their guards.	14. Removable mechanical transmission devices including their guards.
Annex I, point (15)		
15. Guards for removable mechanical transmission devices.	15. Guards for removable mechanical transmission devices.	15. Guards for removable mechanical transmission devices.
Annex I, point (16)		
16. Vehicle servicing lifts.	16. Vehicle servicing lifts.	16. Vehicle servicing lifts.
Annex I, point (18)		
18. Portable cartridge-operated fixing and other impact machinery.	18. Portable cartridge-operated fixing and other impact machinery.	18. Portable cartridge-operated fixing and other impact machinery.
Annex I, point (24)		
24. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions	<u>24. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex I, point (25)		
25. Machinery embedding Systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only to those systems.	<u>25. Machinery embedding Systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only to those systems.</u>	
PART B		
Part B	<u>Part B</u>	
Categories of machinery or related products to which one of the procedures referred to in Article 21 (2a) shall be applied:	<u>Categories of machinery or related products to which one of the procedures referred to in Article 21 (2a) shall be applied:</u>	
Annex I, point (25a)		
1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:	1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:	1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;	1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;	1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;
1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;	1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;	1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;
1.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;	1.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;	1.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;

<b>DRAFT Machinery Regulation</b>	<b>Comparison</b>	<b>Machinery Directive</b>
1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.	1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.	1.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.
2. Hand-fed surface planing machinery for woodworking.	2. Hand-fed surface planing machinery for woodworking.	2. Hand-fed surface planing machinery for woodworking.
3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.	3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.	3. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.
4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:	4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:	4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:
4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;	4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;	4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;
4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.	4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.	4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.
5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.	5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.	5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.
6. Hand-fed tenoning machinery with several tool holders for woodworking.	6. Hand-fed tenoning machinery with several tool holders for woodworking.	6. Hand-fed tenoning machinery with several tool holders for woodworking.
7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.	7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.	7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.
8. Portable chainsaws for woodworking.	8. Portable chainsaws for woodworking.	8. Portable chainsaws for woodworking.

DRAFT Machinery Regulation	Comparison	Machinery Directive
9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.	9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.	9. Presses, including press-brakes, for the cold working of metals, with manual loading and/or unloading, whose movable working parts may have a travel exceeding 6 mm and a speed exceeding 30 mm/s.
10. Injection or compression plastics-moulding machinery with manual loading or unloading.	10. Injection or compression plastics-moulding machinery with manual loading or unloading.	10. Injection or compression plastics-moulding machinery with manual loading or unloading.
11. Injection or compression rubber-moulding machinery with manual loading or unloading.	11. Injection or compression rubber-moulding machinery with manual loading or unloading.	11. Injection or compression rubber-moulding machinery with manual loading or unloading.
12. Machinery for underground working of the following types:	12. Machinery for underground working of the following types:	12. Machinery for underground working of the following types:
12.1. locomotives and brake-vans;	12.1. locomotives and brake-vans;	12.1. locomotives and brake-vans;
12.2. hydraulic-powered roof supports.	12.2. hydraulic-powered roof supports.	12.2. hydraulic-powered roof supports.
13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.	13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.	13. Manually loaded trucks for the collection of household refuse incorporating a compression mechanism.
17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres	17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.	17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.
19. Protective devices designed to detect the presence of persons.	19. Protective devices designed to detect the presence of persons.	19. Protective devices designed to detect the presence of persons.
20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9 of Part A, 10 and 11 of Part B.	20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9 of Part A, 10 and 11 of Part B.	20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.
21. Logic units to ensure safety functions.	21. Logic units to ensure safety functions.	21. Logic units to ensure safety functions.
22. Roll-over protective structures (ROPS).	22. Roll-over protective structures (ROPS).	22. Roll-over protective structures (ROPS).

<b>DRAFT Machinery Regulation</b>	<b>Comparison</b>	<b>Machinery Directive</b>
23. Falling-object protective structures (FOPS).	23. Falling-object protective structures (FOPS).	23. Falling-object protective structures (FOPS).

## Annex II: Indicative list of safety components

DRAFT Machinery Regulation	Comparison	Machinery Directive
ANNEX II	ANNEX II <del>V</del>	ANNEX V
Annex II, first heading		
INDICATIVE LIST OF SAFETY COMPONENTS	<del>INDICATIVE LIST OF SAFETY COMPONENTS</del> Indicative list of the safety components referred to in Article 2(c)	Indicative list of the safety components referred to in Article 2(c)
Annex II, point (1)		
1. Guards for removable mechanical transmission devices.	1. Guards for removable mechanical transmission devices.	1. Guards for removable mechanical transmission devices.
Annex II, point (2)		
2. Protective devices designed to detect the presence of persons.	2. Protective devices designed to detect the presence of persons.	2. Protective devices designed to detect the presence of persons.
Annex II, point (3)		
3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11 of Annex I.	3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in <del>points</del> items 9, 10 and 11 of Annex <del>I</del> IV.	3. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in items 9, 10 and 11 of Annex IV.
Annex II, point (4)		
4. Logic units to ensure safety functions.	4. Logic units to ensure safety functions.	4. Logic units to ensure safety functions.
Annex II, point (5)		
5. Valves with additional means for failure detection intended for the control of dangerous movements of machinery.	5. Valves with additional means for failure detection intended for the control of dangerous movements <del>of</del> machinery.	5. Valves with additional means for failure detection intended for the control of dangerous movements on machinery.
Annex II, point (6)		
6. Extraction systems for machinery emissions.	6. Extraction systems for machinery emissions.	6. Extraction systems for machinery emissions.
Annex II, point (7)		
7. Guards and protective devices designed to protect persons against moving parts involved in the process of the machinery.	7. Guards and protective devices designed to protect persons against moving parts involved in the process <del>of</del> the machinery.	7. Guards and protective devices designed to protect persons against moving parts involved in the process on the machinery.
Annex II, point (8)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
8. Monitoring devices for loading and movement control in lifting machinery.	8. Monitoring devices for loading and movement control in lifting machinery.	8. Monitoring devices for loading and movement control in lifting machinery.
Annex II, point (9)		
9. Restraint systems to keep persons in their seats.	9. Restraint systems to keep persons <del>in</del> on their seats.	9. Restraint systems to keep persons on their seats.
Annex II, point (10)		
10. Emergency stop devices.	10. Emergency stop devices.	10. Emergency stop devices.
Annex II, point (11)		
11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.	11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.	11. Discharging systems to prevent the build-up of potentially dangerous electrostatic charges.
Annex II, point (12)		
12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex III.	12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex III <del>I</del> .	12. Energy limiters and relief devices referred to in sections 1.5.7, 3.4.7 and 4.1.2.6 of Annex I.
Annex II, point (13)		
13. Systems and devices to reduce the emission of noise and vibrations.	13. Systems and devices to reduce the emission of noise and vibrations.	13. Systems and devices to reduce the emission of noise and vibrations.
Annex II, point (14)		
14. Roll-over protective structures (ROPS).	14. Roll-over protective structures (ROPS).	14. Roll-over protective structures (ROPS).
Annex II, point (15)		
15. Falling-object protective structures (FOPS).	15. Falling-object protective structures (FOPS).	15. Falling-object protective structures (FOPS).
Annex II, point (16)		
16. Two-hand control devices.	16. Two-hand control devices.	16. Two-hand control devices.
Annex II, point (17), introductory part		
17. The following components for machinery designed for lifting and/or lowering persons between different landings:	17. <u>The following components</u> <del>Components</del> for machinery designed for lifting and/or lowering persons between different landings <del>and included in the following list:</del>	17. Components for machinery designed for lifting and/or lowering persons between different landings and included in the following list:
Annex II, point (17)(a)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(a) devices for locking landing doors; Annex II, point (17)(b)	(a) devices for locking landing doors;	(a) devices for locking landing doors;
(b) devices to prevent the load-carrying unit from falling or unchecked upwards movement; Annex II, point (17)(c)	(b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;	(b) devices to prevent the load-carrying unit from falling or unchecked upwards movement;
(c) overspeed limitation devices; Annex II, point (17)(d)	(c) overspeed limitation devices;	(c) overspeed limitation devices;
(d) energy-accumulating shock absorbers, non-linear or with damping of the return movement;	(d) energy-accumulating shock absorbers, <u>non-linear or with damping of the return movement;</u> <del>— non-linear, or</del> <del>— with damping of the return movement;</del>	(d) energy-accumulating shock absorbers, — non-linear, or — with damping of the return movement;
(e) energy-dissipating shock absorbers; Annex II, point (17)(f)	(e) energy-dissipating shock absorbers;	(e) energy-dissipating shock absorbers;
(f) safety devices fitted to jacks of hydraulic power circuits and used to prevent falls; Annex II, point (17)(g)	(f) safety devices fitted to jacks of hydraulic power circuits <u>and where these are used as devices</u> to prevent falls;	(f) safety devices fitted to jacks of hydraulic power circuits where these are used as devices to prevent falls;
(g) safety switches containing electronic components. Annex II, point (18)	<u>(g) (g) electric safety devices in the form of</u> safety switches containing electronic components.	(g) electric safety devices in the form of safety switches containing electronic components.
18. Software ensuring safety functions. Annex II, point (18a)	<u>18. Software ensuring safety functions.</u>	
(18a) Safety components with fully or partially self-evolving behavior using machine learning approaches ensuring safety functions. Annex II, point (19)	<u>(18a) Safety components with fully or partially self-evolving behavior using machine learning approaches ensuring safety functions.</u>	
19. Filtration systems intended to be integrated into machinery cabins in order	<u>19. Filtration systems intended to be integrated into machinery cabins in order</u>	

<b>DRAFT Machinery Regulation</b>	<b>Comparison</b>	<b>Machinery Directive</b>
to protect operators or other persons against hazardous materials and substances, including pesticides, and filters for such filtration systems.	<u>to protect operators or other persons against hazardous materials and substances, including pesticides, and filters for such filtration systems.</u>	

### Annex III: Essential Health and Safety Requirements ...

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, first heading -a		
ANNEX III	ANNEX <del>III</del>	ANNEX I
Annex III, first heading		
ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY OR RELATED PRODUCTS	<u>ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY OR RELATED PRODUCTS</u> <del>Essential health and safety requirements relating to the the design and construction of machinery</del>	Essential health and safety requirements relating to the the design and construction of machinery
Annex III, point (1)		Annex I, point (1.1.1)
A DEFINITIONS	<u>A DEFINITIONS</u> <del>1.1.1.—Definitions</del>	1.1.1. Definitions
Annex III, first heading a		
For the purpose of this Annex:	For the purpose of this Annex:	For the purpose of this Annex:
Annex III, point (2)		Annex I, point (1.1.1)(a)
(b) 'hazard' means a potential source of injury or damage to health;	( <del>b</del> a) 'hazard' means a potential source of injury or damage to health;	(a) 'hazard' means a potential source of injury or damage to health;
Annex III, point (3)		Annex I, point (1.1.1)(b)
(c) 'danger zone' means any zone within and/or around a machinery or related product in which a person is subject to a risk to his or her health or safety;	( <del>c</del> b) 'danger zone' means any zone within and/or around <u>a machinery or related product</u> in which a person is subject to a risk to his <u>or her</u> health or safety;	(b) 'danger zone' means any zone within and/or around machinery in which a person is subject to a risk to his health or safety;
Annex III, point (4)		Annex I, point (1.1.1)(c)
(d) 'exposed person' means any person wholly or partially in a danger zone;	( <del>d</del> e) 'exposed person' means any person wholly or partially in a danger zone;	(c) 'exposed person' means any person wholly or partially in a danger zone;
Annex III, point (5)		Annex I, point (1.1.1)(d)
(e) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving a machinery or related product;	( <del>e</del> ) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving <u>a machinery or related product</u> ;	(d) 'operator' means the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery;
Annex III, point (6)		Annex I, point (1.1.1)(e)

DRAFT Machinery Regulation	Comparison	Machinery Directive
(f) 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;	(f <del>e</del> ) 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;	(e) 'risk' means a combination of the probability and the degree of an injury or damage to health that can arise in a hazardous situation;
Annex III, point (7)		Annex I, point (1.1.1)(f)
(g) 'guard' means a part of a machinery or related product used specifically to provide protection by means of a physical barrier;	(g <del>f</del> ) 'guard' means a part of <del>a</del> <u>the</u> machinery <u>or related product</u> used specifically to provide protection by means of a physical barrier;	(f) 'guard' means a part of the machinery used specifically to provide protection by means of a physical barrier;
Annex III, point (8)		Annex I, point (1.1.1)(g)
(h) 'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;	(h <del>e</del> ) 'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;	(g) 'protective device' means a device (other than a guard) which reduces the risk, either alone or in conjunction with a guard;
Annex III, point (9)		Annex I, point (1.1.1)(h)
(i) 'intended use' means the use of a machinery or related product in accordance with the information provided in the instructions for use;	(i <del>h</del> ) 'intended use' means the use of <u>a</u> machinery <u>or related product</u> in accordance with the information provided in the instructions for use;	(h) 'intended use' means the use of machinery in accordance with the information provided in the instructions for use;
Annex III, point (10)		Annex I, point (1.1.1)(i)
(j) 'reasonably foreseeable misuse' means the use of a machinery or related product in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.	(j <del>i</del> ) 'reasonably foreseeable misuse' means the use of <u>a</u> machinery <u>or related product</u> in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.	(i) 'reasonably foreseeable misuse' means the use of machinery in a way not intended in the instructions for use, but which may result from readily predictable human behaviour.
Annex III, second heading		Annex I, General Principles
B. GENERAL PRINCIPLES	B. GENERAL PRINCIPLES	GENERAL PRINCIPLES
Annex III, point (1), introductory part		Annex I, General Principles, (1), first paragraph
1. The manufacturer of a machinery or related product shall ensure that a risk assessment is carried out in order to	1. The manufacturer of <u>a</u> machinery or <u>related product</u> shall <del>his authorised representative must</del> ensure that a risk	1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>determine the health and safety requirements, which apply to the machinery or related product. The machinery or related product shall then be designed and constructed to eliminate hazards or, if that is not possible, to minimise all relevant risks, taking into account the results of the risk assessment.</p>	<p>assessment is carried out in order to determine the health and safety requirements, which apply to the machinery <u>or related product</u>.<del>;</del> The machinery <u>or related product shall</u><del>must</del> then be designed and constructed <u>to eliminate hazards or, if that is not possible, to minimise all relevant risks,</u> taking into account the results of the risk assessment.</p>	<p>order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.</p>
<p>Annex III, point (1), first paragraph, introductory part</p>		<p>Annex I, General Principles, (1), second paragraph</p>
<p>By the iterative process of risk assessment and risk reduction referred to in the first subparagraph, the manufacturer shall:</p>	<p>By the iterative process of risk assessment and risk reduction referred to <u>in the first subparagraph</u><del>above</del>, the manufacturer <del>or his authorised representative</del> shall:</p>	<p>By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:</p>
<p>Annex III, point (1), first paragraph(a)</p>		<p>Annex I, General Principles, (1), second paragraph, dash 1</p>
<p>(a) determine the limits of the machinery or related product, which include the intended use and any reasonably foreseeable misuse thereof;</p>	<p><u>(a)</u>— determine the limits of the machinery <u>or related product</u>, which include the intended use and any reasonably foreseeable misuse thereof;<del>;</del></p>	<p>— determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,</p>
<p>Annex III, point (1), first paragraph(b)</p>		
<p>(b) deleted</p>	<p><u>(b) deleted</u></p>	
<p>Annex III, point (1), first paragraph(c)</p>		<p>Annex I, General Principles, (1), second paragraph, dash 2</p>
<p>(c) identify the hazards that may be generated by the machinery or related product and the associated hazardous situations;</p>	<p><u>(c)</u>— identify the hazards that <del>may can</del> be generated by the machinery <u>or related product</u> and the associated hazardous situations;<del>;</del></p>	<p>— identify the hazards that can be generated by the machinery and the associated hazardous situations,</p>
<p>Annex III, point (1), first paragraph(d)</p>		<p>Annex I, General Principles, (1), second paragraph, dash 3</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
(d) estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence;	<u>(d)</u> — estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence; <del>;</del>	— estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,
Annex III, point (1), first paragraph(e)		Annex I, General Principles, (1), second paragraph, dash 4
(e) evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Regulation;	<u>(e)</u> — evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this <del>Regulation</del> <del>Directive</del> ;	— evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Directive,
Annex III, point (1), first paragraph(f)		Annex I, General Principles, (1), second paragraph, dash 5
(f) eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).	<u>(f)</u> — eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).	— eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).
Annex III, point (1), first paragraph(fa)		
The risk assessment and risk reduction shall include hazards that may be generated during the lifecycle of the machinery or related product that are foreseeable at the time of placing of the machinery or related product on the market as an intended evolution of its fully or partially self-evolving behaviour or logic as a result of the machinery or related product designed to operate with varying levels of autonomy. The risk assessment and risk reduction shall include risks resulting from interactions between machinery in order to achieve the same end that are arranged and controlled so that they function as an	<u>The risk assessment and risk reduction shall include hazards that may be generated during the lifecycle of the machinery or related product that are foreseeable at the time of placing of the machinery or related product on the market as an intended evolution of its fully or partially self-evolving behaviour or logic as a result of the machinery or related product designed to operate with varying levels of autonomy. The risk assessment and risk reduction shall include risks resulting from interactions between machinery in order to achieve the same end that are arranged and controlled so that they function as an</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>integral whole, thus forming a machinery as defined in Article 3, point 1(d);</p>	<p><u>integral whole, thus forming a machinery as defined in Article 3, point 1(d);</u></p>	
<p>Annex III, point (2)</p>		<p>Annex I, General Principles, (2)</p>
<p>2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery or related product in question when it is used under the conditions foreseen by the manufacturer or in foreseeable abnormal situations. However, the principles of safety integration established in section 1.1.2 and the obligations concerning marking of machinery or related product referred to in section 1.7.3, and instructions for use referred to in section 1.7.4 apply in all cases.</p>	<p>2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery <u>or related product</u> in question when it is used under the conditions foreseen by the manufacturer or <del>his authorised representative or</del> in foreseeable abnormal situations. <del>However</del><u>In any event</u>, the principles of safety integration <del>established</del><u>referred to</u> in section 1.1.2 and the obligations concerning marking of machinery <u>or related product referred to in section 1.7.3</u>, and instructions for use referred to in <del>section</del><u>sections 1.7.3 and 1.7.4</u> apply <u>in all cases</u>.</p>	<p>2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery in question when it is used under the conditions foreseen by the manufacturer or his authorised representative or in foreseeable abnormal situations. In any event, the principles of safety integration referred to in section 1.1.2 and the obligations concerning marking of machinery and instructions referred to in sections 1.7.3 and 1.7.4 apply.</p>
<p>Annex III, point (3)</p>		<p>Annex I, General Principles, (3)</p>
<p>3. The essential health and safety requirements laid down in this Annex are mandatory; however, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery or related product shall, as far as possible, be designed and constructed with the purpose of approaching those objectives.</p>	<p>3. The essential health and safety requirements laid down in this Annex are mandatory; <del>however</del><u>However</u>, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery <u>or related product shall</u> <del>must</del>, as far as possible, be designed and constructed with the purpose of approaching <del>those</del><u>these</u> objectives.</p>	<p>3. The essential health and safety requirements laid down in this Annex are mandatory; However, taking into account the state of the art, it may not be possible to meet the objectives set by them. In that event, the machinery must, as far as possible, be designed and constructed with the purpose of approaching these objectives.</p>
<p>Annex III, point (4)</p>		<p>Annex I, General Principles, (4)</p>
<p>4. This Annex is organised into six chapters. The first chapter is of general scope and applicable to all machinery or</p>	<p>4. This Annex is organised <u>into six chapters</u>. <del>in several parts</del>. The first <del>chapter</del><u>one</u> is of general scope and</p>	<p>4. This Annex is organised in several parts. The first one is of general scope and applicable to all kinds of machinery.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>related product. The other chapters refer to certain sorts of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When a machinery or related product is being designed, the requirements of the first chapter and the requirements of one or more of the other chapters shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles. Essential health and safety requirements for the protection of the environment are applicable only to the machinery or related product referred to in section 2.4.</p>	<p>applicable to all <del>kinds of</del> <u>machinery or related product</u>. The other <del>chapters</del> <u>parts</u> refer to certain <del>sorts</del> <u>kinds</u> of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When <u>a machinery or related product</u> is being designed, the requirements of the <u>first chapter</u> <del>general part</del> and the requirements of one or more of the other <del>chapters</del> <u>parts</u> shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles. Essential health and safety requirements for the protection of the environment are applicable only to the machinery <u>or related product</u> referred to in section 2.4.</p>	<p>The other parts refer to certain kinds of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential requirements. When machinery is being designed, the requirements of the general part and the requirements of one or more of the other parts shall be taken into account, depending on the results of the risk assessment carried out in accordance with point 1 of these General Principles. Essential health and safety requirements for the protection of the environment are applicable only to the machinery referred to in section 2.4.</p>
Annex III, point (4a)		
<p>5. These general principles shall apply to the risk assessment carried out by the manufacturer of partly completed machinery.</p>	<p><u>5. These general principles shall apply to the risk assessment carried out by the manufacturer of partly completed machinery.</u></p>	
Annex III, 1		Annex I, 1
<p>1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS</p>	<p>1.– ESSENTIAL HEALTH AND SAFETY REQUIREMENTS</p>	<p>1. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS</p>
Annex III, 1, point (1.1), introductory part		Annex I, 1.1
<p>1.1. GENERAL REMARKS</p>	<p>1.1. –GENERAL REMARKS</p>	<p>1.1. GENERAL REMARKS</p>
Annex III, 1, point (1.1)(1.1.1), introductory part		
<p>1.1.1. Applicability</p>	<p><u>1.1.1. Applicability</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.1)(1.1.1), first paragraph, introductory part -a		
The obligations laid down by the essential health and safety requirements are applicable to partly completed machinery in as much those requirements are relevant.	<u>The obligations laid down by the essential health and safety requirements are applicable to partly completed machinery in as much those requirements are relevant.</u>	
Annex III, 1, point (1.1)(1.1.1), first paragraph -b		
The relevant requirements in relation to partly completed machinery do not cover the requirements that can only be fulfilled at the time of the incorporation of the partly completed machinery. However the principles of safety integration established in section 1.1.2 are applicable in all cases.	<u>The relevant requirements in relation to partly completed machinery do not cover the requirements that can only be fulfilled at the time of the incorporation of the partly completed machinery. However the principles of safety integration established in section 1.1.2 are applicable in all cases.</u>	
Annex III, 1, point (1.1)(1.1.2), introductory part		
1.1.2. Principles of safety integration	1.1.2. –Principles of safety integration	1.1.2. Principles of safety integration
Annex III, 1, point (1.1)(1.1.2)(a)		
(a) A machinery or related product shall be designed and constructed so that it is fit for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof. The aim of protective measures shall be to eliminate any risk throughout the foreseeable lifetime of the machinery or related product including the phases of	(a) <u>A machinery or related product shall</u> <del>Machinery must</del> be designed and constructed so that it is <del>fit</del> <u>fitted</u> for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof. The aim of <u>protective</u> measures <del>shall</del> <del>taken must</del> be to eliminate any risk throughout the foreseeable lifetime of the <u>machinery or related product</u> including	(a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof. The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport,

DRAFT Machinery Regulation	Comparison	Machinery Directive
transport, assembly, dismantling, disabling and scrapping.	the phases of transport, assembly, dismantling, disabling and scrapping.	assembly, dismantling, disabling and scrapping.
Annex III, 1, point (1.1)(1.1.2)(b), introductory part		
(b) In selecting the most appropriate methods, the manufacturer shall apply the following principles, in the order given:	(b) In selecting the most appropriate methods, the manufacturer <del>shall</del> <del>or his authorised representative must</del> apply the following principles, in the order given:	(b) In selecting the most appropriate methods, the manufacturer or his authorised representative must apply the following principles, in the order given:
Annex III, 1, point (1.1)(1.1.2)(b)(i)		
i. eliminate hazards or, if that is not possible, minimise risks (inherently safe machinery or related product design and construction);	i.— eliminate <u>hazards</u> or, <u>if that is not possible</u> , <u>minimise risks</u> -(inherently safe machinery <u>or related product</u> design and construction); <del>;</del>	— eliminate or reduce risks as far as possible (inherently safe machinery design and construction),
Annex III, 1, point (1.1)(1.1.2)(b)(ii)		
ii. take the necessary protective measures in relation to risks that cannot be eliminated;	ii.— take the necessary protective measures in relation to risks that cannot be eliminated; <del>;</del>	— take the necessary protective measures in relation to risks that cannot be eliminated,
Annex III, 1, point (1.1)(1.1.2)(b)(iii)		
iii. inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.	iii.— inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.	— inform users of the residual risks due to any shortcomings of the protective measures adopted, indicate whether any particular training is required and specify any need to provide personal protective equipment.
Annex III, 1, point (1.1)(1.1.2)(c)		
(c) When designing and constructing a machinery or related product and when drafting the instructions for use, the manufacturer shall envisage not only the intended use of the machinery or related product but also any reasonably foreseeable misuse thereof. The machinery or related product shall be	(c) When designing and constructing <u>a</u> machinery <u>or related product</u> and when drafting the instructions <u>for use</u> , the manufacturer <del>shall</del> <del>or his authorised representative must</del> envisage not only the intended use of the machinery <u>or related product</u> but also any reasonably foreseeable misuse thereof.	(c) When designing and constructing machinery and when drafting the instructions, the manufacturer or his authorised representative must envisage not only the intended use of the machinery but also any reasonably foreseeable misuse thereof.

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions for use shall draw the user's attention to ways — which experience has shown might occur — in which the machinery or related product should not be used.</p>	<p>The machinery <u>or related product shall</u><del>must</del> be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions <u>for use shall</u><del>must</del> draw the user's attention to ways — which experience has shown might occur — in which the machinery <u>or related product</u> should not be used.</p>	<p>The machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions must draw the user's attention to ways — which experience has shown might occur — in which the machinery should not be used.</p>
<p>Annex III, 1, point (1.1)(1.1.2)(d)</p>		
<p>(d) A machinery or related product shall be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.</p>	<p><u>(d) A machinery or related product shall</u><del>(d) Machinery must</del> be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.</p>	<p>(d) Machinery must be designed and constructed to take account of the constraints to which the operator is subject as a result of the necessary or foreseeable use of personal protective equipment.</p>
<p>Annex III, 1, point (1.1)(1.1.2)(e)</p>		
<p>(e) A machinery or related product shall be designed and constructed in such a way that it is possible for the user, where applicable, to test the safety functions. The machinery or related product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.</p>	<p><u>(e) A machinery or related product shall be designed and constructed in such a way that it is possible for the user, where applicable, to test the safety functions.</u> <del>The machinery or related product shall</del><del>Machinery must</del> be supplied with all the special equipment and accessories, <u>and where appropriate, with the description of specific functional test procedures,</u> essential to enable it to be <u>tested,</u> adjusted, maintained and used safely.</p>	<p>(e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.</p>
<p>Annex III, 1, point (1.1)(1.1.3), introductory part</p>		
<p>1.1.3. Materials and products</p>	<p>1.1.3. –Materials and products</p>	<p>1.1.3. Materials and products</p>
<p>Annex III, 1, point (1.1)(1.1.3), first paragraph</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>The materials used to construct a machinery or related product, or products used or created during its use, shall not endanger persons' safety or health. In particular, where fluids are used, machinery or related product shall be designed and constructed to prevent risks due to filling, use, recovery or draining.</p>	<p>The materials used to construct <u>a</u> machinery or <u>related product, or</u> products used or created during its use, <del>shall</del><b>must</b> not endanger persons' safety or health. In particular, where fluids are used, machinery <u>or related product shall</u><del>must</del> be designed and constructed to prevent risks due to filling, use, recovery or draining.</p>	<p>The materials used to construct machinery or products used or created during its use must not endanger persons' safety or health. In particular, where fluids are used, machinery must be designed and constructed to prevent risks due to filling, use, recovery or draining.</p>
<p>Annex III, 1, point (1.1)(1.1.4), introductory part</p>		
<p>1.1.4. Lighting</p>	<p>1.1.4. <del>Lighting</del></p>	<p>1.1.4. Lighting</p>
<p>Annex III, 1, point (1.1)(1.1.4), first paragraph</p>		
<p>A machinery or related product shall be supplied with integral lighting suitable for the operations concerned, where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.</p>	<p><u>A machinery or related product shall</u><del>Machinery must</del> be supplied with integral lighting suitable for the operations concerned, where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.</p>	<p>Machinery must be supplied with integral lighting suitable for the operations concerned where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.</p>
<p>Annex III, 1, point (1.1)(1.1.4), second paragraph</p>		
<p>A machinery or related product shall be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.</p>	<p><u>A machinery or related product shall</u><del>Machinery must</del> be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.</p>	<p>Machinery must be designed and constructed so that there is no area of shadow likely to cause nuisance, that there is no irritating dazzle and that there are no dangerous stroboscopic effects on moving parts due to the lighting.</p>
<p>Annex III, 1, point (1.1)(1.1.4), third paragraph</p>		
<p>Internal parts requiring frequent inspection and adjustment, and</p>	<p>Internal parts requiring frequent inspection and adjustment, and</p>	<p>Internal parts requiring frequent inspection and adjustment, and</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
maintenance areas shall be provided with appropriate lighting.	maintenance areas <del>shall</del> <b>must</b> be provided with appropriate lighting.	maintenance areas must be provided with appropriate lighting.
Annex III, 1, point (1.1)(1.1.5), introductory part		
1.1.5. Design of a machinery or related product to facilitate its handling	1.1.5. <del>Design of a machinery or related product</del> to facilitate its handling	1.1.5. Design of machinery to facilitate its handling
Annex III, 1, point (1.1)(1.1.5), first paragraph, introductory part		
(i) A machinery or related product or each component part thereof, shall:	(i) <del>A machinery or related product</del> <b>Machinery</b> , or each component part thereof, <del>shall</del> <b>must</b> :	Machinery, or each component part thereof, must:
Annex III, 1, point (1.1)(1.1.5), first paragraph(a)		
(a) be capable of being handled and transported safely;	(a) <del>be capable of being handled and transported safely;</del>	— be capable of being handled and transported safely,
Annex III, 1, point (1.1)(1.1.5), first paragraph(b)		
(b) be packaged or designed so that it can be stored safely and without damage.	(b) <del>be packaged or designed so that it can be stored safely and without damage.</del>	— be packaged or designed so that it can be stored safely and without damage.
Annex III, 1, point (1.1)(1.1.5), second paragraph		
During the transportation of the machinery or related product or its component parts, there shall be no possibility of sudden movements or of hazards due to instability as long as the machinery or related product or its component parts are handled in accordance with the instructions.	During the transportation of the machinery <del>or related product and</del> /or its component parts, there <del>shall</del> <b>must</b> be no possibility of sudden movements or of hazards due to instability as long as the machinery <del>or related product and</del> /or its component parts are handled in accordance with the instructions.	During the transportation of the machinery and/or its component parts, there must be no possibility of sudden movements or of hazards due to instability as long as the machinery and/or its component parts are handled in accordance with the instructions.
Annex III, 1, point (1.1)(1.1.5), third paragraph, introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(ii) Where the weight, size or shape of a machinery or related product or its various component parts prevents it or them from being moved by hand, the machinery or related product or each component part shall:	(ii) Where the weight, size or shape of <u>a</u> machinery or <u>related product</u> or its various component parts prevents <u>it or</u> them from being moved by hand, the machinery or <u>related product</u> or each component part <del>shall</del> <b>must</b> :	Where the weight, size or shape of machinery or its various component parts prevents them from being moved by hand, the machinery or each component part must:
Annex III, 1, point (1.1)(1.1.5), third paragraph(a)		
(a) either be fitted with attachments for lifting gear, or	<del>(a)</del> — either be fitted with attachments for lifting gear, or	— either be fitted with attachments for lifting gear, or
Annex III, 1, point (1.1)(1.1.5), third paragraph(b)		
(b) be designed so that it can be fitted with such attachments, or	<del>(b)</del> — be designed so that it can be fitted with such attachments, or	— be designed so that it can be fitted with such attachments, or
Annex III, 1, point (1.1)(1.1.5), third paragraph(c)		
(c) be shaped in such a way that standard lifting gear can easily be attached.	<del>(c)</del> — be shaped in such a way that standard lifting gear can easily be attached.	— be shaped in such a way that standard lifting gear can easily be attached.
Annex III, 1, point (1.1)(1.1.5), fourth paragraph, introductory part		
(iii) Where a machinery or related product or one of its component parts is to be moved by hand, it shall either:	(iii) Where <u>a</u> machinery or <u>related product</u> or one of its component parts is to be moved by hand, it <del>shall either</del> <b>must</b> :	Where machinery or one of its component parts is to be moved by hand, it must:
Annex III, 1, point (1.1)(1.1.5), fourth paragraph(a)		
(a) be easily moveable, or	<del>(a)</del> — <del>either</del> be easily moveable, or	— either be easily moveable, or
Annex III, 1, point (1.1)(1.1.5), fourth paragraph(b)		
(b) be equipped for picking up and moving safely.	<del>(b)</del> — be equipped for picking up and moving safely.	— be equipped for picking up and moving safely.
Annex III, 1, point (1.1)(1.1.5), fifth paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Special arrangements shall be made for the handling of tools and/or machinery or related product parts, which, even if lightweight, could be hazardous.	Special arrangements <del>shall</del> <b>must</b> be made for the handling of tools and/or machinery <u>or related product parts</u> , which, even if lightweight, could be hazardous.	Special arrangements must be made for the handling of tools and/or machinery parts which, even if lightweight, could be hazardous.
Annex III, 1, point (1.1)(1.1.6), introductory part		
1.1.6. Ergonomics	1.1.6. <del>—</del> Ergonomics	1.1.6. Ergonomics
Annex III, 1, point (1.1)(1.1.6), first paragraph, introductory part		
Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator shall be eliminated or reduced to the minimum possible, taking into account at least, the following ergonomic principles:	Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator <del>shall</del> <b>must</b> be <u>eliminated or reduced to the minimum possible</u> , taking into account <u>at least, the following ergonomic principles</u> <del>such as</del> :	Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles such as:
Annex III, 1, point (1.1)(1.1.6), first paragraph(a)		
(a) allowing for the variability of the operator's physical dimensions, strength and stamina;	<u>(a)</u> <del>—</del> allowing for the variability of the operator's physical dimensions, strength and stamina; <del>;</del>	— allowing for the variability of the operator's physical dimensions, strength and stamina,
Annex III, 1, point (1.1)(1.1.6), first paragraph(aa)		
(aa) avoiding the need for demanding work postures or movements and manual force exertions that exceed the operator's capacity;	<u>(aa) avoiding the need for demanding work postures or movements and manual force exertions that exceed the operator's capacity;</u>	
Annex III, 1, point (1.1)(1.1.6), first paragraph(b)		
(b) providing enough space for movements of the parts of the operator's body;	<u>(b)</u> <del>—</del> providing enough space for movements of the parts of the operator's body; <del>;</del>	— providing enough space for movements of the parts of the operator's body,

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.1)(1.1.6), first paragraph(c)		
(c) avoiding a machine-determined work rate;	<u>(c)</u> — avoiding a machine-determined work rate; <del>;</del>	— avoiding a machine-determined work rate,
Annex III, 1, point (1.1)(1.1.6), first paragraph(d)		
(d) avoiding monitoring that requires lengthy concentration;	<u>(d)</u> — avoiding monitoring that requires lengthy concentration; <del>;</del>	— avoiding monitoring that requires lengthy concentration,
Annex III, 1, point (1.1)(1.1.6), first paragraph(e)		
(e) adapting the human-machine interface to the foreseeable characteristics of the operators, including with respect to a machinery or related product with intended fully or partially self-evolving behaviour or logic that is designed to operate with varying levels of autonomy;	<u>(e)</u> — adapting the <u>human-machine man/machinery</u> -interface to the foreseeable characteristics of the operators, <u>including with respect to a machinery or related product with intended fully or partially self-evolving behaviour or logic that is designed to operate with varying levels of autonomy;</u> <del>;</del>	— adapting the man/machinery interface to the foreseeable characteristics of the operators.
Annex III, 1, point (1.1)(1.1.6), first paragraph(f)		
(f) where relevant, adapting a machinery or related product with intended fully or partially self-evolving behaviour or logic that is designed to operate with varying levels of autonomy to respond to people adequately and appropriately (such as verbally through words and non-verbally through gestures, facial expressions or body movement) and to communicate its planned actions (such as what it is going to do and why) to operators in a comprehensible manner.	<u>(f) where relevant, adapting a machinery or related product with intended fully or partially self-evolving behaviour or logic that is designed to operate with varying levels of autonomy to respond to people adequately and appropriately (such as verbally through words and non-verbally through gestures, facial expressions or body movement) and to communicate its planned actions (such as what it is going to do and why) to operators in a comprehensible manner.</u>	
Annex III, 1, point (1.1)(1.1.7), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
1.1.7. Operating positions	1.1.7. –Operating positions	1.1.7. Operating positions
Annex III, 1, point (1.1)(1.1.7), first paragraph		
The operating position shall be designed and constructed in such a way as to avoid any risk due to exhaust gases or lack of oxygen.	The operating position <del>shall</del> <b>must</b> be designed and constructed in such a way as to avoid any risk due to exhaust gases <del>and/or</del> lack of oxygen.	The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen.
Annex III, 1, point (1.1)(1.1.7), second paragraph		
If the machinery or related product is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery or related product itself gives rise to a hazardous environment, adequate means shall be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.	If the machinery <del>or related product</del> is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery <del>or related product</del> itself gives rise to a hazardous environment, adequate means <del>shall</del> <b>must</b> be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.	If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.
Annex III, 1, point (1.1)(1.1.7), third paragraph		
Where appropriate, the operating position shall be fitted with an adequate cabin designed, constructed or equipped to fulfil the above requirements. The exit shall allow rapid evacuation. Moreover, when applicable, an emergency exit shall be provided in a direction which is different from the usual exit.	Where appropriate, the operating position <del>shall</del> <b>must</b> be fitted with an adequate cabin designed, constructed <del>and/or</del> equipped to fulfil the above requirements. The exit <del>shall</del> <b>must</b> allow rapid evacuation. Moreover, when applicable, an emergency exit <del>shall</del> <b>must</b> be provided in a direction which is different from the usual exit.	Where appropriate, the operating position must be fitted with an adequate cabin designed, constructed and/or equipped to fulfil the above requirements. The exit must allow rapid evacuation. Moreover, when applicable, an emergency exit must be provided in a direction which is different from the usual exit.
Annex III, 1, point (1.1)(1.1.8), introductory part		
1.1.8. Seating	1.1.8. –Seating	1.1.8. Seating
Annex III, 1, point (1.1)(1.1.8), first paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery or related product shall be designed for the installation of seats.</p>	<p>Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery <u>or related product</u> <del>shall</del><b>must</b> be designed for the installation of seats.</p>	<p>Where appropriate and where the working conditions so permit, work stations constituting an integral part of the machinery must be designed for the installation of seats.</p>
<p>Annex III, 1, point (1.1)(1.1.8), second paragraph</p>		
<p>If the operator is intended to sit during operation and the operating position is an integral part of the machinery or related product, the seat shall be provided with the machinery or related product.</p>	<p>If the operator is intended to sit during operation and the operating position is an integral part of the machinery <u>or related product</u>, the seat <del>shall</del><b>must</b> be provided with the machinery <u>or related product</u>.</p>	<p>If the operator is intended to sit during operation and the operating position is an integral part of the machinery, the seat must be provided with the machinery.</p>
<p>Annex III, 1, point (1.1)(1.1.8), third paragraph</p>		
<p>The operator's seat shall enable him or her to maintain a stable position. Furthermore, the seat and its distance from the control devices shall be capable of being adapted to the operator.</p>	<p>The operator's seat <del>shall</del><b>must</b> enable him <u>or her</u> to maintain a stable position. Furthermore, the seat and its distance from the control devices <del>shall</del><b>must</b> be capable of being adapted to the operator.</p>	<p>The operator's seat must enable him to maintain a stable position. Furthermore, the seat and its distance from the control devices must be capable of being adapted to the operator.</p>
<p>Annex III, 1, point (1.1)(1.1.8), fourth paragraph</p>		
<p>If the machinery or related product is subject to vibrations, the seat shall be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings shall withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material shall be provided.</p>	<p>If the machinery <u>or related product</u> is subject to vibrations, the seat <del>shall</del><b>must</b> be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings <del>shall</del><b>must</b> withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material <del>shall</del><b>must</b> be provided.</p>	<p>If the machinery is subject to vibrations, the seat must be designed and constructed in such a way as to reduce the vibrations transmitted to the operator to the lowest level that is reasonably possible. The seat mountings must withstand all stresses to which they can be subjected. Where there is no floor beneath the feet of the operator, footrests covered with a slip-resistant material must be provided.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.1)(1.1.9), introductory part		
1.1.9. Protection against corruption	<u>1.1.9. Protection against corruption</u>	
Annex III, 1, point (1.1)(1.1.9), first paragraph		
<p>The machinery or related product shall be designed and constructed so that the connection to it of another device, via any feature of the connected device itself or via any remote device that communicates with the machinery or related product does not lead to a hazardous situation.</p>	<p><u>The machinery or related product shall be designed and constructed so that the connection to it of another device, via any feature of the connected device itself or via any remote device that communicates with the machinery or related product does not lead to a hazardous situation.</u></p>	
Annex III, 1, point (1.1)(1.1.9), second paragraph		
<p>A hardware component transmitting signal or data, relevant for connection or access to software that is critical for the compliance of the machinery or related product with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption. The machinery or related product shall collect evidence of a legitimate or illegitimate intervention in that hardware component, when relevant for connection or access to software that is critical for the compliance of the machinery or related product.</p>	<p><u>A hardware component transmitting signal or data, relevant for connection or access to software that is critical for the compliance of the machinery or related product with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption. The machinery or related product shall collect evidence of a legitimate or illegitimate intervention in that hardware component, when relevant for connection or access to software that is critical for the compliance of the machinery or related product.</u></p>	
Annex III, 1, point (1.1)(1.1.9), third paragraph		
<p>Software and data that are critical for the compliance of the machinery or related product with the relevant health and</p>	<p><u>Software and data that are critical for the compliance of the machinery or related product with the relevant health and</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
safety requirements shall be identified as such and shall be adequately protected against accidental or intentional corruption.	<u>safety requirements shall be identified as such and shall be adequately protected against accidental or intentional corruption.</u>	
Annex III, 1, point (1.1)(1.1.9), fourth paragraph		
The machinery or related product shall identify the software installed on it that is necessary for it to operate safely, and shall be able to provide that information at all times in an easily accessible form.	<u>The machinery or related product shall identify the software installed on it that is necessary for it to operate safely, and shall be able to provide that information at all times in an easily accessible form.</u>	
Annex III, 1, point (1.1)(1.1.9), fifth paragraph		
The machinery or related product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery or related product or its configuration.	<u>The machinery or related product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery or related product or its configuration.</u>	
Annex III, 1, point (1.2), introductory part		
1.2. CONTROL SYSTEMS	1.2. <del>CONTROL SYSTEMS</del>	1.2. CONTROL SYSTEMS
Annex III, 1, point (1.2)(1.2.1), introductory part		
1.2.1. Safety and reliability of control systems	1.2.1. <del>Safety and reliability of control systems</del>	1.2.1. Safety and reliability of control systems
Annex III, 1, point (1.2)(1.2.1), first paragraph		
Control systems shall be designed and constructed in such a way as to prevent hazardous situations from arising.	Control systems <del>shall</del> <b>must</b> be designed and constructed in such a way as to prevent hazardous situations from arising. <del>Above all, they must be designed and constructed in such a way that:</del>	Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:
Annex III, 1, point (1.2)(1.2.1), second paragraph, introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(i) Control systems shall be designed and constructed in such a way that:	<u>(i) Control systems shall be designed and constructed in such a way that:</u>	
Annex III, 1, point (1.2)(1.2.1), second paragraph(a)		
(a) they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including reasonably foreseeable malicious attempts from third parties leading to a hazardous situation;	<u>(a)— they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including reasonably foreseeable malicious attempts from third parties leading to a hazardous situation;</u>	— they can withstand the intended operating stresses and external influences,
Annex III, 1, point (1.2)(1.2.1), second paragraph(b)		
(b) a fault in the hardware or the logic of the control system shall not lead to hazardous situations;	<u>(b)— a fault in the hardware or the logic</u> <del>software</del> of the control system <del>shall</del> <u>does</u> not lead to hazardous situations; <u>;</u>	— a fault in the hardware or the software of the control system does not lead to hazardous situations,
Annex III, 1, point (1.2)(1.2.1), second paragraph(c)		
(c) errors in the control system logic shall not lead to hazardous situations;	<u>(c)— errors in the control system logic shall</u> <del>de</del> not lead to hazardous situations; <u>;</u>	— errors in the control system logic do not lead to hazardous situations,
Annex III, 1, point (1.2)(1.2.1), second paragraph(d)		
(d) the limits of the safety functions shall be established as part of the risk assessment performed by the manufacturer. In this respect no modification is allowed to the settings or rules generated by the machinery or related product or by operators, including during the machinery or related product learning phase, where such modifications may lead to hazardous situations;	<u>(d) the limits of the safety functions shall be established as part of the risk assessment performed by the manufacturer. In this respect no modification is allowed to the settings or rules generated by the machinery or related product or by operators, including during the machinery or related product learning phase, where such modifications may lead to hazardous situations;</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.2)(1.2.1), second paragraph(e)		
(e) reasonably foreseeable human errors during operation shall not lead to hazardous situations;	<u>(e)</u> — reasonably foreseeable human <del>errors</del> <del>error</del> during operation <del>shall</del> <del>does</del> not lead to hazardous situations;:-	— reasonably foreseeable human error during operation does not lead to hazardous situations.
Annex III, 1, point (1.2)(1.2.1), second paragraph(f)		
(f) the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery or related product has been placed on the market or put into service, is enabled for five years after such upload, exclusively to demonstrate the conformity of the machinery or related product with this Annex further to a reasoned request from a competent national authority;	<u>(f) the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery or related product has been placed on the market or put into service, is enabled for five years after such upload, exclusively to demonstrate the conformity of the machinery or related product with this Annex further to a reasoned request from a competent national authority;</u>	
Annex III, 1, point (1.2)(1.2.1), third paragraph, introductory part		
(ii) Control systems of machinery or related product with fully or partially self-evolving behaviour or logic that is designed to operate with varying levels of autonomy shall be designed and constructed in such a way that:	<u>(ii) Control systems of machinery or related product with fully or partially self-evolving behaviour or logic that is designed to operate with varying levels of autonomy shall be designed and constructed in such a way that:</u>	
Annex III, 1, point (1.2)(1.2.1), third paragraph(a)		
(a) they shall not cause the machinery or related product to perform actions beyond its defined task and movement space;	<u>(a) they shall not cause the machinery or related product to perform actions beyond its defined task and movement space;</u>	
Annex III, 1, point (1.2)(1.2.1), third paragraph(aa)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(aa) recording of data on the safety related decision-making process for software based safety systems ensuring safety function including safety components, after the machinery or related product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection, exclusively to demonstrate the conformity of the machinery or related product with this Annex further to a reasoned request from a competent national authority	<u>(aa) recording of data on the safety related decision-making process for software based safety systems ensuring safety function including safety components, after the machinery or related product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection, exclusively to demonstrate the conformity of the machinery or related product with this Annex further to a reasoned request from a competent national authority</u>	
Annex III, 1, point (1.2)(1.2.1), third paragraph(b)		
(b) it shall be possible at all times to correct the machinery or related product in order to maintain its inherent safety.	<u>(b) it shall be possible at all times to correct the machinery or related product in order to maintain its inherent safety.</u>	
Annex III, 1, point (1.2)(1.2.1), fourth paragraph, introductory part		
(iii) Particular attention shall be given to the following points:	<u>(iii) Particular attention shall <del>shall</del> must be given to the following points:</u>	Particular attention must be given to the following points:
Annex III, 1, point (1.2)(1.2.1), fourth paragraph(a)		
(a) the machinery or related product shall not start unexpectedly;	<u>(a) — the machinery or related product shall <del>shall</del> must not start unexpectedly;</u>	— the machinery must not start unexpectedly,
Annex III, 1, point (1.2)(1.2.1), fourth paragraph(b)		
(b) the parameters of the machinery or related product shall not change in an uncontrolled way, where such change may lead to hazardous situations;	<u>(b) — the parameters of the machinery or related product shall <del>shall</del> must not change in an uncontrolled way, where such change may lead to hazardous situations;</u>	— the parameters of the machinery must not change in an uncontrolled way, where such change may lead to hazardous situations,
Annex III, 1, point (1.2)(1.2.1), fourth paragraph(c)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(c) modifications to the settings or rules, generated by the machinery or related product or by operators, including during the machinery or related product learning phase, shall be prevented, where such modifications may lead to hazardous situations;	<u>(c) modifications to the settings or rules, generated by the machinery or related product or by operators, including during the machinery or related product learning phase, shall be prevented, where such modifications may lead to hazardous situations;</u>	
Annex III, 1, point (1.2)(1.2.1), fourth paragraph(d)		
(d) the machinery or related product shall not be prevented from stopping if the stop command has already been given;	<u>(d)— the machinery or related product shall <del>must</del> not be prevented from stopping if the stop command has already been given;</u>	— the machinery must not be prevented from stopping if the stop command has already been given,
Annex III, 1, point (1.2)(1.2.1), fourth paragraph(e)		
(e) no moving part of the machinery or related product or piece held by the machinery or related product shall fall or be ejected;	<u>(e)— no moving part of the machinery or related product or piece held by the machinery or related product shall <del>must</del> fall or be ejected;</u>	— no moving part of the machinery or piece held by the machinery must fall or be ejected,
Annex III, 1, point (1.2)(1.2.1), fourth paragraph(f)		
(f) automatic or manual stopping of the moving parts, whatever they may be, shall be unimpeded;	<u>(f)— automatic or manual stopping of the moving parts, whatever they may be, shall <del>must</del> be unimpeded;</u>	— automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,
Annex III, 1, point (1.2)(1.2.1), fourth paragraph(g)		
(g) the protective devices shall remain fully effective or give a stop command;	<u>(g)— the protective devices shall <del>must</del> remain fully effective or give a stop command;</u>	— the protective devices must remain fully effective or give a stop command,
Annex III, 1, point (1.2)(1.2.1), fourth paragraph(h)		
(h) the safety-related parts of the control system shall apply in a coherent way to	<u>(h)— the safety-related parts of the control system shall <del>must</del> apply in a coherent way to the whole of an</u>	— the safety-related parts of the control system must apply in a coherent way to

DRAFT Machinery Regulation	Comparison	Machinery Directive
the whole of an assembly of a machinery or related product.	assembly of <u>a machinery and/or related product</u> <del>partly completed machinery</del> .	the whole of an assembly of machinery and/or partly completed machinery.
Annex III, 1, point (1.2)(1.2.1), fifth paragraph		
For wireless control, a failure of the communication or connection or a faulty connection shall not lead to a hazardous situation.	For <del>wireless</del> <u>cable-less</u> control, <del>a failure</del> <u>an automatic stop must be activated when correct control signals are not received, including loss</u> of <u>the communication or connection or a faulty connection shall not lead to a hazardous situation</u> .	For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.
Annex III, 1, point (1.2)(1.2.2), introductory part		
1.2.2. Control devices	1.2.2. <del>–</del> Control devices	1.2.2. Control devices
Annex III, 1, point (1.2)(1.2.2), first paragraph, introductory part		
Control devices shall be:	Control devices <del>shall</del> <u>must</u> be:	Control devices must be:
Annex III, 1, point (1.2)(1.2.2), first paragraph(a)		
(a) clearly visible and identifiable, using pictograms where appropriate;	<u>(a)</u> <del>—</del> clearly visible and identifiable, using pictograms where appropriate; <del>;</del>	— clearly visible and identifiable, using pictograms where appropriate,
Annex III, 1, point (1.2)(1.2.2), first paragraph(b)		
(b) positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity;	<u>(b)</u> <del>—</del> positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity; <del>;</del>	— positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity,
Annex III, 1, point (1.2)(1.2.2), first paragraph(c)		
(c) designed in such a way that the movement of the control device is consistent with its effect;	<u>(c)</u> <del>—</del> designed in such a way that the movement of the control device is consistent with its effect; <del>;</del>	— designed in such a way that the movement of the control device is consistent with its effect,
Annex III, 1, point (1.2)(1.2.2), first paragraph(d)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(d) located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant;	(d)— located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant; <del>;</del>	— located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant,
Annex III, 1, point (1.2)(1.2.2), first paragraph(e)		
(e) positioned in such a way that their operation cannot cause additional risk;	(e)— positioned in such a way that their operation cannot cause additional risk; <del>;</del>	— positioned in such a way that their operation cannot cause additional risk,
Annex III, 1, point (1.2)(1.2.2), first paragraph(f)		
(f) designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action;	(f)— designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action; <del>;</del>	— designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action,
Annex III, 1, point (1.2)(1.2.2), first paragraph(g)		
(g) made in such a way as to withstand foreseeable forces, paying particular attention to emergency stop devices liable to be subjected to considerable forces.	(g)— made in such a way as to withstand foreseeable forces, <u>paying</u> ; particular attention <del>must be paid</del> to emergency stop devices liable to be subjected to considerable forces.	— made in such a way as to withstand foreseeable forces; particular attention must be paid to emergency stop devices liable to be subjected to considerable forces.
Annex III, 1, point (1.2)(1.2.2), second paragraph		
Where a control device is designed and constructed to perform several different actions, namely, where there is no one-to-one correspondence, the action to be performed shall be clearly displayed and subject to confirmation, where necessary.	Where a control device is designed and constructed to perform several different actions, namely, where there is no one-to-one correspondence, the action to be performed <del>shall</del> <u>must</u> be clearly displayed and subject to confirmation, where necessary.	Where a control device is designed and constructed to perform several different actions, namely where there is no one-to-one correspondence, the action to be performed must be clearly displayed and subject to confirmation, where necessary.
Annex III, 1, point (1.2)(1.2.2), third paragraph		
Control devices shall be so arranged that their layout, travel and resistance to	Control devices <del>shall</del> <u>must</u> be so arranged that their layout, travel and resistance to	Control devices must be so arranged that their layout, travel and resistance to

DRAFT Machinery Regulation	Comparison	Machinery Directive
operation are compatible with the action to be performed, taking account of ergonomic principles.	operation are compatible with the action to be performed, taking account of ergonomic principles.	operation are compatible with the action to be performed, taking account of ergonomic principles.
Annex III, 1, point (1.2)(1.2.2), fourth paragraph		
Machinery or related products shall be fitted with indicators as required for safe operation. The operator shall be able to read them from the control position.	Machinery <u>or related products shall</u> <del>must</del> be fitted with indicators as required for safe operation. The operator <u>shall</u> <del>must</del> be able to read them from the control position.	Machinery must be fitted with indicators as required for safe operation. The operator must be able to read them from the control position.
Annex III, 1, point (1.2)(1.2.2), fifth paragraph		
From each control position, the operator shall be able to ensure that no one is in the danger zones, or the control system shall be designed and constructed in such a way that starting is prevented while someone is in the danger zone.	From each control position, the operator <u>shall</u> <del>must</del> be able to ensure that no <u>one</u> is in the danger zones, or the control system <u>shall</u> <del>must</del> be designed and constructed in such a way that starting is prevented while someone is in the danger zone.	From each control position, the operator must be able to ensure that no-one is in the danger zones, or the control system must be designed and constructed in such a way that starting is prevented while someone is in the danger zone.
Annex III, 1, point (1.2)(1.2.2), sixth paragraph		
If neither of these possibilities is applicable, before the machinery or related product starts, an acoustic and/or visual warning signal shall be given. The exposed persons shall have time to leave the danger zone or prevent the machinery starting up.	If neither of these possibilities is applicable, before the machinery <u>or related product</u> starts, an acoustic and/or visual warning signal <u>shall</u> <del>must</del> be given. The exposed persons <u>shall</u> <del>must</del> have time to leave the danger zone or prevent the machinery starting up.	If neither of these possibilities is applicable, before the machinery starts, an acoustic and/or visual warning signal must be given. The exposed persons must have time to leave the danger zone or prevent the machinery starting up.
Annex III, 1, point (1.2)(1.2.2), seventh paragraph		
If necessary, means shall be provided to ensure that the machinery or related product can be controlled only from	If necessary, means <u>shall</u> <del>must</del> be provided to ensure that the machinery <u>or related product</u> can be controlled only	If necessary, means must be provided to ensure that the machinery can be controlled only from control positions

DRAFT Machinery Regulation	Comparison	Machinery Directive
control positions located in one or more predetermined zones or locations.	from control positions located in one or more predetermined zones or locations.	located in one or more predetermined zones or locations.
Annex III, 1, point (1.2)(1.2.2), eighth paragraph		
Where there is more than one control position, the control system shall be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.	Where there is more than one control position, the control system <del>shall</del> <b>must</b> be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.	Where there is more than one control position, the control system must be designed in such a way that the use of one of them precludes the use of the others, except for stop controls and emergency stops.
Annex III, 1, point (1.2)(1.2.2), ninth paragraph		
When the machinery or related product has two or more operating positions, each position shall be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.	When <u>the machinery or related product</u> has two or more operating positions, each position <del>shall</del> <b>must</b> be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.	When machinery has two or more operating positions, each position must be provided with all the required control devices without the operators hindering or putting each other into a hazardous situation.
Annex III, 1, point (1.2)(1.2.3), introductory part		
1.2.3. Starting	1.2.3. <del>Starting</del>	1.2.3. Starting
Annex III, 1, point (1.2)(1.2.3), first paragraph		
It shall be possible to start the machinery or related product only by voluntary actuation of a control device provided for the purpose.	It <del>shall</del> <b>must</b> be possible to start <u>the machinery or related product</u> only by voluntary actuation of a control device provided for the purpose.	It must be possible to start machinery only by voluntary actuation of a control device provided for the purpose.
Annex III, 1, point (1.2)(1.2.3), second paragraph, introductory part		
The same requirement applies:	The same requirement applies:	The same requirement applies:
Annex III, 1, point (1.2)(1.2.3), second paragraph(a)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(a) when restarting the machinery or related product after a stoppage, whatever the cause;	<u>(a)</u> — when restarting the machinery <u>or related product</u> after a stoppage, whatever the cause;	— when restarting the machinery after a stoppage, whatever the cause,
Annex III, 1, point (1.2)(1.2.3), second paragraph(b)		
(b) when effecting a significant change in the operating conditions.	<u>(b)</u> — when effecting a significant change in the operating conditions.	— when effecting a significant change in the operating conditions.
Annex III, 1, point (1.2)(1.2.3), third paragraph		
However, the restarting of the machinery or related product or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.	However, the restarting of the machinery <u>or related product</u> or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.	However, the restarting of the machinery or a change in operating conditions may be effected by voluntary actuation of a device other than the control device provided for the purpose, on condition that this does not lead to a hazardous situation.
Annex III, 1, point (1.2)(1.2.3), fourth paragraph		
For the machinery or related product functioning in automatic mode, the starting of the machinery or related product, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.	For <u>the machinery or related product</u> functioning in automatic mode, the starting of the machinery <u>or related product</u> , restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.	For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.
Annex III, 1, point (1.2)(1.2.3), fifth paragraph		
Where the machinery or related product has several starting control devices and the operators can therefore put each other in danger, additional devices shall be fitted to rule out such risks. If safety requires that starting and/or stopping	Where <u>the machinery or related product</u> has several starting control devices and the operators can therefore put each other in danger, additional devices <u>shall</u> <del>must</del> be fitted to rule out such risks. If safety requires that starting and/or	Where machinery has several starting control devices and the operators can therefore put each other in danger, additional devices must be fitted to rule out such risks. If safety requires that starting and/or stopping must be

DRAFT Machinery Regulation	Comparison	Machinery Directive
shall be performed in a specific sequence, there shall be devices that ensure that these operations are performed in the correct order.	stopping <del>shall</del> <b>must</b> be performed in a specific sequence, there <del>shall</del> <b>must</b> be devices <del>that</del> <b>which</b> ensure that these operations are performed in the correct order.	performed in a specific sequence, there must be devices which ensure that these operations are performed in the correct order.
Annex III, 1, point (1.2)(1.2.4), introductory part		
1.2.4. Stopping	1.2.4. <del>Stopping</del>	1.2.4. Stopping
Annex III, 1, point (1.2)(1.2.4)(1.2.4.1), introductory part		
1.2.4.1. Normal stop	1.2.4.1. <del>Normal stop</del>	1.2.4.1. Normal stop
Annex III, 1, point (1.2)(1.2.4)(1.2.4.1), first paragraph		
The machinery or related product shall be fitted with a control device whereby the machinery can be brought safely to a complete stop.	<u>The machinery or related product shall</u> <del>Machinery must</del> be fitted with a control device whereby the machinery can be brought safely to a complete stop.	Machinery must be fitted with a control device whereby the machinery can be brought safely to a complete stop.
Annex III, 1, point (1.2)(1.2.4)(1.2.4.1), second paragraph		
Each workstation shall be fitted with a control device to stop some or all of the functions of the machinery or related product, depending on the existing hazards, so that the machinery or related product is rendered safe.	Each workstation <del>shall</del> <b>must</b> be fitted with a control device to stop some or all of the functions of the machinery <u>or related product</u> , depending on the existing hazards, so that the machinery <u>or related product</u> is rendered safe.	Each workstation must be fitted with a control device to stop some or all of the functions of the machinery, depending on the existing hazards, so that the machinery is rendered safe.
Annex III, 1, point (1.2)(1.2.4)(1.2.4.1), third paragraph		
The machinery or related product's stop control shall have priority over the start controls	The <u>machinery or related product's</u> <del>machinery's</del> stop control <del>shall</del> <b>must</b> have priority over the start controls.	The machinery's stop control must have priority over the start controls.
Annex III, 1, point (1.2)(1.2.4)(1.2.4.1), fourth paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Once the machinery or related product or its hazardous functions have stopped, the energy supply to the actuators concerned shall be cut off.	Once the machinery or <u>related product or</u> its hazardous functions have stopped, the energy supply to the actuators concerned <del>shall</del> <b>must</b> be cut off.	Once the machinery or its hazardous functions have stopped, the energy supply to the actuators concerned must be cut off.
Annex III, 1, point (1.2)(1.2.4)(1.2.4.2), introductory part		
1.2.4.2. Operational stop	1.2.4.2. –Operational stop	1.2.4.2. Operational stop
Annex III, 1, point (1.2)(1.2.4)(1.2.4.2), first paragraph		
Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition shall be monitored and maintained.	Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition <del>shall</del> <b>must</b> be monitored and maintained.	Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition must be monitored and maintained.
Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), introductory part		
1.2.4.3. Emergency stop	1.2.4.3. –Emergency stop	1.2.4.3. Emergency stop
Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), first paragraph		
The machinery or related product shall be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.	<u>The machinery or related product shall</u> <del>Machinery must</del> be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.	Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.
Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), second paragraph, introductory part		
The following exceptions apply:	The following exceptions apply:	The following exceptions apply:
Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), second paragraph(a)		
(a) the machinery or related product in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or	<del>(a) the</del> <u>machinery or related product</u> in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or	— machinery in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the

DRAFT Machinery Regulation	Comparison	Machinery Directive
because it would not enable the special measures required to deal with the risk to be taken;	because it would not enable the special measures required to deal with the risk to be taken; <del>it</del>	special measures required to deal with the risk to be taken,
Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), second paragraph(b)		
(b) portable hand-held and/or hand-guided machinery or related product.	<del>(b)</del> — portable hand-held and/or hand-guided machinery or related product.	— portable hand-held and/or hand-guided machinery.
Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), third paragraph, introductory part		
The device shall:	The device <del>shall</del> <b>must</b> :	The device must:
Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), third paragraph(a)		
(a) have clearly identifiable, clearly visible and quickly accessible control devices;	<del>(a)</del> — have clearly identifiable, clearly visible and quickly accessible control devices; <del>it</del>	— have clearly identifiable, clearly visible and quickly accessible control devices,
Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), third paragraph(b)		
(b) stop the hazardous process as quickly as possible, without creating additional risks;	<del>(b)</del> — stop the hazardous process as quickly as possible, without creating additional risks; <del>it</del>	— stop the hazardous process as quickly as possible, without creating additional risks,
Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), third paragraph(c)		
(c) where necessary, trigger or permit the triggering of certain safeguard movements.	<del>(c)</del> — where necessary, trigger or permit the triggering of certain safeguard movements.	— where necessary, trigger or permit the triggering of certain safeguard movements.
Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), fourth paragraph		
Once active operation of the emergency stop device has ceased following a stop command, that command shall be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it	Once active operation of the emergency stop device has ceased following a stop command, that command <del>shall</del> <b>must</b> be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it	Once active operation of the emergency stop device has ceased following a stop command, that command must be sustained by engagement of the emergency stop device until that engagement is specifically overridden; it

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>shall not be possible to engage the device without triggering a stop command; it shall be possible to disengage the device only by an appropriate operation, and disengaging the device shall not restart the machinery or related product but only permit restarting.</p>	<p><del>shall</del><b>must</b> not be possible to engage the device without triggering a stop command; it <del>shall</del><b>must</b> be possible to disengage the device only by an appropriate operation, and disengaging the device <del>shall</del><b>must</b> not restart the machinery <u>or related product</u> but only permit restarting.</p>	<p>must not be possible to engage the device without triggering a stop command; it must be possible to disengage the device only by an appropriate operation, and disengaging the device must not restart the machinery but only permit restarting.</p>
<p>Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), fifth paragraph</p>		
<p>The emergency stop function shall be available and operational at all times, regardless of the operating mode.</p>	<p>The emergency stop function <del>shall</del><b>must</b> be available and operational at all times, regardless of the operating mode.</p>	<p>The emergency stop function must be available and operational at all times, regardless of the operating mode.</p>
<p>Annex III, 1, point (1.2)(1.2.4)(1.2.4.3), sixth paragraph</p>		
<p>Emergency stop devices shall be a backup to other safeguarding measures and not a substitute for them.</p>	<p>Emergency stop devices <del>shall</del><b>must</b> be a <del>backup</del><b>back-up</b> to other safeguarding measures and not a substitute for them.</p>	<p>Emergency stop devices must be a back-up to other safeguarding measures and not a substitute for them.</p>
<p>Annex III, 1, point (1.2)(1.2.4)(1.2.4.4), introductory part</p>		
<p>1.2.4.4. Assembly of machinery or related products</p>	<p>1.2.4.4. <del>Assembly of machinery</del> <u>or related products</u></p>	<p>1.2.4.4. Assembly of machinery</p>
<p>Annex III, 1, point (1.2)(1.2.4)(1.2.4.4), first paragraph</p>		
<p>In the case of a machinery or related products or parts of a machinery or related products designed to work together, the machinery shall be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery or related products itself but also all related equipment, if its continued operation may be dangerous.</p>	<p>In the case of <u>a machinery or related products or parts of a machinery or related products</u> designed to work together, the machinery <del>shall</del><b>must</b> be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery <u>or related products</u> itself but also all related equipment, if its continued operation may be dangerous.</p>	<p>In the case of machinery or parts of machinery designed to work together, the machinery must be designed and constructed in such a way that the stop controls, including the emergency stop devices, can stop not only the machinery itself but also all related equipment, if its continued operation may be dangerous.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.2)(1.2.5), introductory part		
1.2.5. Selection of control or operating modes	1.2.5. –Selection of control or operating modes	1.2.5. Selection of control or operating modes
Annex III, 1, point (1.2)(1.2.5), first paragraph		
The control or operating mode selected shall override all other control or operating modes, with the exception of the emergency stop.	The control or operating mode selected <del>shall</del> <b>must</b> override all other control or operating modes, with the exception of the emergency stop.	The control or operating mode selected must override all other control or operating modes, with the exception of the emergency stop.
Annex III, 1, point (1.2)(1.2.5), second paragraph		
If the machinery or related product has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it shall be fitted with a mode selector, which can be locked in each position. Each position of the selector shall be clearly identifiable and shall correspond to a single operating or control mode.	If <u>the machinery or related product</u> has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it <del>shall</del> <b>must</b> be fitted with a mode selector, which can be locked in each position. Each position of the selector <del>shall</del> <b>must</b> be clearly identifiable and <del>shall</del> <b>must</b> correspond to a single operating or control mode.	If machinery has been designed and constructed to allow its use in several control or operating modes requiring different protective measures and/or work procedures, it must be fitted with a mode selector which can be locked in each position. Each position of the selector must be clearly identifiable and must correspond to a single operating or control mode.
Annex III, 1, point (1.2)(1.2.5), third paragraph		
The selector may be replaced by another selection method, which restricts the use of certain functions of the machinery or related product to certain categories of operator.	The selector may be replaced by another selection method, which restricts the use of certain functions of the machinery <u>or related product</u> to certain categories of operator.	The selector may be replaced by another selection method which restricts the use of certain functions of the machinery to certain categories of operator.
Annex III, 1, point (1.2)(1.2.5), fourth paragraph, introductory part		
If, for certain operations, the machinery shall be able to operate with a guard	If, for certain operations, the machinery <del>shall</del> <b>must</b> be able to operate with a guard	If, for certain operations, the machinery must be able to operate with a guard

DRAFT Machinery Regulation	Comparison	Machinery Directive
displaced or removed and/or a protective device disabled, the control or operating mode selector shall simultaneously:	displaced or removed and/or a protective device disabled, the control or operating mode selector <del>shall</del> <b>must</b> simultaneously:	displaced or removed and/or a protective device disabled, the control or operating mode selector must simultaneously:
Annex III, 1, point (1.2)(1.2.5), fourth paragraph(a)		
(a) disable all other control or operating modes;	<u>(a)</u> — disable all other control or operating modes; <del>;</del>	— disable all other control or operating modes,
Annex III, 1, point (1.2)(1.2.5), fourth paragraph(b)		
(b) permit operation of hazardous functions only by control devices requiring sustained action;	<u>(b)</u> — permit operation of hazardous functions only by control devices requiring sustained action; <del>;</del>	— permit operation of hazardous functions only by control devices requiring sustained action,
Annex III, 1, point (1.2)(1.2.5), fourth paragraph(c)		
(c) permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences;	<u>(c)</u> — permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences; <del>;</del>	— permit the operation of hazardous functions only in reduced risk conditions while preventing hazards from linked sequences,
Annex III, 1, point (1.2)(1.2.5), fourth paragraph(d)		
(d) prevent any operation of hazardous functions by voluntary or involuntary action on the machine product's sensors.	<u>(d)</u> — prevent any operation of hazardous functions by voluntary or involuntary action on the <u>machine product's</u> <del>machine's</del> sensors.	— prevent any operation of hazardous functions by voluntary or involuntary action on the machine's sensors.
Annex III, 1, point (1.2)(1.2.5), fifth paragraph		
If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector shall activate other protective measures designed and constructed to ensure a safe intervention zone.	If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector <del>shall</del> <b>must</b> activate other protective measures designed and constructed to ensure a safe intervention zone.	If these four conditions cannot be fulfilled simultaneously, the control or operating mode selector must activate other protective measures designed and constructed to ensure a safe intervention zone.
Annex III, 1, point (1.2)(1.2.5), sixth paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
In addition, the operator shall be able to control the operation of the parts he or she is working on from the adjustment point.	In addition, the operator <del>shall</del> <b>must</b> be able to control <u>the</u> operation of the parts he <u>or she</u> is working on from the adjustment point.	In addition, the operator must be able to control operation of the parts he is working on from the adjustment point.
Annex III, 1, point (1.2)(1.2.6), introductory part		
1.2.6. Failure of the power supply or communication network connection	1.2.6. <del>Failure of the power supply</del> <u>or communication network connection</u>	1.2.6. Failure of the power supply
Annex III, 1, point (1.2)(1.2.6), first paragraph		
The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply or communication network connection to the machinery or related product shall not lead to hazardous situations.	The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply <u>or communication network connection to the machinery or related product</u> <del>shall</del> <b>must</b> not lead to <del>hazardous</del> <b>dangerous</b> situations.	The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply to the machinery must not lead to dangerous situations.
Annex III, 1, point (1.2)(1.2.6), second paragraph, introductory part		
Particular attention shall be given to the following:	Particular attention <del>shall</del> <b>must</b> be given to the following <del>points</del> :	Particular attention must be given to the following points:
Annex III, 1, point (1.2)(1.2.6), second paragraph(a)		
(a) the machinery or related products shall not start unexpectedly;	<u>(a)</u> <del>the machinery or related products shall</del> <b>must</b> not start unexpectedly; <b>;</b>	— the machinery must not start unexpectedly,
Annex III, 1, point (1.2)(1.2.6), second paragraph(b)		
(b) the parameters of the machinery shall not change in an uncontrolled way when such change can lead to hazardous situations;	<u>(b)</u> <del>the parameters of the machinery shall</del> <b>must</b> not change in an uncontrolled way when such change can lead to hazardous situations; <b>;</b>	— the parameters of the machinery must not change in an uncontrolled way when such change can lead to hazardous situations,
Annex III, 1, point (1.2)(1.2.6), second paragraph(c)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(c) the machinery or related products shall not be prevented from stopping if the stop command has already been given;	<del>(c)</del> — the machinery <u>or related products</u> shall <del>must</del> not be prevented from stopping if the <u>stop</u> command has already been given; <del>;</del>	— the machinery must not be prevented from stopping if the command has already been given,
Annex III, 1, point (1.2)(1.2.6), second paragraph(d)		
(d) no moving part of the machinery or related products or piece held by the machinery or related products shall fall or be ejected;	<del>(d)</del> — no moving part of the machinery or <u>related products or piece</u> held by the machinery <u>or related products</u> shall <del>must</del> fall or be ejected; <del>;</del>	— no moving part of the machinery or piece held by the machinery must fall or be ejected,
Annex III, 1, point (1.2)(1.2.6), second paragraph(e)		
(e) automatic or manual stopping of the moving parts, whatever they may be, shall be unimpeded;	<del>(e)</del> — automatic or manual stopping of the moving parts, whatever they may be, shall <del>must</del> be unimpeded; <del>;</del>	— automatic or manual stopping of the moving parts, whatever they may be, must be unimpeded,
Annex III, 1, point (1.2)(1.2.6), second paragraph(f)		
(f) the protective devices shall remain fully effective or give a stop command.	<del>(f)</del> — the protective devices shall <del>must</del> remain fully effective or give a stop command.	— the protective devices must remain fully effective or give a stop command.
Annex III, 1, point (1.3), introductory part		
1.3. PROTECTION AGAINST MECHANICAL RISKS	1.3. –PROTECTION AGAINST MECHANICAL <del>RISKS</del> HAZARDS	1.3. PROTECTION AGAINST MECHANICAL HAZARDS
Annex III, 1, point (1.3)(1.3.1), introductory part		
1.3.1. Risk of loss of stability	1.3.1. –Risk of loss of stability	1.3.1. Risk of loss of stability
Annex III, 1, point (1.3)(1.3.1), first paragraph		
The machinery or related product and its components and fittings shall be stable enough to avoid overturning, falling or uncontrolled movements during transportation, assembly, dismantling and	<u>The machinery or related product</u> <del>Machinery</del> and its components and fittings shall <del>must</del> be stable enough to avoid overturning, falling or uncontrolled movements during transportation,	Machinery and its components and fittings must be stable enough to avoid overturning, falling or uncontrolled movements during transportation,

DRAFT Machinery Regulation	Comparison	Machinery Directive
any other action involving the machinery or related products.	assembly, dismantling and any other action involving the machinery <u>or related products</u> .	assembly, dismantling and any other action involving the machinery.
Annex III, 1, point (1.3)(1.3.1), second paragraph		
If the shape of the machinery or related products itself or its intended installation does not offer sufficient stability, appropriate means of anchorage shall be incorporated and indicated in the instructions for use.	If the shape of the machinery <u>or related products</u> itself or its intended installation does not offer sufficient stability, appropriate means of anchorage <u>shall</u> <del>must</del> be incorporated and indicated in the instructions <u>for use</u> .	If the shape of the machinery itself or its intended installation does not offer sufficient stability, appropriate means of anchorage must be incorporated and indicated in the instructions.
Annex III, 1, point (1.3)(1.3.2), introductory part		
1.3.2. Risk of break-up during operation	1.3.2. <del>–</del> Risk of break-up during operation	1.3.2. Risk of break-up during operation
Annex III, 1, point (1.3)(1.3.2), first paragraph		
The various parts of machinery or related product and their linkages shall be able to withstand the stresses to which they are subject when used.	The various parts of machinery <u>or related product</u> and their linkages <u>shall</u> <del>must</del> be able to withstand the stresses to which they are subject when used.	The various parts of machinery and their linkages must be able to withstand the stresses to which they are subject when used.
Annex III, 1, point (1.3)(1.3.2), second paragraph		
The durability of the materials used shall be adequate for the nature of the working environment foreseen by the manufacturer, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.	The durability of the materials used <u>shall</u> <del>must</del> be adequate for the nature of the working environment foreseen by the manufacturer <del>or his authorised representative</del> , in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.	The durability of the materials used must be adequate for the nature of the working environment foreseen by the manufacturer or his authorised representative, in particular as regards the phenomena of fatigue, ageing, corrosion and abrasion.
Annex III, 1, point (1.3)(1.3.2), third paragraph		
The instructions for use shall indicate the type and frequency of inspections and maintenance required for safety reasons.	The instructions <u>for use shall</u> <del>must</del> indicate the type and frequency of inspections and maintenance required for	The instructions must indicate the type and frequency of inspections and maintenance required for safety reasons.

DRAFT Machinery Regulation	Comparison	Machinery Directive
They shall, where appropriate, indicate the parts subject to wear and the criteria for replacement.	safety reasons. They <del>shall</del> <b>must</b> , where appropriate, indicate the parts subject to wear and the criteria for replacement.	They must, where appropriate, indicate the parts subject to wear and the criteria for replacement.
Annex III, 1, point (1.3)(1.3.2), fourth paragraph		
Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned shall be mounted, positioned or guarded in such a way that any fragments will be contained, preventing hazardous situations.	Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned <del>shall</del> <b>must</b> be mounted, positioned <del>and/or</del> guarded in such a way that any fragments will be contained, preventing hazardous situations.	Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned must be mounted, positioned and/or guarded in such a way that any fragments will be contained, preventing hazardous situations.
Annex III, 1, point (1.3)(1.3.2), fifth paragraph		
Both rigid and flexible pipes carrying fluids, particularly those under high pressure, shall be able to withstand the foreseen internal and external stresses and shall be firmly attached or protected to ensure that no risk is presented by a rupture.	Both rigid and flexible pipes carrying fluids, particularly those under high pressure, <del>shall</del> <b>must</b> be able to withstand the foreseen internal and external stresses and <del>shall</del> <b>must</b> be firmly attached <del>and/or</del> protected to ensure that no risk is <del>presented</del> <b>posed</b> by a rupture.	Both rigid and flexible pipes carrying fluids, particularly those under high pressure, must be able to withstand the foreseen internal and external stresses and must be firmly attached and/or protected to ensure that no risk is posed by a rupture.
Annex III, 1, point (1.3)(1.3.2), sixth paragraph, introductory part		
Where the material to be processed is fed to the tool automatically, the following conditions shall be fulfilled to avoid risks to persons:	Where the material to be processed is fed to the tool automatically, the following conditions <del>shall</del> <b>must</b> be fulfilled to avoid risks to persons:	Where the material to be processed is fed to the tool automatically, the following conditions must be fulfilled to avoid risks to persons:
Annex III, 1, point (1.3)(1.3.2), sixth paragraph(a)		
(a) when the work piece comes into contact with the tool, the latter shall have attained its normal working condition;	<del>(a)</del> — when the <del>work piece</del> <b>workpiece</b> comes into contact with the tool, the latter <del>shall</del> <b>must</b> have attained its normal working condition <del>;</del> ;	— when the workpiece comes into contact with the tool, the latter must have attained its normal working condition,
Annex III, 1, point (1.3)(1.3.2), sixth paragraph(b)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(b) when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement shall be coordinated.	(b) — when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement <del>shall</del> <b>must</b> be coordinated.	— when the tool starts and/or stops (intentionally or accidentally), the feed movement and the tool movement must be coordinated.
Annex III, 1, point (1.3)(1.3.3), introductory part		
1.3.3. Risks due to falling or ejected objects	1.3.3. —Risks due to falling or ejected objects	1.3.3. Risks due to falling or ejected objects
Annex III, 1, point (1.3)(1.3.3), first paragraph		
Precautions shall be taken to prevent risks from falling or ejected objects.	Precautions <del>shall</del> <b>must</b> be taken to prevent risks from falling or ejected objects.	Precautions must be taken to prevent risks from falling or ejected objects.
Annex III, 1, point (1.3)(1.3.4), introductory part		
1.3.4. Risks due to surfaces, edges or angles	1.3.4. —Risks due to surfaces, edges or angles	1.3.4. Risks due to surfaces, edges or angles
Annex III, 1, point (1.3)(1.3.4), first paragraph		
Insofar as their purpose allows, accessible parts of the machinery shall have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.	Insofar as their purpose allows, accessible parts of the machinery <del>shall</del> <b>must</b> have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.	Insofar as their purpose allows, accessible parts of the machinery must have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.
Annex III, 1, point (1.3)(1.3.5), introductory part		
1.3.5. Risks related to a combined machinery or related product	1.3.5. —Risks related to <u>a</u> combined machinery <u>or related product</u>	1.3.5. Risks related to combined machinery
Annex III, 1, point (1.3)(1.3.5), first paragraph		
Where the machinery or related product is intended to carry out several different operations with manual removal of the	Where the machinery <u>or related product</u> is intended to carry out several different operations with manual removal of the	Where the machinery is intended to carry out several different operations with manual removal of the piece between

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>piece between each operation (combined machinery or related product), it shall be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons.</p>	<p>piece between each operation (combined machinery <u>or related product</u>), it <u>shall</u><del>must</del> be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons.</p>	<p>each operation (combined machinery), it must be designed and constructed in such a way as to enable each element to be used separately without the other elements constituting a risk for exposed persons.</p>
<p>Annex III, 1, point (1.3)(1.3.5), second paragraph</p>		
<p>For this purpose, it shall be possible to start and stop separately any elements that are not protected.</p>	<p>For this purpose, it <u>shall</u><del>must</del> be possible to start and stop separately any elements that are not protected.</p>	<p>For this purpose, it must be possible to start and stop separately any elements that are not protected.</p>
<p>Annex III, 1, point (1.3)(1.3.6), introductory part</p>		
<p>1.3.6. Risks related to variations in operating conditions</p>	<p>1.3.6. <del>–</del>Risks related to variations in operating conditions</p>	<p>1.3.6. Risks related to variations in operating conditions</p>
<p>Annex III, 1, point (1.3)(1.3.6), first paragraph</p>		
<p>Where the machinery or related product performs operations under different conditions of use, it shall be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.</p>	<p>Where the machinery <u>or related product</u> performs operations under different conditions of use, it <u>shall</u><del>must</del> be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.</p>	<p>Where the machinery performs operations under different conditions of use, it must be designed and constructed in such a way that selection and adjustment of these conditions can be carried out safely and reliably.</p>
<p>Annex III, 1, point (1.3)(1.3.7), introductory part</p>		
<p>1.3.7. Risks related to moving parts</p>	<p>1.3.7. <del>–</del>Risks related to moving parts</p>	<p>1.3.7. Risks related to moving parts</p>
<p>Annex III, 1, point (1.3)(1.3.7), first paragraph</p>		
<p>The moving parts of the machinery or related product shall be designed and constructed in such a way as to prevent risks of contact which could lead to</p>	<p>The moving parts of <u>the machinery or related product</u> <u>shall</u><del>must</del> be designed and constructed in such a way as to prevent risks of contact which could lead</p>	<p>The moving parts of machinery must be designed and constructed in such a way as to prevent risks of contact which could lead to accidents or must, where risks</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
accidents or shall, where risks persist, be fitted with guards or protective devices.	to accidents or <del>shall</del> <b>must</b> , where risks persist, be fitted with guards or protective devices.	persist, be fitted with guards or protective devices.
Annex III, 1, point (1.3)(1.3.7), second paragraph		
All necessary steps shall be taken to prevent accidental blockage of moving parts. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools shall, when appropriate, be provided to enable the equipment to be safely unblocked.	All necessary steps <del>shall</del> <b>must</b> be taken to prevent accidental blockage of moving parts <del>involved in the work</del> . In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools <del>shall</del> <b>must</b> , when appropriate, be provided to enable the equipment to be safely unblocked.	All necessary steps must be taken to prevent accidental blockage of moving parts involved in the work. In cases where, despite the precautions taken, a blockage is likely to occur, the necessary specific protective devices and tools must, when appropriate, be provided to enable the equipment to be safely unblocked.
Annex III, 1, point (1.3)(1.3.7), third paragraph		
The instructions for use and, where possible, a sign on the machinery or related product shall identify these specific protective devices and how they are to be used.	The instructions <del>for use</del> and, where possible, a sign on the machinery <del>or related product</del> shall identify these specific protective devices and how they are to be used.	The instructions and, where possible, a sign on the machinery shall identify these specific protective devices and how they are to be used.
Annex III, 1, point (1.3)(1.3.7), fourth paragraph, introductory part		
The prevention of risks of contact leading to hazard situations and the psychological stress that may be caused by the interaction with the machine shall be adapted to:	<u>The prevention of risks of contact leading to hazard situations and the psychological stress that may be caused by the interaction with the machine shall be adapted to:</u>	
Annex III, 1, point (1.3)(1.3.7), fourth paragraph(a)		
(a) human-machine coexistence in a shared space without direct collaboration;	<u>(a) human-machine coexistence in a shared space without direct collaboration;</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.3)(1.3.7), fourth paragraph(b)		
(b) human-machine interaction.	<u>(b) human-machine interaction.</u>	
Annex III, 1, point (1.3)(1.3.7), fifth paragraph		
deleted	<u>deleted</u>	
Annex III, 1, point (1.3)(1.3.8), introductory part		
1.3.8. Choice of protection against risks arising from moving parts	1.3.8. <del>Choice of protection against risks arising from moving parts</del>	1.3.8. Choice of protection against risks arising from moving parts
Annex III, 1, point (1.3)(1.3.8), first paragraph		
Guards or protective devices designed to protect against risks arising from moving parts shall be selected on the basis of the type of risk. The following guidelines shall be used to help to make the choice.	Guards or protective devices designed to protect against risks arising from moving parts <del>shall</del> <b>must</b> be selected on the basis of the type of risk. The following guidelines <del>shall</del> <b>must</b> be used to help to make the choice.	Guards or protective devices designed to protect against risks arising from moving parts must be selected on the basis of the type of risk. The following guidelines must be used to help to make the choice.
Annex III, 1, point (1.3)(1.3.8)(1.3.8.1), introductory part		
1.3.8.1. Moving transmission parts	1.3.8.1. <del>Moving transmission parts</del>	1.3.8.1. Moving transmission parts
Annex III, 1, point (1.3)(1.3.8)(1.3.8.1), first paragraph, introductory part		
Guards designed to protect persons against the hazards generated by moving transmission parts shall be:	Guards designed to protect persons against the hazards generated by moving transmission parts <del>shall</del> <b>must</b> be:	Guards designed to protect persons against the hazards generated by moving transmission parts must be:
Annex III, 1, point (1.3)(1.3.8)(1.3.8.1), first paragraph(a)		
(a) either fixed guards as referred to in section 1.4.2.1, or	<u>(a)</u> <del>—</del> either fixed guards as referred to in section 1.4.2.1, or	— either fixed guards as referred to in section 1.4.2.1, or
Annex III, 1, point (1.3)(1.3.8)(1.3.8.1), first paragraph(b)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(b) interlocking movable guards as referred to in section 1.4.2.2.	<del>(b)</del> — interlocking movable guards as referred to in section 1.4.2.2.	— interlocking movable guards as referred to in section 1.4.2.2.
Annex III, 1, point (1.3)(1.3.8)(1.3.8.1), second paragraph		
Interlocking movable guards shall be used where frequent access is envisaged.	Interlocking movable guards <del>shall</del> <del>should</del> be used where frequent access is envisaged.	Interlocking movable guards should be used where frequent access is envisaged.
Annex III, 1, point (1.3)(1.3.8)(1.3.8.2), introductory part		
1.3.8.2. Moving parts involved in the process	1.3.8.2. <del>—</del> Moving parts involved in the process	1.3.8.2. Moving parts involved in the process
Annex III, 1, point (1.3)(1.3.8)(1.3.8.2), first paragraph, introductory part		
(i) Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process shall be:	<del>(i)</del> Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process <del>shall</del> <del>must</del> be:	Guards or protective devices designed to protect persons against the hazards generated by moving parts involved in the process must be:
Annex III, 1, point (1.3)(1.3.8)(1.3.8.2), first paragraph(a)		
(a) either fixed guards as referred to in section 1.4.2.1, or	<del>(a)</del> either fixed guards as referred to in section 1.4.2.1, or	
Annex III, 1, point (1.3)(1.3.8)(1.3.8.2), first paragraph(b)		
(b) interlocking movable guards as referred to in section 1.4.2.2, or	<del>(b)</del> — interlocking movable guards as referred to in section 1.4.2.2, or	— interlocking movable guards as referred to in section 1.4.2.2, or
Annex III, 1, point (1.3)(1.3.8)(1.3.8.2), first paragraph(c)		
(c) protective devices as referred to in section 1.4.3, or	<del>(c)</del> — protective devices as referred to in section 1.4.3, or	— protective devices as referred to in section 1.4.3, or
Annex III, 1, point (1.3)(1.3.8)(1.3.8.2), first paragraph(d)		
(d) a combination of the above.	<del>(d)</del> — a combination of the above.	— a combination of the above.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.3)(1.3.8)(1.3.8.2), second paragraph, introductory part		
(ii) However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts shall be fitted with:	(ii) However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts <del>shall</del> <b>must</b> be fitted with:	However, when certain moving parts directly involved in the process cannot be made completely inaccessible during operation owing to operations requiring operator intervention, such parts must be fitted with:
Annex III, 1, point (1.3)(1.3.8)(1.3.8.2), second paragraph(a)		
(a) fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and	(a) — fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and	— fixed guards or interlocking movable guards preventing access to those sections of the parts that are not used in the work, and
Annex III, 1, point (1.3)(1.3.8)(1.3.8.2), second paragraph(b)		
(b) adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.	(b) — adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.	— adjustable guards as referred to in section 1.4.2.3 restricting access to those sections of the moving parts where access is necessary.
Annex III, 1, point (1.3)(1.3.9), introductory part		
1.3.9. Risks of uncontrolled movements	1.3.9. —Risks of uncontrolled movements	1.3.9. Risks of uncontrolled movements
Annex III, 1, point (1.3)(1.3.9), first paragraph		
When a part of the machinery or related product has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, shall be prevented or shall be such that it does not present a risk.	When a part of the machinery <u>or related product</u> has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, <del>shall</del> <b>must</b> be prevented or <del>shall</del> <b>must</b> be such that it does not present a <del>risk</del> <b>hazard</b> .	When a part of the machinery has been stopped, any drift away from the stopping position, for whatever reason other than action on the control devices, must be prevented or must be such that it does not present a hazard.
Annex III, 1, point (1.4), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
1.4. REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES	1.4. – REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES	1.4. REQUIRED CHARACTERISTICS OF GUARDS AND PROTECTIVE DEVICES
Annex III, 1, point (1.4)(1.4.1), introductory part		
1.4.1. General requirements	1.4.1. –General requirements	1.4.1. General requirements
Annex III, 1, point (1.4)(1.4.1), first paragraph, introductory part		
Guards and protective devices shall:	Guards and protective devices <del>shall</del> <b>must</b> :	Guards and protective devices must:
Annex III, 1, point (1.4)(1.4.1), first paragraph(a)		
(a) be of robust construction;	<del>(a)</del> – be of robust construction; <sub>i</sub>	– be of robust construction,
Annex III, 1, point (1.4)(1.4.1), first paragraph(b)		
(b) be securely held in place;	<del>(b)</del> – be securely held in place; <sub>i</sub>	– be securely held in place,
Annex III, 1, point (1.4)(1.4.1), first paragraph(c)		
(c) not give rise to any additional hazard;	<del>(c)</del> – not give rise to any additional hazard; <sub>i</sub>	– not give rise to any additional hazard,
Annex III, 1, point (1.4)(1.4.1), first paragraph(d)		
(d) not be easy to by-pass or render non-operational;	<del>(d)</del> – not be easy to by-pass or render non-operational; <sub>i</sub>	– not be easy to by-pass or render non-operational,
Annex III, 1, point (1.4)(1.4.1), first paragraph(e)		
(e) be located at an adequate distance from the danger zone;	<del>(e)</del> – be located at an adequate distance from the danger zone; <sub>i</sub>	– be located at an adequate distance from the danger zone,
Annex III, 1, point (1.4)(1.4.1), first paragraph(f)		
(f) cause minimum obstruction to the view of the production process, and;	<del>(f)</del> – cause minimum obstruction to the view of the production process, and; <sub>i</sub>	– cause minimum obstruction to the view of the production process, and
Annex III, 1, point (1.4)(1.4.1), first paragraph(g)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(g) enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible without the guard having to be removed or the protective device having to be disabled.	(g) — enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible without the guard having to be removed or the protective device having to be disabled.	— enable essential work to be carried out on the installation and/or replacement of tools and for maintenance purposes by restricting access exclusively to the area where the work has to be done, if possible without the guard having to be removed or the protective device having to be disabled.
Annex III, 1, point (1.4)(1.4.1), second paragraph		
In addition, guards shall, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery or related product.	In addition, guards <del>shall</del> <b>must</b> , where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery <u>or related product</u> .	In addition, guards must, where possible, protect against the ejection or falling of materials or objects and against emissions generated by the machinery.
Annex III, 1, point (1.4)(1.4.2), introductory part		
1.4.2. Special requirements for guards	1.4.2. <del>—</del> Special requirements for guards	1.4.2. Special requirements for guards
Annex III, 1, point (1.4)(1.4.2)(1.4.2.1), introductory part		
1.4.2.1. Fixed guards	1.4.2.1. <del>—</del> Fixed guards	1.4.2.1. Fixed guards
Annex III, 1, point (1.4)(1.4.2)(1.4.2.1), first paragraph		
Fixed guards shall be fixed by systems that can be opened or removed only with tools.	Fixed guards <del>shall</del> <b>must</b> be fixed by systems that can be opened or removed only with tools.	Fixed guards must be fixed by systems that can be opened or removed only with tools.
Annex III, 1, point (1.4)(1.4.2)(1.4.2.1), second paragraph		
Their fixing systems shall remain attached to the guards or to the machinery or related product when the guards are removed	Their fixing systems <del>shall</del> <b>must</b> remain attached to the guards or to the machinery <u>or related product</u> when the guards are removed.	Their fixing systems must remain attached to the guards or to the machinery when the guards are removed.
Annex III, 1, point (1.4)(1.4.2)(1.4.2.1), third paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Where possible, guards shall be incapable of remaining in place without their fixings.	Where possible, guards <del>shall</del> <b>must</b> be incapable of remaining in place without their fixings.	Where possible, guards must be incapable of remaining in place without their fixings.
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), introductory part		
1.4.2.2. Interlocking movable guards	1.4.2.2. <del>Interlocking</del> movable guards	1.4.2.2. Interlocking movable guards
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), first paragraph, introductory part		
(i) Interlocking movable guards shall:	<u>(i)</u> Interlocking movable guards <del>shall</del> <b>must</b> :	Interlocking movable guards must:
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), first paragraph(a)		
(a) as far as possible remain attached to the machinery or related product when open;	<u>(a)</u> — as far as possible remain attached to the machinery <u>or related product</u> when open; <del>;</del>	— as far as possible remain attached to the machinery when open,
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), first paragraph(b)		
(b) be designed and constructed in such a way that they can be adjusted only by means of an intentional action.	<u>(b)</u> — be designed and constructed in such a way that they can be adjusted only by means of an intentional action.	— be designed and constructed in such a way that they can be adjusted only by means of an intentional action.
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), second paragraph, introductory part		
(ii) Interlocking movable guards shall be associated with an interlocking device that:	<u>(ii)</u> Interlocking movable guards <del>shall</del> <b>must</b> be associated with an interlocking device that:	Interlocking movable guards must be associated with an interlocking device that:
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), second paragraph(a)		
(a) prevents the start of hazardous machinery or related product functions until they are closed and	<u>(a)</u> — prevents the start of hazardous machinery <u>or related product</u> functions until they are closed and	— prevents the start of hazardous machinery functions until they are closed and
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), second paragraph(b)		
(b) gives a stop command whenever they are no longer closed.	<u>(b)</u> — gives a stop command whenever they are no longer closed.	— gives a stop command whenever they are no longer closed.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), third paragraph, introductory part		
(iii) Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery or related product functions has ceased, movable guards shall be associated with a guard locking device in addition to an interlocking device that:	(iii) Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery <u>or related product</u> functions has ceased, movable guards <del>shall</del> <b>must</b> be associated with a guard locking device in addition to an interlocking device that:	Where it is possible for an operator to reach the danger zone before the risk due to the hazardous machinery functions has ceased, movable guards must be associated with a guard locking device in addition to an interlocking device that:
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), third paragraph(a)		
(a) prevents the start of hazardous machinery or related product functions until the guard is closed and locked, and	(a) <del>—</del> prevents the start of hazardous machinery <u>or related product</u> functions until the guard is closed and locked, and	— prevents the start of hazardous machinery functions until the guard is closed and locked, and
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), third paragraph(b)		
(b) keeps the guard closed and locked until the risk of injury from the hazardous machinery or related product functions has ceased.	(b) <del>—</del> keeps the guard closed and locked until the risk of injury from the hazardous machinery <u>or related product</u> functions has ceased.	— keeps the guard closed and locked until the risk of injury from the hazardous machinery functions has ceased.
Annex III, 1, point (1.4)(1.4.2)(1.4.2.2), fourth paragraph		
Interlocking movable guards shall be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery or related product functions.	Interlocking movable guards <del>shall</del> <b>must</b> be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery <u>or related product</u> functions.	Interlocking movable guards must be designed in such a way that the absence or failure of one of their components prevents starting or stops the hazardous machinery functions.
Annex III, 1, point (1.4)(1.4.2)(1.4.2.3), introductory part		
1.4.2.3. Adjustable guards restricting access	1.4.2.3. <del>—</del> Adjustable guards restricting access	1.4.2.3. Adjustable guards restricting access
Annex III, 1, point (1.4)(1.4.2)(1.4.2.3), first paragraph, introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work shall be:	Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work <del>shall</del> <b>must</b> be:	Adjustable guards restricting access to those areas of the moving parts strictly necessary for the work must be:
Annex III, 1, point (1.4)(1.4.2)(1.4.2.3), first paragraph(a)		
(a) adjustable manually or automatically, depending on the type of work involved; and	<u>(a)</u> — adjustable manually or automatically, depending on the type of work involved; <del>;</del> and	— adjustable manually or automatically, depending on the type of work involved, and
Annex III, 1, point (1.4)(1.4.2)(1.4.2.3), first paragraph(b)		
(b) readily adjustable without the use of tools.	<u>(b)</u> — readily adjustable without the use of tools.	— readily adjustable without the use of tools.
Annex III, 1, point (1.4)(1.4.3), introductory part		
1.4.3. Special requirements for protective devices	1.4.3. <del>—</del> Special requirements for protective devices	1.4.3. Special requirements for protective devices
Annex III, 1, point (1.4)(1.4.3), first paragraph, introductory part		
Protective devices shall be designed and incorporated into the control system in such a way that:	Protective devices <del>shall</del> <b>must</b> be designed and incorporated into the control system in such a way that:	Protective devices must be designed and incorporated into the control system in such a way that:
Annex III, 1, point (1.4)(1.4.3), first paragraph(a)		
(a) moving parts cannot start up while they are within the operator's reach;	<u>(a)</u> — moving parts cannot start up while they are within the operator's reach; <del>;</del>	— moving parts cannot start up while they are within the operator's reach,
Annex III, 1, point (1.4)(1.4.3), first paragraph(b)		
(b) persons cannot reach moving parts while the parts are moving, and	<u>(b)</u> — persons cannot reach moving parts while the parts are moving, and	— persons cannot reach moving parts while the parts are moving, and
Annex III, 1, point (1.4)(1.4.3), first paragraph(c)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(c) the absence or failure of one of their components prevents starting or stops the moving parts.	(c) — the absence or failure of one of their components prevents starting or stops the moving parts.	— the absence or failure of one of their components prevents starting or stops the moving parts.
Annex III, 1, point (1.4)(1.4.3), second paragraph		
Protective devices shall be adjustable only by means of an intentional action.	Protective devices <del>shall</del> <b>must</b> be adjustable only by means of an intentional action.	Protective devices must be adjustable only by means of an intentional action.
Annex III, 1, point (1.5), introductory part		
1.5. RISKS DUE TO OTHER CAUSES	1.5. <del>—RISKS DUE TO OTHER CAUSES</del> <b>HAZARDS</b>	1.5. RISKS DUE TO OTHER HAZARDS
Annex III, 1, point (1.5)(1.5.1), introductory part		
1.5.1. Electricity supply	1.5.1. <del>—</del> Electricity supply	1.5.1. Electricity supply
Annex III, 1, point (1.5)(1.5.1), first paragraph		
Where a machinery or related product has an electricity supply, it shall be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.	Where <u>a machinery or related product</u> has an electricity supply, it <del>shall</del> <b>must</b> be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.	Where machinery has an electricity supply, it must be designed, constructed and equipped in such a way that all hazards of an electrical nature are or can be prevented.
Annex III, 1, point (1.5)(1.5.1), second paragraph		
The safety objectives set out in Directive 2014/35/EU shall apply to a machinery or related product. However, the obligations concerning conformity assessment and the placing on the market or putting into service of a machinery or related product with regard to electrical risks are governed solely by this Regulation.	The safety objectives set out in Directive <del>2014/35/EU</del> <b>73/23/EEC</b> shall apply to <u>a machinery or related product</u> . However, the obligations concerning conformity assessment and the placing on the market <del>and/or</del> putting into service of <u>a machinery or related product</u> with regard to electrical <del>risks</del> <b>hazards</b> are governed solely by this <del>Regulation</del> <b>Directive</b> .	The safety objectives set out in Directive 73/23/EEC shall apply to machinery. However, the obligations concerning conformity assessment and the placing on the market and/or putting into service of machinery with regard to electrical hazards are governed solely by this Directive.
Annex III, 1, point (1.5)(1.5.2), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
1.5.2. Static electricity	1.5.2. <del>–</del> Static electricity	1.5.2. Static electricity
Annex III, 1, point (1.5)(1.5.2), first paragraph		
A machinery or related product shall be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.	<u>A machinery or related product shall</u> <del>Machinery must</del> be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.	Machinery must be designed and constructed to prevent or limit the build-up of potentially dangerous electrostatic charges and/or be fitted with a discharging system.
Annex III, 1, point (1.5)(1.5.3), introductory part		
1.5.3. Energy supply other than electricity	1.5.3. <del>–</del> Energy supply other than electricity	1.5.3. Energy supply other than electricity
Annex III, 1, point (1.5)(1.5.3), first paragraph		
Where a machinery or related product is powered by source of energy other than electricity, it shall be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.	Where <u>a machinery or related product</u> is powered by source of energy other than electricity, it <u>shall</u> <del>must</del> be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.	Where machinery is powered by source of energy other than electricity, it must be so designed, constructed and equipped as to avoid all potential risks associated with such sources of energy.
Annex III, 1, point (1.5)(1.5.4), introductory part		
1.5.4. Errors of fitting	1.5.4. <del>–</del> Errors of fitting	1.5.4. Errors of fitting
Annex III, 1, point (1.5)(1.5.4), first paragraph		
Errors likely to be made when fitting or refitting certain parts, which could be a source of risk, shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves or their housings. The same information shall be given on moving parts or their housings	Errors likely to be made when fitting or refitting certain parts, which could be a source of risk, <u>shall</u> <del>must</del> be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves <del>and</del> /or their housings. The same information <u>shall</u> <del>must</del> be given on	Errors likely to be made when fitting or refitting certain parts which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their

DRAFT Machinery Regulation	Comparison	Machinery Directive
where the direction of movement needs to be known in order to avoid a risk.	moving parts <del>and</del> /or their housings where the direction of movement needs to be known in order to avoid a risk.	housings where the direction of movement needs to be known in order to avoid a risk.
Annex III, 1, point (1.5)(1.5.4), second paragraph		
Where necessary, the instructions for use shall give further information on these risks.	Where necessary, the instructions <u>for use</u> shall <del>must</del> give further information on these risks.	Where necessary, the instructions must give further information on these risks.
Annex III, 1, point (1.5)(1.5.4), third paragraph		
Where a faulty connection can be the source of risk, incorrect connections shall be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.	Where a faulty connection can be the source of risk, incorrect connections shall <del>must</del> be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.	Where a faulty connection can be the source of risk, incorrect connections must be made impossible by design or, failing this, by information given on the elements to be connected and, where appropriate, on the means of connection.
Annex III, 1, point (1.5)(1.5.5), introductory part		
1.5.5. Extreme temperatures	1.5.5. <del>–</del> Extreme temperatures	1.5.5. Extreme temperatures
Annex III, 1, point (1.5)(1.5.5), first paragraph		
Steps shall be taken to eliminate any risk of injury arising from contact with or proximity to machinery or related product parts or materials at high or very low temperatures.	Steps shall <del>must</del> be taken to eliminate any risk of injury arising from contact with or proximity to machinery <u>or related product</u> parts or materials at high or very low temperatures.	Steps must be taken to eliminate any risk of injury arising from contact with or proximity to machinery parts or materials at high or very low temperatures.
Annex III, 1, point (1.5)(1.5.5), second paragraph		
The necessary steps shall also be taken to avoid or protect against the risk of hot or very cold material being ejected.	The necessary steps shall <del>must</del> also be taken to avoid or protect against the risk of hot or very cold material being ejected.	The necessary steps must also be taken to avoid or protect against the risk of hot or very cold material being ejected.
Annex III, 1, point (1.5)(1.5.6), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
1.5.6. Fire	1.5.6. –Fire	1.5.6. Fire
Annex III, 1, point (1.5)(1.5.6), first paragraph		
A machinery or related product shall be designed and constructed in such a way as to avoid any risk of fire or overheating presented by the machinery or related product itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery or related product.	<u>A machinery or related product shall</u> <del>Machinery must</del> be designed and constructed in such a way as to avoid any risk of fire or overheating <u>presented</u> <del>posed</del> by the machinery <u>or related product</u> itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery <u>or related product</u> .	Machinery must be designed and constructed in such a way as to avoid any risk of fire or overheating posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.
Annex III, 1, point (1.5)(1.5.7), introductory part		
1.5.7. Explosion	1.5.7. –Explosion	1.5.7. Explosion
Annex III, 1, point (1.5)(1.5.7), first paragraph		
A machinery or related product shall be designed and constructed in such a way as to avoid any risk of explosion presented by the machinery or related product itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery or related product.	<u>A machinery or related product shall</u> <del>Machinery must</del> be designed and constructed in such a way as to avoid any risk of explosion <u>presented</u> <del>posed</del> by the machinery <u>or related product</u> itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery <u>or related product</u> .	Machinery must be designed and constructed in such a way as to avoid any risk of explosion posed by the machinery itself or by gases, liquids, dust, vapours or other substances produced or used by the machinery.
Annex III, 1, point (1.5)(1.5.7), second paragraph		
A machinery or related product shall comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Union harmonisation legislation	<u>A machinery or related product shall</u> <del>Machinery must</del> comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific <u>Union harmonisation legislation</u> <del>Community Directives</del> .	Machinery must comply, as far as the risk of explosion due to its use in a potentially explosive atmosphere is concerned, with the provisions of the specific Community Directives.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.5)(1.5.8), introductory part		
1.5.8. Noise	1.5.8. <del>Noise</del>	1.5.8. Noise
Annex III, 1, point (1.5)(1.5.8), first paragraph		
A machinery or related product shall be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source.	<u>A machinery or related product shall</u> <del>Machinery must</del> be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source.	Machinery must be designed and constructed in such a way that risks resulting from the emission of airborne noise are reduced to the lowest level, taking account of technical progress and the availability of means of reducing noise, in particular at source.
Annex III, 1, point (1.5)(1.5.8), second paragraph		
The level of noise emission may be assessed with reference to comparative emission data for similar machinery or related product.	The level of noise emission may be assessed with reference to comparative emission data for similar machinery <u>or related product.</u>	The level of noise emission may be assessed with reference to comparative emission data for similar machinery.
Annex III, 1, point (1.5)(1.5.9), introductory part		
1.5.9. Vibrations	1.5.9. <del>Vibrations</del>	1.5.9. Vibrations
Annex III, 1, point (1.5)(1.5.9), first paragraph		
A machinery or related product shall be designed and constructed in such a way that risks resulting from vibrations produced by the machinery or related product are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.	<u>A machinery or related product shall</u> <del>Machinery must</del> be designed and constructed in such a way that risks resulting from vibrations produced by the machinery <u>or related product</u> are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.	Machinery must be designed and constructed in such a way that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.5)(1.5.9), second paragraph		
The level of vibration emission may be assessed with reference to comparative emission data for similar machinery or related products.	The level of vibration emission may be assessed with reference to comparative emission data for similar machinery <u>or related products</u> .-	The level of vibration emission may be assessed with reference to comparative emission data for similar machinery.
Annex III, 1, point (1.5)(1.5.10), introductory part		
1.5.10. Radiation	1.5.10. -Radiation	1.5.10. Radiation
Annex III, 1, point (1.5)(1.5.10), first paragraph		
Undesirable radiation emissions from the machinery or related product shall be eliminated or be reduced to levels that do not have adverse effects on persons.	Undesirable radiation emissions from the machinery <u>or related product shall</u> <del>must</del> be eliminated or be reduced to levels that do not have adverse effects on persons.	Undesirable radiation emissions from the machinery must be eliminated or be reduced to levels that do not have adverse effects on persons.
Annex III, 1, point (1.5)(1.5.10), second paragraph		
Any functional ionising radiation emissions shall be limited to the lowest level, which is sufficient for the proper functioning of the machinery or related product during setting, operation and cleaning. Where a risk exists, the necessary protective measures shall be taken.	Any functional ionising radiation emissions <u>shall</u> <del>must</del> be limited to the lowest level, which is sufficient for the proper functioning of the machinery <u>or related product</u> during setting, operation and cleaning. Where a risk exists, the necessary protective measures <u>shall</u> <del>must</del> be taken.	Any functional ionising radiation emissions must be limited to the lowest level which is sufficient for the proper functioning of the machinery during setting, operation and cleaning. Where a risk exists, the necessary protective measures must be taken.
Annex III, 1, point (1.5)(1.5.10), third paragraph		
Any functional non-ionising radiation emissions during setting, operation and cleaning shall be limited to levels that do not have adverse effects on persons.	Any functional non-ionising radiation emissions during setting, operation and cleaning <u>shall</u> <del>must</del> be limited to levels that do not have adverse effects on persons.	Any functional non-ionising radiation emissions during setting, operation and cleaning must be limited to levels that do not have adverse effects on persons.
Annex III, 1, point (1.5)(1.5.11), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
1.5.11. External radiation	1.5.11. <del>External radiation</del>	1.5.11. External radiation
Annex III, 1, point (1.5)(1.5.11), first paragraph		
A machinery or related product shall be designed and constructed in such a way that external radiation does not interfere with its operation.	<u>A machinery or related product shall</u> <del>Machinery must</del> be designed and constructed in such a way that external radiation does not interfere with its operation.	Machinery must be designed and constructed in such a way that external radiation does not interfere with its operation.
Annex III, 1, point (1.5)(1.5.12), introductory part		
1.5.12. Laser radiation	1.5.12. <del>Laser radiation</del>	1.5.12. Laser radiation
Annex III, 1, point (1.5)(1.5.12), first paragraph, introductory part		
Where laser equipment is used, the following shall be taken into account:	Where laser equipment is used, the following <u>shall</u> <del>should</del> be taken into account:	Where laser equipment is used, the following should be taken into account:
Annex III, 1, point (1.5)(1.5.12), first paragraph(a)		
(a) laser equipment on a machinery or related product shall be designed and constructed in such a way as to prevent any accidental radiation;	<u>(a)</u> <del>—</del> laser equipment on <u>a machinery or related product shall</u> <del>must</del> be designed and constructed in such a way as to prevent any accidental radiation; <del>;</del>	— laser equipment on machinery must be designed and constructed in such a way as to prevent any accidental radiation,
Annex III, 1, point (1.5)(1.5.12), first paragraph(b)		
(b) laser equipment on a machinery or related product shall be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health;	<u>(b)</u> <del>—</del> laser equipment on <u>a machinery or related product shall</u> <del>must</del> be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health; <del>;</del>	— laser equipment on machinery must be protected in such a way that effective radiation, radiation produced by reflection or diffusion and secondary radiation do not damage health,
Annex III, 1, point (1.5)(1.5.12), first paragraph(c)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(c) optical equipment for the observation or adjustment of laser equipment on a machinery or related product shall be such that no health risk is created by laser radiation.	<u>(c)</u> — optical equipment for the observation or adjustment of laser equipment on <u>a machinery or related product shall</u> <del>must</del> be such that no health risk is created by laser radiation.	— optical equipment for the observation or adjustment of laser equipment on machinery must be such that no health risk is created by laser radiation.
Annex III, 1, point (1.5)(1.5.13), introductory part		
1.5.13. Emissions of hazardous materials and substances	1.5.13. –Emissions of hazardous materials and substances	1.5.13. Emissions of hazardous materials and substances
Annex III, 1, point (1.5)(1.5.13), first paragraph		
A machinery or related product shall be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.	<u>A machinery or related product shall</u> <del>Machinery must</del> be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.	Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.
Annex III, 1, point (1.5)(1.5.13), second paragraph		
Where a risk cannot be eliminated, the machinery or related product shall be so equipped that hazardous materials and substances can be contained, captured, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.	Where a <del>risk</del> <del>hazard</del> cannot be eliminated, the machinery <u>or related product shall</u> <del>must</del> be so equipped that hazardous materials and substances can be contained, <u>captured</u> , evacuated, precipitated by water spraying, filtered or treated by another equally effective method.	Where a hazard cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.
Annex III, 1, point (1.5)(1.5.13), third paragraph		
Where the process is not totally enclosed during normal operation of the machinery or related product, the devices for	Where the process is not totally enclosed during normal operation of the machinery <u>or related product</u> , the devices for	Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or

DRAFT Machinery Regulation	Comparison	Machinery Directive
containment or capture, filtration or separation and evacuation shall be situated in such a way as to have the maximum effect.	containment <u>or capture, filtration or separation</u> and <del>for</del> evacuation <u>shall</u> <del>must</del> be situated in such a way as to have the maximum effect.	evacuation must be situated in such a way as to have the maximum effect.
Annex III, 1, point (1.5)(1.5.14), introductory part		
1.5.14. Risk of being trapped in a machine	1.5.14. <del>–</del> Risk of being trapped in a machine	1.5.14. Risk of being trapped in a machine
Annex III, 1, point (1.5)(1.5.14), first paragraph		
A machinery or related products shall be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.	<u>A machinery or related products shall</u> <del>Machinery must</del> be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.	Machinery must be designed, constructed or fitted with a means of preventing a person from being enclosed within it or, if that is impossible, with a means of summoning help.
Annex III, 1, point (1.5)(1.5.15), introductory part		
1.5.15. Risk of slipping, tripping or falling	1.5.15. <del>–</del> Risk of slipping, tripping or falling	1.5.15. Risk of slipping, tripping or falling
Annex III, 1, point (1.5)(1.5.15), first paragraph		
Parts of the machinery or related products where persons are liable to move about or stand shall be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts.	Parts of the machinery <u>or related products</u> where persons are liable to move about or stand <u>shall</u> <del>must</del> be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts.	Parts of the machinery where persons are liable to move about or stand must be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts.
Annex III, 1, point (1.5)(1.5.15), second paragraph		
Where appropriate, these parts shall be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.	Where appropriate, these parts <u>shall</u> <del>must</del> be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.	Where appropriate, these parts must be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.5)(1.5.16), introductory part		
1.5.16. Lightning	1.5.16. –Lightning	1.5.16. Lightning
Annex III, 1, point (1.5)(1.5.16), first paragraph		
A machinery or related product in need of protection against the effects of lightning while being used shall be fitted with a system for conducting the resultant electrical charge to earth.	A <u>machinery or related product</u> <del>Machinery</del> in need of protection against the effects of lightning while being used <del>shall</del> <b>must</b> be fitted with a system for conducting the resultant electrical charge to earth.	Machinery in need of protection against the effects of lightning while being used must be fitted with a system for conducting the resultant electrical charge to earth.
Annex III, 1, point (1.6), introductory part		
1.6. MAINTENANCE	1.6. –MAINTENANCE	1.6. MAINTENANCE
Annex III, 1, point (1.6)(1.6.1), introductory part		
1.6.1. Machinery or related product maintenance	1.6.1. –Machinery <u>or related product</u> maintenance	1.6.1. Machinery maintenance
Annex III, 1, point (1.6)(1.6.1), first paragraph		
Adjustment and maintenance points shall be located outside danger zones. It shall be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while the machinery or related product is at a standstill.	Adjustment and maintenance points <del>shall</del> <b>must</b> be located outside danger zones. It <del>shall</del> <b>must</b> be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while <u>the machinery or related product</u> is at a standstill.	Adjustment and maintenance points must be located outside danger zones. It must be possible to carry out adjustment, maintenance, repair, cleaning and servicing operations while machinery is at a standstill.
Annex III, 1, point (1.6)(1.6.1), second paragraph		
If one or more of the above conditions cannot be satisfied for technical reasons, measures shall be taken to ensure that these operations can be carried out safely (see section 1.2.5).	If one or more of the above conditions cannot be satisfied for technical reasons, measures <del>shall</del> <b>must</b> be taken to ensure that these operations can be carried out safely (see section 1.2.5).	If one or more of the above conditions cannot be satisfied for technical reasons, measures must be taken to ensure that these operations can be carried out safely (see section 1.2.5).

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.6)(1.6.1), third paragraph		
In the case of automated machinery and, where necessary, other machinery or related product, a connecting device for mounting diagnostic fault-finding equipment shall be provided.	In the case of automated machinery and, where necessary, other machinery <u>or related product</u> , a connecting device for mounting diagnostic fault-finding equipment <del>shall</del> <u>must</u> be provided.	In the case of automated machinery and, where necessary, other machinery, a connecting device for mounting diagnostic fault-finding equipment must be provided.
Annex III, 1, point (1.6)(1.6.1), fourth paragraph		
Automated machinery components, which have to be changed frequently, shall be capable of being removed and replaced easily and safely. Access to the components shall enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.	Automated machinery components, which have to be changed frequently, <del>shall</del> <u>must</u> be capable of being removed and replaced easily and safely. Access to the components <del>shall</del> <u>must</u> enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.	Automated machinery components which have to be changed frequently must be capable of being removed and replaced easily and safely. Access to the components must enable these tasks to be carried out with the necessary technical means in accordance with a specified operating method.
Annex III, 1, point (1.6)(1.6.2), introductory part		
1.6.2. Access to operating positions and servicing points	1.6.2. <del>–</del> Access to operating positions and servicing points	1.6.2. Access to operating positions and servicing points
Annex III, 1, point (1.6)(1.6.2), first paragraph		
Machinery shall be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment, maintenance and cleaning of the machinery.	Machinery <del>shall</del> <u>must</u> be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment, <del>and</del> <u>and cleaning</u> of the machinery.	Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment and maintenance of the machinery.
Annex III, 1, point (1.6)(1.6.2), second paragraph		
In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the	<u>In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>machinery accesses shall be dimensioned and adapted for the use of rescue equipment in such a way that a emergency rescue of the persons is possible.</p>	<p><u>machinery accesses shall be dimensioned and adapted for the use of rescue equipment in such a way that a emergency rescue of the persons is possible.</u></p>	
<p>Annex III, 1, point (1.6)(1.6.3), introductory part</p>		
<p>1.6.3. Isolation of energy sources</p>	<p>1.6.3. <del>Isolation of energy sources</del></p>	<p>1.6.3. Isolation of energy sources</p>
<p>Annex III, 1, point (1.6)(1.6.3), first paragraph</p>		
<p>A machinery or related product shall be fitted with means to isolate it from all energy sources. Such isolators shall be clearly identified. They shall be capable of being locked if reconnection could endanger persons. Isolators shall also be capable of being locked where an operator is unable, from any of the points to which he or she has access, to check that the energy is still cut off.</p>	<p><u>A machinery or related product shall</u><del>Machinery must</del> be fitted with means to isolate it from all energy sources. Such isolators <u>shall</u><del>must</del> be clearly identified. They <u>shall</u><del>must</del> be capable of being locked if reconnection could endanger persons. Isolators <u>shall</u><del>must</del> also be capable of being locked where an operator is unable, from any of the points to which he <u>or she</u> has access, to check that the energy is still cut off.</p>	<p>Machinery must be fitted with means to isolate it from all energy sources. Such isolators must be clearly identified. They must be capable of being locked if reconnection could endanger persons. Isolators must also be capable of being locked where an operator is unable, from any of the points to which he has access, to check that the energy is still cut off.</p>
<p>Annex III, 1, point (1.6)(1.6.3), second paragraph</p>		
<p>In the case of machinery or related products capable of being plugged into an electricity supply, removal of the plug is sufficient, if the operator can check from any of the points to which he or she has access that the plug remains removed.</p>	<p>In the case of machinery <u>or related products</u> capable of being plugged into an electricity supply, removal of the plug is sufficient, <del>if provided that</del> the operator can check from any of the points to which he <u>or she</u> has access that the plug remains removed.</p>	<p>In the case of machinery capable of being plugged into an electricity supply, removal of the plug is sufficient, provided that the operator can check from any of the points to which he has access that the plug remains removed.</p>
<p>Annex III, 1, point (1.6)(1.6.3), third paragraph</p>		
<p>After the energy is cut off, it shall be possible to dissipate normally any energy</p>	<p>After the energy is cut off, it <u>shall</u><del>must</del> be possible to dissipate normally any energy</p>	<p>After the energy is cut off, it must be possible to dissipate normally any energy</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
remaining or stored in the circuits of the machinery or related product without risk to persons.	remaining or stored in the circuits of the machinery <u>or related product</u> without risk to persons.	remaining or stored in the circuits of the machinery without risk to persons.
Annex III, 1, point (1.6)(1.6.3), fourth paragraph		
As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps shall be taken to ensure operator safety.	As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps <del>shall</del> <b>must</b> be taken to ensure operator safety.	As an exception to the requirement laid down in the previous paragraphs, certain circuits may remain connected to their energy sources in order, for example, to hold parts, to protect information, to light interiors, etc. In this case, special steps must be taken to ensure operator safety.
Annex III, 1, point (1.6)(1.6.4), introductory part		
1.6.4. Operator intervention	1.6.4. <del>Operator</del> intervention	1.6.4. Operator intervention
Annex III, 1, point (1.6)(1.6.4), first paragraph		
The machinery or related product shall be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it shall be possible to carry it out easily and safely.	<u>The machinery or related product</u> <del>shall</del> <b>Machinery must</b> be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it <del>shall</del> <b>must</b> be possible to carry it out easily and safely.	Machinery must be so designed, constructed and equipped that the need for operator intervention is limited. If operator intervention cannot be avoided, it must be possible to carry it out easily and safely.
Annex III, 1, point (1.6)(1.6.5), introductory part		
1.6.5. Cleaning of internal parts	1.6.5. <del>Cleaning</del> of internal parts	1.6.5. Cleaning of internal parts
Annex III, 1, point (1.6)(1.6.5), first paragraph		
The machinery shall be designed and constructed in such a way that it is possible to clean internal parts, which have contained dangerous substances or	The machinery <del>shall</del> <b>must</b> be designed and constructed in such a way that it is possible to clean internal parts, which have contained dangerous substances or	The machinery must be designed and constructed in such a way that it is possible to clean internal parts which have contained dangerous substances or

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>preparations without entering them; any necessary unblocking shall also be possible from the outside. If it is impossible to avoid entering the machinery, it shall be designed and constructed in such a way as to allow cleaning to take place safely.</p>	<p>preparations without entering them; any necessary unblocking <del>shall</del><b>must</b> also be possible from the outside. If it is impossible to avoid entering the machinery, it <del>shall</del><b>must</b> be designed and constructed in such a way as to allow cleaning to take place safely.</p>	<p>preparations without entering them; any necessary unblocking <b>must</b> also be possible from the outside. If it is impossible to avoid entering the machinery, it <b>must</b> be designed and constructed in such a way as to allow cleaning to take place safely.</p>
<p>Annex III, 1, point (1.7), introductory part</p>		<p>Annex I, 1, point (1.7), introductory part</p>
<p>1.7. INFORMATION</p>	<p>1.7. <del>INFORMATION</del></p>	<p>1.7. INFORMATION</p>
<p>Annex III, 1, point (1.7)(1.7.1), introductory part</p>		<p>Annex I, 1, point (1.7)(1.7.1), introductory part</p>
<p>1.7.1. Information and warnings on the machinery or related product</p>	<p>1.7.1. <del>Information and warnings on the machinery or related product</del></p>	<p>1.7.1. Information and warnings on the machinery</p>
<p>Annex III, 1, point (1.7)(1.7.1), first paragraph</p>		<p>Annex I, 1, point (1.7)(1.7.1), first sentence</p>
<p>Information and warnings on the machinery or related product shall preferably be provided in the form of readily understandable symbols or pictograms.</p>	<p>Information and warnings on the machinery <u>or related product</u> <del>shall</del><b>should</b> preferably be provided in the form of readily understandable symbols or pictograms.</p>	<p>Information and warnings on the machinery <b>should</b> preferably be provided in the form of readily understandable symbols or pictograms.</p>
<p>Annex III, 1, point (1.7)(1.7.1)(-a)</p>		<p>Annex I, 1, point (1.7)(1.7.1), second sentence</p>
<p>Any written or verbal information and warnings must be expressed in a language which can be easily understood by users, as determined by the Member State concerned.</p>	<p>Any written or verbal information and warnings must be expressed in <del>an official Community language or languages,</del> which <del>can</del><b>may</b> be <u>easily understood by users, as determined in accordance with the Treaty</u> by the Member State <u>concerned in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.</u></p>	<p>Any written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.7)(1.7.1)(1.7.1.1), introductory part		
1.7.1.1. Information and information devices	1.7.1.1. –Information and information devices	1.7.1.1. Information and information devices
Annex III, 1, point (1.7)(1.7.1)(1.7.1.1), first paragraph		
The information needed to control a machinery or related product shall be provided in a form that is unambiguous and easily understood. It shall not be excessive to the extent of overloading the operator.	The information needed to control <u>a</u> machinery <u>or related product shall</u> <del>must</del> be provided in a form that is unambiguous and easily understood. It <u>shall</u> <del>must</del> not be excessive to the extent of overloading the operator.	The information needed to control machinery must be provided in a form that is unambiguous and easily understood. It must not be excessive to the extent of overloading the operator.
Annex III, 1, point (1.7)(1.7.1)(1.7.1.1), second paragraph		
Visual display units or any other interactive means of communication between the operator and the machinery or related product shall be easily understood and easy to use.	Visual display units or any other interactive means of communication between the operator and the <u>machinery or related product shall</u> <del>machine must</del> be easily understood and easy to use.	Visual display units or any other interactive means of communication between the operator and the machine must be easily understood and easy to use.
Annex III, 1, point (1.7)(1.7.1)(1.7.1.2), introductory part		
1.7.1.2. Warning devices	1.7.1.2. –Warning devices	1.7.1.2. Warning devices
Annex III, 1, point (1.7)(1.7.1)(1.7.1.2), first paragraph		
Where the health and safety of persons may be endangered by a fault in the operation of an unsupervised machinery or related product, the machinery or related product shall be equipped in such a way as to give an appropriate acoustic or light signal as a warning.	Where the health and safety of persons may be endangered by a fault in the operation of <u>an</u> unsupervised machinery <u>or related product</u> , the machinery <u>or related product shall</u> <del>must</del> be equipped in such a way as to give an appropriate acoustic or light signal as a warning.	Where the health and safety of persons may be endangered by a fault in the operation of unsupervised machinery, the machinery must be equipped in such a way as to give an appropriate acoustic or light signal as a warning.
Annex III, 1, point (1.7)(1.7.1)(1.7.1.2), second paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Where a machinery or related product is equipped with warning devices, these shall be unambiguous and easily perceived. The operator shall have facilities to check the operation of such warning devices at all times.	Where <u>a machinery or related product</u> is equipped with warning devices, these <del>shall</del> <b>must</b> be unambiguous and easily perceived. The operator <del>shall</del> <b>must</b> have facilities to check the operation of such warning devices at all times.	Where machinery is equipped with warning devices these must be unambiguous and easily perceived. The operator must have facilities to check the operation of such warning devices at all times.
Annex III, 1, point (1.7)(1.7.1)(1.7.1.2), third paragraph		
The requirements of the specific Union legislation concerning colours and safety signals shall be complied with.	The requirements of the specific <u>Union legislation</u> <del>Community Directives</del> concerning colours and safety signals <del>shall</del> <b>must</b> be complied with.	The requirements of the specific Community Directives concerning colours and safety signals must be complied with.
Annex III, 1, point (1.7)(1.7.2), introductory part		
1.7.2. Warning of residual risks	1.7.2. <del>Warning of residual risks</del>	1.7.2. Warning of residual risks
Annex III, 1, point (1.7)(1.7.2), first paragraph		
Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, shall be provided.	Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, <del>shall</del> <b>must</b> be provided.	Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, must be provided.
Annex III, 1, point (1.7)(1.7.3), introductory part		Annex I, 1, point (1.7)(1.7.3), introductory part
1.7.3. Marking of a machinery or related product	1.7.3. <del>Marking of a machinery or related product</del>	1.7.3. Marking of machinery
Annex III, 1, point (1.7)(1.7.3), first paragraph, introductory part		Annex I, 1, point (1.7)(1.7.3), first paragraph
In addition to the marking requirements in Article 10 and 20, machinery or related products shall be marked visibly, legibly and indelibly.	In addition to the marking requirements in <u>Article 10 and 20, machinery or related products shall be marked visibly, legibly and indelibly.</u> <del>[Compared to Article 10(5)]</del>	[Compared to Article 10(5)]

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 1, point (1.7)(1.7.3), second paragraph		
Products covered by Annex III points 2 to 6 shall also be marked according to the additional requirements set out in these sections.	<u>Products covered by Annex III points 2 to 6 shall also be marked according to the additional requirements set out in these sections.</u>	
	<del>It is prohibited to pre-date or post-date the machinery when affixing the CE marking.</del>	It is prohibited to pre-date or post-date the machinery when affixing the CE marking.
Annex III, 1, point (1.7)(1.7.3), third paragraph		
Furthermore, a machinery or related product designed and constructed for use in a potentially explosive atmosphere shall be marked accordingly.	Furthermore, <u>a machinery or related product</u> designed and constructed for use in a potentially explosive atmosphere <del>shall</del> <b>must</b> be marked accordingly.	Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.
Annex III, 1, point (1.7)(1.7.3), fourth paragraph		
A machinery or related product shall also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.	<u>A machinery or related product shall</u> <del>Machinery must</del> also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.	Machinery must also bear full information relevant to its type and essential for safe use. Such information is subject to the requirements set out in section 1.7.1.
Annex III, 1, point (1.7)(1.7.3), fifth paragraph		
Where a machinery or related product part shall be handled during use with lifting equipment, its mass shall be indicated legibly, indelibly and unambiguously.	Where a <u>machinery or related product</u> <del>machine</del> part <del>shall</del> <b>must</b> be handled during use with lifting equipment, its mass <del>shall</del> <b>must</b> be indicated legibly, indelibly and unambiguously.	Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.
Annex III, 1, point (1.7)(1.7.4), introductory part		
1.7.4. Instructions for use	1.7.4. <del>Instructions</del> <u>for use</u>	1.7.4. Instructions
		Annex I, (1.7.4), first paragraph

DRAFT Machinery Regulation	Comparison	Machinery Directive
In addition to the obligations set out in Article 10(7), instructions shall be drawn up as follows.	<del>In addition</del> <u>[Compared to the obligations set out in Article 10(7), instructions shall be drawn up as follows.]</u>	[Compared to Article 10(7)]
	<del>The instructions accompanying the machinery must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.</del>	The instructions accompanying the machinery must be either 'Original instructions' or a 'Translation of the original instructions', in which case the translation must be accompanied by the original instructions.
Annex III, 1, point (1.7)(1.7.4), second paragraph		
By way of exception from Article 10(7), the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his or her authorised representative may be supplied in only one official language of the Union which the specialised personnel understand.	By way of exception <u>from Article 10(7),</u> the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his <u>or her</u> authorised representative may be supplied in only one <u>official Community language of the Union</u> which the specialised personnel understand.	By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his authorised representative may be supplied in only one Community language which the specialised personnel understand.
	<del>The instructions must be drafted in accordance with the principles set out below.</del>	The instructions must be drafted in accordance with the principles set out below.
Annex III, 1, point (1.7)(1.7.4)(1.7.4.1), introductory part		
1.7.4.1. General principles for the drafting of instructions for use	1.7.4.1. <del>–</del> General principles for the drafting of instructions <u>for use</u>	1.7.4.1. General principles for the drafting of instructions
Annex III, 1, point (1.7)(1.7.4)(1.7.4.1)(a)		Annex I, (1.7.4.1)(a)
(a) DELETE	<u>(a) DELETE</u> <del>[Compared to Article 10(7)]</del>	[Compared to Article 10(7)]
Annex III, 1, point (1.7)(1.7.4)(1.7.4.1)(b)		
(b) DELETE	<u>(b) DELETE</u> <del>(b) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided</del>	(b) Where no 'Original instructions' exist in the official language(s) of the country where the machinery is to be used, a translation into that/those language(s) must be provided by the manufacturer or

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>by the manufacturer or his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words 'Translation of the original instructions'.</del>	his authorised representative or by the person bringing the machinery into the language area in question. The translations must bear the words 'Translation of the original instructions'.
Annex III, 1, point (1.7)(1.7.4)(1.7.4.1)(c)		
(a) The contents of the instructions for use shall cover not only the intended use of the machinery or related product but also take into account any reasonably foreseeable misuse thereof;	(a <del>e</del> ) The contents of the instructions <u>for use shall</u> <del>must</del> cover not only the intended use of the machinery <u>or related product</u> but also take into account any reasonably foreseeable misuse thereof <del>;</del> ;	(c) The contents of the instructions must cover not only the intended use of the machinery but also take into account any reasonably foreseeable misuse thereof.
Annex III, 1, point (1.7)(1.7.4)(1.7.4.1)(d)		
(d) In the case of a machinery or related product intended for use by non-professional operators, the wording and layout of the instructions for use shall take into account the level of general education and acumen that can reasonably be expected from such operators.	(d) In the case of <u>a machinery or related product</u> intended for use by non-professional operators, the wording and layout of the instructions for use <u>shall</u> <del>must</del> take into account the level of general education and acumen that can reasonably be expected from such operators.	(d) In the case of machinery intended for use by non-professional operators, the wording and layout of the instructions for use must take into account the level of general education and acumen that can reasonably be expected from such operators.
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2), introductory part		
1.7.4.2. Contents of the instructions for use	1.7.4.2. –Contents of the instructions <u>for use</u>	1.7.4.2. Contents of the instructions
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1), introductory part		
1. Instructions for use shall contain, where applicable, at least the following information:	<u>1. Instructions for use shall</u> <del>Each instruction manual must</del> contain, where applicable, at least the following information:	Each instruction manual must contain, where applicable, at least the following information:
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(a)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(a) the business name and full address of the manufacturer and, where applicable, of his or her authorised representative;	(a) the business name and full address of the manufacturer and, <u>where applicable</u> , of his <u>or her</u> authorised representative;	(a) the business name and full address of the manufacturer and of his authorised representative;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(b)		
(b) the designation of the machinery or related product as marked on the machinery or related product itself, except for the serial number (see section 1.7.3);	(b) the designation of the machinery <u>or related product</u> as marked on the machinery <u>or related product</u> itself, except for the serial number (see section 1.7.3);	(b) the designation of the machinery as marked on the machinery itself, except for the serial number (see section 1.7.3);
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(c)		
(c) the EU declaration of conformity, or the internet address or machine readable code, where the EU declaration of conformity can be accessed, in accordance with Article 10(8).	(c) the <u>EU</u> <del>EG</del> declaration of conformity, or <del>a document setting out</del> the <u>internet address or machine readable code</u> , <u>where contents of the EU</u> <del>EG</del> declaration of conformity <u>can be accessed, in accordance with Article 10(8)</u> , <del>showing the particulars of the machinery, not necessarily including the serial number and the signature</del> ;	(c) the EC declaration of conformity, or a document setting out the contents of the EC declaration of conformity, showing the particulars of the machinery, not necessarily including the serial number and the signature;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(d)		
(d) a general description of the machinery or related product;	(d) a general description of the machinery <u>or related product</u> ;	(d) a general description of the machinery;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(e)		
(e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery or related product and for checking its correct functioning;	(e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery <u>or related product</u> and for checking its correct functioning;	(e) the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machinery and for checking its correct functioning;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(f)		
(f) a description of the workstation(s) likely to be occupied by operators;	(f) a description of the workstation(s) likely to be occupied by operators;	(f) a description of the workstation(s) likely to be occupied by operators;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(g)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(g) a description of the intended use of the machinery or related product; Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(h)	(g) a description of the intended use of the machinery <u>or related product</u> ;	(g) a description of the intended use of the machinery;
(h) warnings concerning ways in which the machinery or related product shall not be used that experience has shown might occur; Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(i)	(h) warnings concerning ways in which the machinery <u>or related product</u> <del>shall</del> <u>must</u> not be used that experience has shown might occur;	(h) warnings concerning ways in which the machinery must not be used that experience has shown might occur;
(i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery or related product is to be mounted; Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(j)	(i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery <u>or related product</u> is to be mounted;	(i) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the machinery is to be mounted;
(j) instructions relating to installation and assembly for reducing noise or vibration; Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(k)	(j) instructions relating to installation and assembly for reducing noise or vibration;	(j) instructions relating to installation and assembly for reducing noise or vibration;
(k) instructions for the putting into service and use of the machinery or related product and, if necessary, instructions for the training of operators; Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(l)	(k) instructions for the putting into service and use of the machinery <u>or related product</u> and, if necessary, instructions for the training of operators;	(k) instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators;
(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted; Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(m)	(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;	(l) information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted;
(m) instructions on the protective measures to be taken by the user, including, where appropriate, the	(m) instructions on the protective measures to be taken by the user, including, where appropriate, the	(m) instructions on the protective measures to be taken by the user, including, where appropriate, the

DRAFT Machinery Regulation	Comparison	Machinery Directive
personal protective equipment to be provided;	personal protective equipment to be provided;	personal protective equipment to be provided;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(n)		
(n) the essential characteristics of tools, which may be fitted to the machinery or related product;	(n) the essential characteristics of tools, which may be fitted to the machinery <u>or related product</u> ;	(n) the essential characteristics of tools which may be fitted to the machinery;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(o)		
(o) the conditions in which the machinery or related product meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;	(o) the conditions in which the machinery <u>or related product</u> meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;	(o) the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(p)		
(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery or related product and of its various parts where these are regularly to be transported separately;	(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery <u>or related product</u> and of its various parts where these are regularly to be transported separately;	(p) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(q)		
(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;	(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;	(q) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(r)		
(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed taking account of the	(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed <u>taking account of the</u>	(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;

DRAFT Machinery Regulation	Comparison	Machinery Directive
design and the use of the machinery or related product;	<u>design and the use of the machinery or related product</u> ;	
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(s)		
(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;	(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;	(s) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(t)		
(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;	(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;	(t) the specifications of the spare parts to be used, when these affect the health and safety of operators;
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u), introductory part		
(u) the following information on airborne noise emissions:	(u) the following information on airborne noise emissions:	(u) the following information on airborne noise emissions:
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u)(i)		
i. the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB (A); where this level does not exceed 70 dB (A), this fact shall be indicated;	<del>i.</del> — the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB (A); where this level does not exceed 70 dB (A), this fact <del>shall</del> <b>must</b> be indicated;	— the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u)(ii)		
ii. the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 µPa);	<del>ii.</del> — the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 <del>µPa</del> ; <del>µPa</del> );	— the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 µPa),
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u)(iii)		
iii. the A-weighted sound power level emitted by the machinery or related product, where the A-weighted emission	<del>iii.</del> — the A-weighted sound power level emitted by the machinery <u>or related product</u> , where the A-weighted emission	— the A-weighted sound power level emitted by the machinery, where the A-

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>sound pressure level at workstations exceeds 80 dB(A).</p>	<p>sound pressure level at workstations exceeds 80 dB(A).</p>	<p>weighted emission sound pressure level at workstations exceeds 80 dB(A).</p>
<p>Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u), first paragraph</p>		
<p>These values shall be either those actually measured for the machinery or related product in question or those established on the basis of measurements taken for a technically comparable machinery or related product, which is representative of the machinery or related product to be produced.</p>	<p>These values <del>shall</del><b>must</b> be either those actually measured for the machinery <u>or related product</u> in question or those established on the basis of measurements taken for <u>a</u> technically comparable machinery <u>or related product</u>, which is representative of the machinery <u>or related product</u> to be produced.</p>	<p>These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.</p>
<p>Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u), second paragraph</p>		
<p>In the case of a very large machinery or related product, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery or related product may be indicated.</p>	<p>In the case of <u>a</u> very large machinery <u>or related product</u>, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery <u>or related product</u> may be indicated.</p>	<p>In the case of very large machinery, instead of the A-weighted sound power level, the A-weighted emission sound pressure levels at specified positions around the machinery may be indicated.</p>
<p>Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u), third paragraph</p>		
<p>Where the harmonised standards or common specifications adopted by the Commission in accordance with Article 17(3) cannot be applied, sound levels shall be measured using the most appropriate method for the machinery or related product. Whenever sound emission values are indicated, the uncertainties surrounding these values shall be specified. The operating</p>	<p>Where the harmonised standards <u>or common specifications adopted by the Commission in accordance with Article 17(3) cannot be</u><del>are not</del> applied, sound levels <del>shall</del><b>must</b> be measured using the most appropriate method for the machinery <u>or related product</u>. Whenever sound emission values are indicated, the uncertainties surrounding these values <del>shall</del><b>must</b> be specified. The operating</p>	<p>Where the harmonised standards are not applied, sound levels must be measured using the most appropriate method for the machinery. Whenever sound emission values are indicated the uncertainties surrounding these values must be specified. The operating conditions of the machinery during measurement and the measuring methods used must be described.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>conditions of the machinery or related product during measurement and the measuring methods used shall be described.</p>	<p>conditions of the machinery <u>or related product</u> during measurement and the measuring methods used <u>shall</u><del>must</del> be described.</p>	
<p>Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u), fourth paragraph</p>		
<p>Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels shall be measured at a distance of 1 metre from the surface of the machinery or related product and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure shall be indicated.</p>	<p>Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels <u>shall</u><del>must</del> be measured at a distance of 1 metre from the surface of the machinery <u>or related product</u> and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure <u>shall</u><del>must</del> be indicated.</p>	<p>Where the workstation(s) are undefined or cannot be defined, A-weighted sound pressure levels must be measured at a distance of 1 metre from the surface of the machinery and at a height of 1,6 metres from the floor or access platform. The position and value of the maximum sound pressure must be indicated.</p>
<p>Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u), fifth paragraph</p>		
<p>With respect to noise reduction machinery or related products, the instructions for use shall specify, where appropriate, how to correctly assemble and install that equipment (see also section 1.7.4.2(1), point (j)).</p>	<p><u>With respect to noise reduction machinery or related products, the instructions for use shall specify, where appropriate, how to correctly assemble and install that equipment (see also section 1.7.4.2(1), point (j)).</u></p>	
<p>Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u), sixth paragraph</p>		
<p>Where specific Union legislation lays down other requirements for the measurement of sound pressure levels or sound power levels, those legal acts shall be applied and the corresponding provisions of this section shall not apply;</p>	<p>Where specific <u>Union legislation</u> <del>lays</del><u>Community Directives lay</u> down other requirements for the measurement of sound pressure levels or sound power levels, those <u>legal acts shall</u><del>Directives</del> <del>must</del> be applied and the corresponding provisions of this section shall not apply;</p>	<p>Where specific Community Directives lay down other requirements for the measurement of sound pressure levels or sound power levels, those Directives must be applied and the corresponding provisions of this section shall not apply;</p>
<p>Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(u), sixth paragraph a</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(ua) information on the necessary precautions, devices and means for the immediate and gentle rescue of persons;	<u>(ua) information on the necessary precautions, devices and means for the immediate and gentle rescue of persons;</u>	
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(v)		
(v) where a machinery or related product is likely to emit non-ionising radiation, which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons;	(v) where <u>a machinery or related product</u> is likely to emit non-ionising radiation, which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons;-	(v) where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons.
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(w), introductory part		
(w) where the machinery or related product design allows emissions of hazardous substances from the machinery or related product, the characteristics of the capturing, filtration or discharge device if such device is not provided with the machinery or related product, and any of the following:	<u>(w) where the machinery or related product design allows emissions of hazardous substances from the machinery or related product, the characteristics of the capturing, filtration or discharge device if such device is not provided with the machinery or related product, and any of the following:</u>	
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(w)(i)		
i. the flow rate for the emission of hazardous materials and substances from the machinery or related product,	<u>i. the flow rate for the emission of hazardous materials and substances from the machinery or related product,</u>	
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(w)(ii)		
ii. the concentration of hazardous materials or substances around the machinery or related product coming from the machinery or related product or	<u>ii. the concentration of hazardous materials or substances around the machinery or related product coming from the machinery or related product or</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
from materials or substances used with the machinery or related product,	<u>from materials or substances used with the machinery or related product,</u>	
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(w)(iii)		
iii. the effectiveness of the capturing or filtration device and the conditions to be observed to maintain its effectiveness over time.	<u>iii. the effectiveness of the capturing or filtration device and the conditions to be observed to maintain its effectiveness over time.</u>	
Annex III, 1, point (1.7)(1.7.4)(1.7.4.2)(1)(w), first paragraph		
The values referred to in the first subparagraph shall either be actually measured for the machinery or related product in question or established based on measurements in respect of a technically comparable machinery or related product, which is representative of the state of the art.	<u>The values referred to in the first subparagraph shall either be actually measured for the machinery or related product in question or established based on measurements in respect of a technically comparable machinery or related product, which is representative of the state of the art.</u>	
Annex III, 1, point (1.7)(1.7.4)(1.7.4.3), introductory part		
1.7.5 Sales literature	1.7.5 <del>4.3.</del> Sales literature	1.7.4.3. Sales literature
Annex III, 1, point (1.7)(1.7.4)(1.7.4.3), first paragraph		
Sales literature describing the machinery or related product shall not contradict the instructions for use as regards health and safety aspects. Sales literature describing the performance characteristics of the machinery or related product shall contain the same information on emissions as is contained in the instructions for use.	Sales literature describing the machinery <u>or related product shall</u> <del>must</del> not contradict the instructions <u>for use</u> as regards health and safety aspects. Sales literature describing the performance characteristics of <u>the machinery or related product shall</u> <del>must</del> contain the same information on emissions as is contained in the instructions <u>for use.</u>	Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emissions as is contained in the instructions.
Annex III, 2		

DRAFT Machinery Regulation	Comparison	Machinery Directive
2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY AND RELATED PRODUCTS	2.– SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY AND RELATED PRODUCTS	2. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR CERTAIN CATEGORIES OF MACHINERY
Annex III, 2, first paragraph		
Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics and machinery for pesticide application shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).	Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics and machinery for pesticide application <del>shall</del> must meet all the essential health and safety requirements <del>described</del> set-out in this chapter (see General Principles, point 4).	Foodstuffs machinery, machinery for cosmetics or pharmaceutical products, hand-held and/or hand-guided machinery, portable fixing and other impact machinery, machinery for working wood and material with similar physical characteristics and machinery for pesticide application must meet all the essential health and safety requirements set out in this chapter (see General Principles, point 4).
Annex III, 2, point (2.1), introductory part		
2.1. MACHINERY AND RELATED PRODUCTS FOR FOODSTUFFS AND MACHINERY AND RELATED PRODUCTS FOR COSMETICS OR PHARMACEUTICAL PRODUCTS	2.1. <del>FOODSTUFFS</del> MACHINERY AND RELATED PRODUCTS FOR FOODSTUFFS AND MACHINERY AND RELATED PRODUCTS FOR COSMETICS OR PHARMACEUTICAL PRODUCTS	2.1. FOODSTUFFS MACHINERY AND MACHINERY FOR COSMETICS OR PHARMACEUTICAL PRODUCTS
Annex III, 2, point (2.1)(2.1.1), introductory part		
2.1.1. General	2.1.1. –General	2.1.1. General
Annex III, 2, point (2.1)(2.1.1), first paragraph		
Machinery or related product intended for use with foodstuffs or with cosmetics or pharmaceutical products shall be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.	Machinery <del>or related product</del> intended for use with foodstuffs or with cosmetics or pharmaceutical products <del>shall</del> must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.	Machinery intended for use with foodstuffs or with cosmetics or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, sickness or contagion.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 2, point (2.1)(2.1.1), second paragraph, introductory part		
The following requirements shall be observed:	The following requirements <del>shall</del> <b>must</b> be observed:	The following requirements must be observed:
Annex III, 2, point (2.1)(2.1.1), second paragraph(a)		
(a) materials in contact with, or intended to come into contact with, foodstuffs or water intended for human consumption or cosmetics or pharmaceutical products shall satisfy the conditions set down in the relevant Union legal acts. The machinery or related product shall be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible, disposable parts shall be used;	(a) materials in contact with, or intended to come into contact with, foodstuffs or <u>water intended for human consumption or cosmetics or pharmaceutical products shall</u> <del>must</del> satisfy the conditions set down in the relevant <u>Union legal acts</u> . <del>Directives</del> . The machinery <u>or related product shall</u> <del>must</del> be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible, disposable parts <del>shall</del> <b>must</b> be used;	(a) materials in contact with, or intended to come into contact with, foodstuffs or cosmetics or pharmaceutical products must satisfy the conditions set down in the relevant Directives. The machinery must be designed and constructed in such a way that these materials can be cleaned before each use. Where this is not possible disposable parts must be used;
Annex III, 2, point (2.1)(2.1.1), second paragraph(b), introductory part		
(b) all surfaces in contact with foodstuffs or water intended for human consumption or cosmetics or pharmaceutical products, other than surfaces of disposable parts, shall:	(b) all surfaces in contact with foodstuffs or <u>water intended for human consumption or cosmetics or pharmaceutical products, other than surfaces of disposable parts, shall</u> <del>must</del> :	(b) all surfaces in contact with foodstuffs or cosmetics or pharmaceutical products, other than surfaces of disposable parts, must:
Annex III, 2, point (2.1)(2.1.1), second paragraph(b)(i)		
i. be smooth and have neither ridges nor crevices, which could harbour organic materials. The same applies to their joinings;	<del>i.</del> — be smooth and have neither ridges nor crevices, which could harbour organic materials. The same applies to their joinings; <del>;</del>	— be smooth and have neither ridges nor crevices which could harbour organic materials. The same applies to their joinings,
Annex III, 2, point (2.1)(2.1.1), second paragraph(b)(ii)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>ii. be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum;</p>	<p>ii.— be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum;</p>	<p>— be designed and constructed in such a way as to reduce the projections, edges and recesses of assemblies to a minimum,</p>
<p>Annex III, 2, point (2.1)(2.1.1), second paragraph(b)(iii)</p>		
<p>iii. be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces shall have curves with a radius sufficient to allow thorough cleaning;</p>	<p>iii.— be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces shall <del>must</del> have curves with a radius sufficient to allow thorough cleaning;</p>	<p>— be easily cleaned and disinfected, where necessary after removing easily dismantled parts; the inside surfaces must have curves with a radius sufficient to allow thorough cleaning;</p>
<p>Annex III, 2, point (2.1)(2.1.1), second paragraph(c)</p>		
<p>(c) it shall be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery or related product (if possible, in a 'cleaning' position);</p>	<p>(c) it shall <del>must</del> be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery <u>or related product</u> (if possible, in a 'cleaning' position);</p>	<p>(c) it must be possible for liquids, gases and aerosols deriving from foodstuffs, cosmetics or pharmaceutical products as well as from cleaning, disinfecting and rinsing fluids to be completely discharged from the machinery (if possible, in a 'cleaning' position);</p>
<p>Annex III, 2, point (2.1)(2.1.1), second paragraph(d)</p>		
<p>(d) machinery or related product shall be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;</p>	<p>(d) machinery <u>or related product</u> shall <del>must</del> be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;</p>	<p>(d) machinery must be designed and constructed in such a way as to prevent any substances or living creatures, in particular insects, from entering, or any organic matter from accumulating in, areas that cannot be cleaned;</p>
<p>Annex III, 2, point (2.1)(2.1.1), second paragraph(e)</p>		
<p>(e) machinery or related product shall be designed and constructed in such a way</p>	<p>(e) machinery <u>or related product</u> shall <del>must</del> be designed and constructed in</p>	<p>(e) machinery must be designed and constructed in such a way that no</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery or related product shall be designed and constructed in such a way that continuing compliance with this requirement can be checked.</p>	<p>such a way that no ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery <u>or related product shall</u><del>must</del> be designed and constructed in such a way that continuing compliance with this requirement can be checked.</p>	<p>ancillary substances hazardous to health, including the lubricants used, can come into contact with foodstuffs, cosmetics or pharmaceutical products. Where necessary, machinery must be designed and constructed in such a way that continuing compliance with this requirement can be checked.</p>
<p>Annex III, 2, point (2.1)(2.1.2), introductory part</p>		
<p>2.1.2. Instructions for use</p>	<p>2.1.2. <del>Instructions for use</del></p>	<p>2.1.2. Instructions</p>
<p>Annex III, 2, point (2.1)(2.1.2), first paragraph</p>		
<p>The instructions for use for foodstuffs machinery or related product and machinery or related product for use with cosmetics or pharmaceutical products shall indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.</p>	<p>The instructions for <u>use for</u> foodstuffs machinery <u>or related product</u> and machinery <u>or related product</u> for use with cosmetics or pharmaceutical products <u>shall</u><del>must</del> indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.</p>	<p>The instructions for foodstuffs machinery and machinery for use with cosmetics or pharmaceutical products must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable.</p>
<p>Annex III, 2, point (2.2), introductory part</p>		
<p>2.2. PORTABLE HAND-HELD OR HAND-GUIDED MACHINERY OR RELATED PRODUCTS</p>	<p>2.2. <del>PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY</del> <u>OR RELATED PRODUCTS</u></p>	<p>2.2. PORTABLE HAND-HELD AND/OR HAND-GUIDED MACHINERY</p>
<p>Annex III, 2, point (2.2)(2.2.1), introductory part</p>		
<p>2.2.1. General</p>	<p>2.2.1. <del>General</del></p>	<p>2.2.1. General</p>
<p>Annex III, 2, point (2.2)(2.2.1), first paragraph, introductory part</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Portable hand-held or hand-guided machinery or related product shall:	Portable hand-held <del>and</del> /or hand-guided machinery <u>or related product shall</u> <del>must</del> :	Portable hand-held and/or hand-guided machinery must:
Annex III, 2, point (2.2)(2.2.1), first paragraph(a)		
(a) depending on the type of machinery or related product, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery or related product under the intended operating conditions;	<u>(a)</u> — depending on the type of machinery <u>or related product</u> , have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery <u>or related product</u> under the intended operating conditions; <del>;</del>	— depending on the type of machinery, have a supporting surface of sufficient size and have a sufficient number of handles and supports of an appropriate size, arranged in such a way as to ensure the stability of the machinery under the intended operating conditions,
Annex III, 2, point (2.2)(2.2.1), first paragraph(b)		
(b) except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles;	<u>(b)</u> — except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles; <del>;</del>	— except where technically impossible, or where there is an independent control device, in the case of handles which cannot be released in complete safety, be fitted with manual start and stop control devices arranged in such a way that the operator can operate them without releasing the handles,
Annex III, 2, point (2.2)(2.2.1), first paragraph(c)		
(c) present no risks of accidental starting or continued operation after the operator has released the handles. Equivalent steps shall be taken if this requirement is not technically feasible;	<u>(c)</u> — present no risks of accidental starting <del>and</del> /or continued operation after the operator has released the handles. Equivalent steps <u>shall</u> <del>must</del> be taken if this requirement is not technically feasible; <del>;</del>	— present no risks of accidental starting and/or continued operation after the operator has released the handles. Equivalent steps must be taken if this requirement is not technically feasible,
Annex III, 2, point (2.2)(2.2.1), first paragraph(d)		
(d) permit, where necessary, visual observation of the danger zone and of	<u>(d)</u> — permit, where necessary, visual observation of the danger zone and of	— permit, where necessary, visual observation of the danger zone and of

DRAFT Machinery Regulation	Comparison	Machinery Directive
the action of the tool with the material being processed.	the action of the tool with the material being processed.	the action of the tool with the material being processed.
Annex III, 2, point (2.2)(2.2.1), first paragraph(e)		
(e) have a device or a connected exhaust system, with an extraction connection outlet or equivalent system to capture or reduce emissions of hazardous substances. This requirement does not apply if it leads to a new hazard or where the main function of the machinery or related product is the application of hazardous substances and to emissions of internal combustion engines.	<u>(e) have a device or a connected exhaust system, with an extraction connection outlet or equivalent system to capture or reduce emissions of hazardous substances. This requirement does not apply if it leads to a new hazard or where the main function of the machinery or related product is the application of hazardous substances and to emissions of internal combustion engines.</u>	
Annex III, 2, point (2.2)(2.2.1), first paragraph(ea)		
(f) be designed and constructed in such a way that the handles of portable machinery or related product make starting and stopping straightforward.	<del>(f) The handles of portable machinery must</del> be designed and constructed in such a way <u>that the handles of portable machinery or related product</u> <del>as to</del> make starting and stopping straightforward.	The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward.
Annex III, 2, point (2.2)(2.2.1)(2.2.1.1), introductory part		
2.2.1.1. Instructions for use	2.2.1.1. <del>Instructions for use</del>	2.2.1.1. Instructions
Annex III, 2, point (2.2)(2.2.1)(2.2.1.1), first paragraph, introductory part		
The instructions for use shall give the following information concerning vibrations, expressed as acceleration (m/s <sup>2</sup> ), and transmitted by portable handheld and hand-guided machinery or related product:	The instructions <u>for use shall</u> <del>must</del> give the following information concerning vibrations, <u>expressed as acceleration (m/s<sup>2</sup>), and transmitted by portable handheld</u> <del>hand-held</del> and hand-guided machinery or related product:	The instructions must give the following information concerning vibrations transmitted by portable hand-held and hand-guided machinery:
Annex III, 2, point (2.2)(2.2.1)(2.2.1.1), first paragraph(a)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(a) the vibration total value from continuous vibrations to which the hand-arm system is subjected;	<u>(a)</u> — the vibration total value <u>from continuous vibrations</u> to which the hand-arm system is subjected; <del>if it exceeds 2,5 m/s<sup>2</sup>. Where this value does not exceed 2,5 m/s<sup>2</sup>, this must be mentioned,</del>	— the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s <sup>2</sup> . Where this value does not exceed 2,5 m/s <sup>2</sup> , this must be mentioned,
Annex III, 2, point (2.2)(2.2.1)(2.2.1.1), first paragraph(b)		
(b) the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected;	<u>(b)</u> the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected;	
Annex III, 2, point (2.2)(2.2.1)(2.2.1.1), first paragraph(c)		
(c) the uncertainty of both measurements.	<u>(c)</u> — the uncertainty of <u>both measurements</u> <del>measurement.</del>	— the uncertainty of measurement.
Annex III, 2, point (2.2)(2.2.1)(2.2.1.1), second paragraph		
The values referred to in the first subparagraph shall either be those actually measured for the machinery or related products in question or those established on the basis of measurements in respect of a technically comparable machinery or related product, which is representative of the state of the art.	<del>The</del> <u>These</u> values referred to in the first subparagraph shall <del>must be</del> either <u>be</u> those actually measured for the machinery <u>or related products</u> in question or those established on the basis of measurements <u>in respect of a</u> <del>taken for</del> technically comparable machinery <u>or related product</u> , which is representative of the <u>state of the art</u> <del>machinery to be produced.</del>	These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.
Annex III, 2, point (2.2)(2.2.1)(2.2.1.1), third paragraph		
If harmonised standards or common specifications adopted by the Commission in accordance with Article 17(3) cannot be applied, the vibration data shall be measured using the most	If harmonised standards <u>or common specifications adopted by the Commission in accordance with Article 17(3)</u> <del>cannot be</del> applied, the vibration data <del>shall</del> <u>must</u> be measured	If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery.

DRAFT Machinery Regulation	Comparison	Machinery Directive
appropriate measurement code for the machinery or related products.	using the most appropriate measurement code for the machinery <u>or related products</u> .	
Annex III, 2, point (2.2)(2.2.1)(2.2.1.1), fourth paragraph		
The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, shall be specified.	The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, <del>shall</del> <b>must</b> be specified.	The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, must be specified.
Annex III, 2, point (2.2)(2.2.2), introductory part		
2.2.2. Portable fixing and other impact machinery or related products	2.2.2. <del>Portable fixing and other impact machinery</del> <u>or related products</u>	2.2.2. Portable fixing and other impact machinery
Annex III, 2, point (2.2)(2.2.2)(2.2.2.1), introductory part		
2.2.2.1. General	2.2.2.1. <del>General</del>	2.2.2.1. General
Annex III, 2, point (2.2)(2.2.2)(2.2.2.1), first paragraph, introductory part		
Portable fixing and other impact machinery or related product shall be designed and constructed in such a way that:	Portable fixing and other impact machinery <u>or related product shall</u> <del>must</del> be designed and constructed in such a way that:	Portable fixing and other impact machinery must be designed and constructed in such a way that:
Annex III, 2, point (2.2)(2.2.2)(2.2.2.1), first paragraph(a)		
(a) energy is transmitted to the impacted element by the intermediary component that does not leave the device;	<del>(a)</del> — energy is transmitted to the impacted element by the intermediary component that does not leave the device;	— energy is transmitted to the impacted element by the intermediary component that does not leave the device,
Annex III, 2, point (2.2)(2.2.2)(2.2.2.1), first paragraph(b)		
(b) an enabling device prevents impact unless the machinery or related product	<del>(b)</del> — an enabling device prevents impact unless the machinery <u>or related product</u>	— an enabling device prevents impact unless the machinery is positioned

DRAFT Machinery Regulation	Comparison	Machinery Directive
is positioned correctly with adequate pressure on the base material;	is positioned correctly with adequate pressure on the base material; <del>;</del>	correctly with adequate pressure on the base material,
Annex III, 2, point (2.2)(2.2.2)(2.2.2.1), first paragraph(c)		
(c) involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device shall be required to trigger an impact;	<del>(c)</del> — involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device <del>shall</del> <b>must</b> be required to trigger an impact; <del>;</del>	— involuntary triggering is prevented; where necessary, an appropriate sequence of actions on the enabling device and the control device must be required to trigger an impact,
Annex III, 2, point (2.2)(2.2.2)(2.2.2.1), first paragraph(d)		
(d) accidental triggering is prevented during handling or in case of shock;	<del>(d)</del> — accidental triggering is prevented during handling or in case of shock; <del>;</del>	— accidental triggering is prevented during handling or in case of shock,
Annex III, 2, point (2.2)(2.2.2)(2.2.2.1), first paragraph(e)		
(e) loading and unloading operations can be carried out easily and safely.	<del>(e)</del> — loading and unloading operations can be carried out easily and safely.	— loading and unloading operations can be carried out easily and safely.
Annex III, 2, point (2.2)(2.2.2)(2.2.2.1), second paragraph		
Where necessary, it shall be possible to fit the device with splinter guard(s) and the appropriate guard(s) shall be provided by the manufacturer of the machinery or related product.	Where necessary, it <del>shall</del> <b>must</b> be possible to fit the device with splinter guard(s) and the appropriate guard(s) <del>shall</del> <b>must</b> be provided by the manufacturer of the machinery <del>or related product</del> .	Where necessary, it must be possible to fit the device with splinter guard(s) and the appropriate guard(s) must be provided by the manufacturer of the machinery.
Annex III, 2, point (2.2)(2.2.2)(2.2.2.2), introductory part		
2.2.2.2. Instructions for use	2.2.2.2. <del>Instructions for use</del>	2.2.2.2. Instructions
Annex III, 2, point (2.2)(2.2.2)(2.2.2.2), first paragraph, introductory part		
The instructions for use shall give the necessary information regarding:	The instructions <del>for use</del> <del>shall</del> <b>must</b> give the necessary information regarding:	The instructions must give the necessary information regarding:
Annex III, 2, point (2.2)(2.2.2)(2.2.2.2), first paragraph(a)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(a) the accessories and interchangeable equipment that can be used with the machinery or related product;	(a) — the accessories and interchangeable equipment that can be used with the machinery <u>or related product</u> ;	— the accessories and interchangeable equipment that can be used with the machinery,
Annex III, 2, point (2.2)(2.2.2)(2.2.2.2), first paragraph(b)		
(b) the suitable fixing or other impacted elements to be used with the machinery or related products;	(b) — the suitable fixing or other impacted elements to be used with the machinery <u>or related products</u> ;	— the suitable fixing or other impacted elements to be used with the machinery,
Annex III, 2, point (2.2)(2.2.2)(2.2.2.2), first paragraph(c)		
(c) where appropriate, the suitable cartridges to be used.	(c) — where appropriate, the suitable cartridges to be used.	— where appropriate, the suitable cartridges to be used.
Annex III, 2, point (2.3), introductory part		
2.3. MACHINERY OR RELATED PRODUCTS FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS	2.3. —MACHINERY <u>OR RELATED PRODUCTS</u> FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS	2.3. MACHINERY FOR WORKING WOOD AND MATERIAL WITH SIMILAR PHYSICAL CHARACTERISTICS
Annex III, 2, point (2.3), first paragraph, introductory part		
machinery or related product for working wood and materials with similar physical characteristics shall comply with the following requirements:	<u>machinery or related product</u> <del>Machinery</del> for working wood and materials with similar physical characteristics <del>shall</del> <b>must</b> comply with the following requirements:	Machinery for working wood and materials with similar physical characteristics must comply with the following requirements:
Annex III, 2, point (2.3), first paragraph(a)		
(a) the machinery or related product shall be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter shall be sufficiently stable during the work and shall not impede the movement of the piece;	(a) the machinery <u>or related product</u> <del>shall</del> <b>must</b> be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter <del>shall</del> <b>must</b> be sufficiently stable during the work and <del>shall</del> <b>must</b> not impede the movement of the piece;	(a) the machinery must be designed, constructed or equipped in such a way that the piece being machined can be placed and guided in safety; where the piece is hand-held on a work-bench, the latter must be sufficiently stable during the work and must not impede the movement of the piece;

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Annex III, 2, point (2.3), first paragraph(b)</p> <p>(b) where the machinery or related product is likely to be used in conditions involving the risk of ejection of work pieces or parts of them, it shall be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;</p>	<p>(b) where the machinery <u>or related product</u> is likely to be used in conditions involving the risk of ejection of <u>work pieces</u><del>workpieces</del> or parts of them, it <del>shall</del><b>must</b> be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;</p>	<p>(b) where the machinery is likely to be used in conditions involving the risk of ejection of workpieces or parts of them, it must be designed, constructed, or equipped in such a way as to prevent such ejection, or, if this is not possible, so that the ejection does not engender risks for the operator and/or exposed persons;</p>
<p>Annex III, 2, point (2.3), first paragraph(c)</p> <p>(c) the machinery or related product shall be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;</p>	<p>(c) the machinery <u>or related product</u> <del>shall</del><b>must</b> be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;</p>	<p>(c) the machinery must be equipped with an automatic brake that stops the tool in a sufficiently short time if there is a risk of contact with the tool whilst it runs down;</p>
<p>Annex III, 2, point (2.3), first paragraph(d)</p> <p>(d) where the tool is incorporated into a non-fully automated machine, the latter shall be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.</p>	<p>(d) where the tool is incorporated into a non-fully automated machine, the latter <del>shall</del><b>must</b> be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.</p>	<p>(d) where the tool is incorporated into a non-fully automated machine, the latter must be designed and constructed in such a way as to eliminate or reduce the risk of accidental injury.</p>
<p>Annex III, 2, point (2.4), introductory part</p> <p>2.4. MACHINERY OR RELATED PRODUCTS FOR PLANT PROTECTION PRODUCTS APPLICATION</p>	<p>2.4. <del>–</del>MACHINERY <u>OR RELATED PRODUCTS FOR PLANT PROTECTION PRODUCTS</u><del>PESTICIDE</del> APPLICATION</p>	<p>2.4. MACHINERY FOR PESTICIDE APPLICATION</p>
<p>Annex III, 2, point (2.4)(2.4.1), introductory part</p> <p>2.4.1. Definition</p>	<p>2.4.1. <del>–</del>Definition</p>	<p>2.4.1. Definition</p>
<p>Annex III, 2, point (2.4)(2.4.1), first paragraph</p> <p>‘Machinery for plant protection products application’ means machinery or related products specifically intended for the</p>	<p>‘Machinery for <u>plant protection products</u><del>pesticide</del> application’ means machinery <u>or related products</u> specifically</p>	<p>‘Machinery for pesticide application’ means machinery specifically intended for the application of plant protection</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
application of plant protection products within the meaning of Article 2, point (1), of Regulation (EC) No 1107/2009 of the European Parliament and of the Council <sup>1</sup> .	intended for the application of plant protection products within the meaning of Article 2, <u>point (1),</u> of Regulation (EC) No 1107/2009 of the European Parliament and of the <u>Council</u> <del>1. Council of 21 October 2009 concerning the placing of plant protection products on the market ( 7 ).</del>	products within the meaning of Article 2(1) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market ( 7 ).
1. [1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).	<u>1. [1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).</u>	
Annex III, 2, point (2.4)(2.4.2), introductory part		
2.4.2. General	2.4.2. <del>General</del>	2.4.2. General
Annex III, 2, point (2.4)(2.4.2), first paragraph		
The manufacturer of machinery or related product for pesticide application shall ensure that an assessment is carried out of the risks of unintended exposure of the environment to pesticides, in accordance with the process of risk assessment and risk reduction referred to in the General Principles, point 1.	The manufacturer of machinery <u>or related product</u> for pesticide application <u>shall</u> <del>or his authorised representative must</del> ensure that an assessment is carried out of the risks of unintended exposure of the environment to pesticides, in accordance with the process of risk assessment and risk reduction referred to in the General Principles, point 1.	The manufacturer of machinery for pesticide application or his authorised representative must ensure that an assessment is carried out of the risks of unintended exposure of the environment to pesticides, in accordance with the process of risk assessment and risk reduction referred to in the General Principles, point 1.
Annex III, 2, point (2.4)(2.4.2), second paragraph		
Machinery or related product for pesticide application shall be designed and constructed taking into account the	Machinery <u>or related product</u> for pesticide application <u>shall</u> <del>must</del> be designed and constructed taking into	Machinery for pesticide application must be designed and constructed taking into account the results of the risk

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>results of the risk assessment referred to in the first subparagraph so that the machinery or related product can be operated, adjusted and maintained without unintended exposure of the environment to pesticides.</p>	<p>account the results of the risk assessment referred to in the first <u>subparagraph</u><del>paragraph</del> so that the <u>machinery or related product</u> can be operated, adjusted and maintained without unintended exposure of the environment to pesticides.</p>	<p>assessment referred to in the first paragraph so that the machinery can be operated, adjusted and maintained without unintended exposure of the environment to pesticides.</p>
<p>Annex III, 2, point (2.4)(2.4.2), third paragraph</p>		
<p>Leakage shall be prevented at all times.</p>	<p>Leakage <u>shall</u><del>must</del> be prevented at all times.</p>	<p>Leakage must be prevented at all times.</p>
<p>Annex III, 2, point (2.4)(2.4.3), introductory part</p>		
<p>2.4.3. Controls and monitoring</p>	<p>2.4.3. –Controls and monitoring</p>	<p>2.4.3. Controls and monitoring</p>
<p>Annex III, 2, point (2.4)(2.4.3), first paragraph</p>		
<p>It shall be possible to easily and accurately control, monitor and immediately stop the pesticide application from the operating positions.</p>	<p>It <u>shall</u><del>must</del> be possible to easily and accurately control, monitor and immediately stop the pesticide application from the operating positions.</p>	<p>It must be possible to easily and accurately control, monitor and immediately stop the pesticide application from the operating positions.</p>
<p>Annex III, 2, point (2.4)(2.4.4), introductory part</p>		
<p>2.4.4. Filling and emptying</p>	<p>2.4.4. –Filling and emptying</p>	<p>2.4.4. Filling and emptying</p>
<p>Annex III, 2, point (2.4)(2.4.4), first paragraph</p>		
<p>The machinery or related product shall be designed and constructed to facilitate precise filling with the necessary quantity of pesticide and to ensure easy and complete emptying, while preventing spillage of pesticide and avoiding the contamination of the water source during such operations.</p>	<p>The machinery <u>or related product</u> <u>shall</u><del>must</del> be designed and constructed to facilitate precise filling with the necessary quantity of pesticide and to ensure easy and complete emptying, while preventing spillage of pesticide and avoiding the contamination of the water source during such operations.</p>	<p>The machinery must be designed and constructed to facilitate precise filling with the necessary quantity of pesticide and to ensure easy and complete emptying, while preventing spillage of pesticide and avoiding the contamination of the water source during such operations.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 2, point (2.4)(2.4.5), introductory part		
2.4.5. Application of pesticides	2.4.5. –Application of pesticides	2.4.5. Application of pesticides
Annex III, 2, point (2.4)(2.4.5)(2.4.5.1), introductory part		
2.4.5.1. Application rate	2.4.5.1. –Application rate	2.4.5.1. Application rate
Annex III, 2, point (2.4)(2.4.5)(2.4.5.1), first paragraph		
The machinery or related product shall be fitted with means of adjusting the application rate easily, accurately and reliably.	The machinery <u>or related product shall</u> <del>must</del> be fitted with means of adjusting the application rate easily, accurately and reliably.	The machinery must be fitted with means of adjusting the application rate easily, accurately and reliably.
Annex III, 2, point (2.4)(2.4.5)(2.4.5.2), introductory part		
2.4.5.2. Distribution, deposition and drift of pesticide	2.4.5.2. –Distribution, deposition and drift of pesticide	2.4.5.2. Distribution, deposition and drift of pesticide
Annex III, 2, point (2.4)(2.4.5)(2.4.5.2), first paragraph		
The machinery or related product shall be designed and constructed to ensure that pesticide is deposited on target areas, to minimise losses to other areas and to prevent drift of pesticide to the environment. Where appropriate, an even distribution and homogeneous deposition shall be ensured.	The machinery <u>or related product shall</u> <del>must</del> be designed and constructed to ensure that pesticide is deposited on target areas, to minimise losses to other areas and to prevent drift of pesticide to the environment. Where appropriate, an even distribution and homogeneous deposition <u>shall</u> <del>must</del> be ensured.	The machinery must be designed and constructed to ensure that pesticide is deposited on target areas, to minimise losses to other areas and to prevent drift of pesticide to the environment. Where appropriate, an even distribution and homogeneous deposition must be ensured.
Annex III, 2, point (2.4)(2.4.5)(2.4.5.3), introductory part		
2.4.5.3. Tests	2.4.5.3. –Tests	2.4.5.3. Tests
Annex III, 2, point (2.4)(2.4.5)(2.4.5.3), first paragraph		
In order to verify that the relevant parts of the machinery or related product	In order to verify that the relevant parts of the machinery <u>or related product</u>	In order to verify that the relevant parts of the machinery comply with the

DRAFT Machinery Regulation	Comparison	Machinery Directive
comply with the requirements set out in sections 2.4.5.1 and 2.4.5.2 the manufacturer shall, for each type of machinery or related product concerned, perform appropriate tests, or have such tests performed.	comply with the requirements set out in sections 2.4.5.1 and 2.4.5.2 the manufacturer <del>shall</del> <del>or his authorised representative must</del> , for each type of machinery <del>or related product</del> concerned, perform appropriate tests, or have such tests performed.	requirements set out in sections 2.4.5.1 and 2.4.5.2 the manufacturer or his authorised representative must, for each type of machinery concerned, perform appropriate tests, or have such tests performed.
Annex III, 2, point (2.4)(2.4.5)(2.4.5.4), introductory part		
2.4.5.4. Losses during stoppage	2.4.5.4. <del>Losses during stoppage</del>	2.4.5.4. Losses during stoppage
Annex III, 2, point (2.4)(2.4.5)(2.4.5.4), first paragraph		
The machinery or related product shall be designed and constructed to prevent losses while the pesticide application function is stopped.	The machinery <del>or related product shall</del> <del>must</del> be designed and constructed to prevent losses while the pesticide application function is stopped.	The machinery must be designed and constructed to prevent losses while the pesticide application function is stopped.
Annex III, 2, point (2.4)(2.4.6), introductory part		
2.4.6. Maintenance	2.4.6. <del>Maintenance</del>	2.4.6. Maintenance
Annex III, 2, point (2.4)(2.4.6)(2.4.6.1), introductory part		
2.4.6.1. Cleaning	2.4.6.1. <del>Cleaning</del>	2.4.6.1. Cleaning
Annex III, 2, point (2.4)(2.4.6)(2.4.6.1), first paragraph		
The machinery or related product shall be designed and constructed to allow its easy and thorough cleaning without contamination of the environment.	The machinery <del>or related product shall</del> <del>must</del> be designed and constructed to allow its easy and thorough cleaning without contamination of the environment.	The machinery must be designed and constructed to allow its easy and thorough cleaning without contamination of the environment.
Annex III, 2, point (2.4)(2.4.6)(2.4.6.2), introductory part		
2.4.6.2. Servicing	2.4.6.2. <del>Servicing</del>	2.4.6.2. Servicing

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 2, point (2.4)(2.4.6)(2.4.6.2), first paragraph		
The machinery or related product shall be designed and constructed to facilitate the changing of worn parts without contamination of the environment.	The machinery <u>or related product</u> shall <del>must</del> be designed and constructed to facilitate the changing of worn parts without contamination of the environment.	The machinery must be designed and constructed to facilitate the changing of worn parts without contamination of the environment.
Annex III, 2, point (2.4)(2.4.7), introductory part		
2.4.7. Inspections	2.4.7. –Inspections	2.4.7. Inspections
Annex III, 2, point (2.4)(2.4.7), first paragraph		
It shall be possible to easily connect the necessary measuring instruments to the machinery or related product to check the correct functioning of the machinery or related product.	It shall <del>must</del> be possible to easily connect the necessary measuring instruments to the machinery <u>or related product</u> to check the correct functioning of the machinery <u>or related product</u> .	It must be possible to easily connect the necessary measuring instruments to the machinery to check the correct functioning of the machinery.
Annex III, 2, point (2.4)(2.4.8), introductory part		
2.4.8. Marking of nozzles, strainers and filters	2.4.8. –Marking of nozzles, strainers and filters	2.4.8. Marking of nozzles, strainers and filters
Annex III, 2, point (2.4)(2.4.8), first paragraph		
Nozzles, strainers and filters shall be marked so that their type and size can be clearly identified.	Nozzles, strainers and filters shall <del>must</del> be marked so that their type and size can be clearly identified.	Nozzles, strainers and filters must be marked so that their type and size can be clearly identified.
Annex III, 2, point (2.4)(2.4.9), introductory part		
2.4.9. Indication of pesticide in use	2.4.9. –Indication of pesticide in use	2.4.9. Indication of pesticide in use
Annex III, 2, point (2.4)(2.4.9), first paragraph		
Where appropriate, the machinery or related product shall be fitted with a	Where appropriate, the machinery <u>or related product</u> shall <del>must</del> be fitted with a	Where appropriate, the machinery must be fitted with a specific mounting on

DRAFT Machinery Regulation	Comparison	Machinery Directive
specific mounting on which the operator can place the name of the pesticide in use.	specific mounting on which the operator can place the name of the pesticide in use.	which the operator can place the name of the pesticide in use.
Annex III, 2, point (2.4)(2.4.10), introductory part		
2.4.10. Instructions for use	2.4.10. <del>Instructions for use</del>	2.4.10. Instructions
Annex III, 2, point (2.4)(2.4.10), first paragraph, introductory part		
The instructions for use shall provide the following information:	The instructions <del>for use shall</del> <b>must</b> provide the following information:	The instructions must provide the following information:
Annex III, 2, point (2.4)(2.4.10), first paragraph(a)		
(a) precautions to be taken during mixing, loading, application, emptying, cleaning, servicing and transport operations in order to avoid contamination of the environment;	(a) precautions to be taken during mixing, loading, application, emptying, cleaning, servicing and transport operations in order to avoid contamination of the environment;	(a) precautions to be taken during mixing, loading, application, emptying, cleaning, servicing and transport operations in order to avoid contamination of the environment;
Annex III, 2, point (2.4)(2.4.10), first paragraph(b)		
(b) detailed conditions of use for the different operating environments envisaged, including the corresponding preparation and adjustments required to ensure the deposition of pesticide on target areas while minimising losses to other areas, to prevent drift to the environment and, where appropriate, to ensure an even distribution and homogeneous deposition of pesticide;	(b) detailed conditions of use for the different operating environments envisaged, including the corresponding preparation and adjustments required to ensure the deposition of pesticide on target areas while minimising losses to other areas, to prevent drift to the environment and, where appropriate, to ensure an even distribution and homogeneous deposition of pesticide;	(b) detailed conditions of use for the different operating environments envisaged, including the corresponding preparation and adjustments required to ensure the deposition of pesticide on target areas while minimising losses to other areas, to prevent drift to the environment and, where appropriate, to ensure an even distribution and homogeneous deposition of pesticide;
Annex III, 2, point (2.4)(2.4.10), first paragraph(c)		
(c) the range of types and sizes of nozzles, strainers and filters that can be	(c) the range of types and sizes of nozzles, strainers and filters that can be	(c) the range of types and sizes of nozzles, strainers and filters that can be used with the machinery;

DRAFT Machinery Regulation	Comparison	Machinery Directive
used with the machinery or related product;	used with the machinery <u>or related product</u> ;	
Annex III, 2, point (2.4)(2.4.10), first paragraph(d)		
(d) the frequency of checks and the criteria and method for the replacement of parts subject to wear that affect the correct functioning of the machinery or related product, such as nozzles, strainers and filters;	(d) the frequency of checks and the criteria and method for the replacement of parts subject to wear that affect the correct functioning of the machinery <u>or related product</u> , such as nozzles, strainers and filters;	(d) the frequency of checks and the criteria and method for the replacement of parts subject to wear that affect the correct functioning of the machinery, such as nozzles, strainers and filters;
Annex III, 2, point (2.4)(2.4.10), first paragraph(e)		
(e) specification of calibration, daily maintenance, winter preparation and other checks necessary to ensure the correct functioning of the machinery or related product;	(e) specification of calibration, daily maintenance, winter preparation and other checks necessary to ensure the correct functioning of the machinery <u>or related product</u> ;	(e) specification of calibration, daily maintenance, winter preparation and other checks necessary to ensure the correct functioning of the machinery;
Annex III, 2, point (2.4)(2.4.10), first paragraph(f)		
(f) types of pesticides that may cause incorrect functioning of the machinery or related product;	(f) types of pesticides that may cause incorrect functioning of the machinery <u>or related product</u> ;	(f) types of pesticides that may cause incorrect functioning of the machinery;
Annex III, 2, point (2.4)(2.4.10), first paragraph(g)		
(g) an indication that the operator should keep updated the name of the pesticide in use on the specific mounting referred to in section 2.4.9;	(g) an indication that the operator should keep updated the name of the pesticide in use on the specific mounting referred to in section 2.4.9;	(g) an indication that the operator should keep updated the name of the pesticide in use on the specific mounting referred to in section 2.4.9;
Annex III, 2, point (2.4)(2.4.10), first paragraph(h)		
(h) the connexion and use of any special equipment or accessories, and the necessary precautions to be taken;	(h) the connexion and use of any special equipment or accessories, and the necessary precautions to be taken;	(h) the connexion and use of any special equipment or accessories, and the necessary precautions to be taken;

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 2, point (2.4)(2.4.10), first paragraph(i)		
(i) an indication that the machinery or related product may be subject to national requirements for regular inspection by designated bodies, as provided for in Directive 2009/128/EC of the European Parliament and of the Council 1;	(i) an indication that the machinery <u>or related product</u> may be subject to national requirements for regular inspection by designated bodies, as provided for in Directive 2009/128/EC of the European Parliament and of the Council <del>1; of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (8);</del>	(i) an indication that the machinery may be subject to national requirements for regular inspection by designated bodies, as provided for in Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides ( 8 );
1. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).	<u>1. Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71).</u>	
Annex III, 2, point (2.4)(2.4.10), first paragraph(j)		
(j) the features of the machinery or related product, which shall be inspected to ensure its correct functioning;	(j) the features of the machinery <u>or related product</u> , which <del>shall</del> <b>must</b> be inspected to ensure its correct functioning;	(j) the features of the machinery which must be inspected to ensure its correct functioning;
Annex III, 2, point (2.4)(2.4.10), first paragraph(k)		
(k) instructions for connecting the necessary measuring instruments.	(k) instructions for connecting the necessary measuring instruments.	(k) instructions for connecting the necessary measuring instruments.
Annex III, 3		
3. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY OR RELATED PRODUCTS	3.– SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET <del>RISKS</del> <b>HAZARDS</b> DUE TO THE	3. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO THE MOBILITY OF MACHINERY

DRAFT Machinery Regulation	Comparison	Machinery Directive
	MOBILITY OF MACHINERY <u>OR RELATED PRODUCTS</u>	
Annex III, 3, first paragraph		
Machinery or related product presenting risks due to its mobility shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).	Machinery <u>or related product</u> presenting <del>risks</del> <del>hazards</del> due to its mobility <del>shall</del> <del>must</del> meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).	Machinery presenting hazards due to its mobility must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).
Annex III, 3, point (3.1), introductory part		
3.1. GENERAL	3.1. –GENERAL	3.1. GENERAL
Annex III, 3, point (3.1)(3.1.1), introductory part		
3.1.1. Definitions	3.1.1. –Definitions	3.1.1. Definitions
Annex III, 3, point (3.1)(3.1.1)(a), introductory part		
(a) 'Machinery or related product presenting risks due to its mobility' means	(a) 'Machinery <u>or related product</u> presenting <del>risks</del> <del>hazards</del> due to its mobility' means	(a) 'Machinery presenting hazards due to its mobility' means
Annex III, 3, point (3.1)(3.1.1)(a)(i)		
i. machinery or related product, the operation of which requires either mobility while working, or continuous or semi continuous movement between a succession of fixed working locations, or	<u>i. — machinery <u>or related product</u>, the operation of which requires either mobility while working, or continuous or semi_</u> continuous movement between a succession of fixed working locations, or	— machinery the operation of which requires either mobility while working, or continuous or semi-continuous movement between a succession of fixed working locations, or
Annex III, 3, point (3.1)(3.1.1)(a)(ii)		
ii. machinery or related product which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.	<u>ii. — machinery <u>or related product</u> which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.</u>	— machinery which is operated without being moved, but which may be equipped in such a way as to enable it to be moved more easily from one place to another.
Annex III, 3, point (3.1)(3.1.1)(b)		
(b) 'Driver' means an operator responsible for the movement of a machinery or	(b) 'Driver' means an operator responsible for the movement of a <u>machinery or</u>	(b) 'Driver' means an operator responsible for the movement of a machine. The

DRAFT Machinery Regulation	Comparison	Machinery Directive
related product, who may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.	<u>related product, who</u> <del>machine. The driver</del> may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.	driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.
Annex III, 3, point (3.1)(3.1.1)(c)		
(c) 'Autonomous mobile machinery' means a mobile machinery that has an autonomous mode, in which all the essential safety functions of the mobile machinery are ensured in its travel and working operations area without permanent interaction of an operator.	<u>(c) 'Autonomous mobile machinery' means a mobile machinery that has an autonomous mode, in which all the essential safety functions of the mobile machinery are ensured in its travel and working operations area without permanent interaction of an operator.</u>	
Annex III, 3, point (3.1)(3.1.1)(ca)		
(ca) 'Supervisor' means a person responsible for the supervision of an autonomous mobile machinery.	<u>(ca) 'Supervisor' means a person responsible for the supervision of an autonomous mobile machinery.</u>	
Annex III, 3, point (3.1)(3.1.1)(cb)		
(cb) 'Supervisory function' means remote non permanent surveillance of an autonomous mobile machinery by a device allowing to receive information or alerts and to give limited orders to this machinery.	<u>(cb) 'Supervisory function' means remote non permanent surveillance of an autonomous mobile machinery by a device allowing to receive information or alerts and to give limited orders to this machinery.</u>	
Annex III, 3, point (3.2), introductory part		
3.2. WORK POSITIONS	3.2. <del>WORK POSITIONS</del>	3.2. WORK POSITIONS
Annex III, 3, point (3.2)(3.2.1), introductory part		
3.2.1. Driving position	3.2.1. <del>Driving position</del>	3.2.1. Driving position
Annex III, 3, point (3.2)(3.2.1), first paragraph		
Visibility from the driving position shall be such that the driver can, in complete	Visibility from the driving position <u>shall</u> <del>must</del> be such that the driver can, in	Visibility from the driving position must be such that the driver can, in complete

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>safety for himself or herself and the exposed persons operate the machinery or related product and its tools in their foreseeable conditions of use. Where necessary, appropriate devices shall be provided to remedy risks due to inadequate direct vision.</p>	<p>complete safety for himself <u>or herself</u> and the exposed persons, operate the machinery <u>or related product</u> and its tools in their foreseeable conditions of use. Where necessary, appropriate devices <del>shall</del><b>must</b> be provided to remedy <del>risks</del><b>hazards</b> due to inadequate direct vision.</p>	<p>safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.</p>
<p>Annex III, 3, point (3.2)(3.2.1), second paragraph</p>		
<p>Machinery or related product on which the driver is transported shall be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.</p>	<p>Machinery <u>or related product</u> on which the driver is transported <del>shall</del><b>must</b> be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.</p>	<p>Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.</p>
<p>Annex III, 3, point (3.2)(3.2.1), third paragraph</p>		
<p>The driving position of ride-on drivers shall be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab shall incorporate a place for the instructions for use needed for the driver.</p>	<p>The driving position of ride-on drivers <del>shall</del><b>must</b> be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab <del>shall</del><b>must</b> incorporate a place for the instructions <u>for use</u> needed for the driver.</p>	<p>The driving position of ride-on drivers must be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab must incorporate a place for the instructions needed for the driver.</p>
<p>Annex III, 3, point (3.2)(3.2.2), introductory part</p>		
<p>3.2.2. Seating</p>	<p>3.2.2. –Seating</p>	<p>3.2.2. Seating</p>
<p>Annex III, 3, point (3.2)(3.2.2), first paragraph</p>		
<p>Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the</p>	<p>Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the</p>	<p>Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the ground</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
surroundings should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4:	<u>surroundings</u> <del>ground</del> should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4.;	should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4,
(a) the machinery shall be designed or equipped with a restraint system so as to keep the persons in their seats or in the protective structure, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats.	<u>(a) the machinery shall</u> <del>their seats must</del> be designed or equipped with a restraint system so as to keep the persons in their seats <u>or in the protective structure,</u> without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats.	their seats must be designed or equipped with a restraint system so as to keep the persons in their seats, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats.
Annex III, 3, point (3.2)(3.2.2), first paragraph a		
Where there is a significant roll or tip over risk and its restraint system is not used it shall not be possible for the machinery to move.	<u>Where there is a significant roll or tip over risk and its restraint system is not used it shall not be possible for the machinery to move.</u>	
Annex III, 3, point (3.2)(3.2.2), first paragraph b		
Such restraint systems or provision shall take ergonomic principles into account and shall not be fitted if they increase the risk.	Such restraint systems <u>or provision shall take ergonomic principles into account and shall</u> <del>should</del> not be fitted if they increase the risk.	Such restraint systems should not be fitted if they increase the risk.
Annex III, 3, point (3.2)(3.2.2), second paragraph		
(b) a visual and audible signal shall be provided at the driving position alerting the driver when the driver is in the driving position and not using the restraint system.	<u>(b) a visual and audible signal shall be provided at the driving position alerting the driver when the driver is in the driving position and not using the restraint system.</u>	
Annex III, 3, point (3.2)(3.2.3), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
3.2.3. Positions for other persons	3.2.3. <del>–</del> Positions for other persons	3.2.3. Positions for other persons
Annex III, 3, point (3.2)(3.2.3), first paragraph		
If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions shall be provided which enable them to be transported or to work on it without risk.	If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions <del>shall</del> <b>must</b> be provided which enable them to be transported or to work on it without risk.	If the conditions of use provide that persons other than the driver may occasionally or regularly be transported by the machinery or work on it, appropriate positions must be provided which enable them to be transported or to work on it without risk.
Annex III, 3, point (3.2)(3.2.3), second paragraph		
The second and third subparagraphs of section 3.2.1 also apply to the places provided for persons other than the driver.	The second and third <del>subparagraphs</del> <b>paragraphs</b> of section 3.2.1 also apply to the places provided for persons other than the driver.	The second and third paragraphs of section 3.2.1 also apply to the places provided for persons other than the driver.
Annex III, 3, point (3.2)(3.2.4), introductory part		
3.2.4. Supervisory function	3.2.4. Supervisory function	
Annex III, 3, point (3.2)(3.2.4), first paragraph		
Where relevant, autonomous mobile machinery or related products shall have a supervisory function specific to the autonomous mode. This function shall allow the supervisor to remotely receive information from the machine. The supervisory function shall only allow actions to stop and to start remotely the machinery or move it to a safe position and a safe state to avoid causing other risks. It shall be designed and constructed to allow those actions only when the supervisor can see directly or	<u>Where relevant, autonomous mobile machinery or related products shall have a supervisory function specific to the autonomous mode. This function shall allow the supervisor to remotely receive information from the machine. The supervisory function shall only allow actions to stop and to start remotely the machinery or move it to a safe position and a safe state to avoid causing other risks. It shall be designed and constructed to allow those actions only when the supervisor can see directly or</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
indirectly the machine's movement and working area and the protective devices are operational.	<u>indirectly the machine's movement and working area and the protective devices are operational.</u>	
Annex III, 3, point (3.2)(3.2.4), second paragraph		
The information the supervisor receives from the machine when the supervisory function is active shall enable the supervisor to have a complete and accurate view of the operation, movement and safe positioning of the machine in its travel and working area.	<u>The information the supervisor receives from the machine when the supervisory function is active shall enable the supervisor to have a complete and accurate view of the operation, movement and safe positioning of the machine in its travel and working area.</u>	
Annex III, 3, point (3.2)(3.2.4), third paragraph		
This information shall alert the supervisor of the occurrence of unforeseen or dangerous situations present or impending, which require supervisor's intervention.	<u>This information shall alert the supervisor of the occurrence of unforeseen or dangerous situations present or impending, which require supervisor's intervention.</u>	
Annex III, 3, point (3.2)(3.2.4), fourth paragraph		
If the supervisory function is not active, the machinery shall not be able to operate.	<u>If the supervisory function is not active, the machinery shall not be able to operate.</u>	
Annex III, 3, point (3.3), introductory part		
3.3. CONTROL SYSTEMS	3.3. <del>CONTROL</del> SYSTEMS	3.3. CONTROL SYSTEMS
Annex III, 3, point (3.3), first paragraph		
If necessary, steps shall be taken to prevent unauthorised use of controls.	If necessary, steps <del>shall</del> <b>must</b> be taken to prevent unauthorised use of controls.	If necessary, steps must be taken to prevent unauthorised use of controls.
Annex III, 3, point (3.3), second paragraph		
In the case of remote controls, each control unit shall clearly identify the	In the case of remote controls, each control unit <del>shall</del> <b>must</b> clearly identify the	In the case of remote controls, each control unit must clearly identify the machinery to be controlled from that unit.

DRAFT Machinery Regulation	Comparison	Machinery Directive
machinery or related product to be controlled from that unit.	machinery <u>or related product</u> to be controlled from that unit.	
Annex III, 3, point (3.3), third paragraph, introductory part		
The remote control system shall be designed and constructed in such a way as to affect only:	The remote control system <del>shall</del> <b>must</b> be designed and constructed in such a way as to affect only:	The remote control system must be designed and constructed in such a way as to affect only:
Annex III, 3, point (3.3), third paragraph(a)		
(a) the machinery or related product in question;	<del>(a)</del> — the machinery <u>or related product</u> in question;	— the machinery in question,
Annex III, 3, point (3.3), third paragraph(b)		
(b) the functions in question.	<del>(b)</del> — the functions in question.	— the functions in question.
Annex III, 3, point (3.3), fourth paragraph		
A remote controlled machinery or related product shall be designed and constructed in such a way that it will respond only to signals from the intended control units.	<del>A remote</del> <b>Remote</b> controlled machinery <u>or related product shall</u> <del>shall</del> <b>must</b> be designed and constructed in such a way that it will respond only to signals from the intended control units.	Remote controlled machinery must be designed and constructed in such a way that it will respond only to signals from the intended control units.
Annex III, 3, point (3.3), fourth paragraph a		
For autonomous mobile machinery or related product, the control system shall be designed to perform the safety functions by itself as set out in this section, even when actions are ordered by using a remote supervisory function.	<u>For autonomous mobile machinery or related product, the control system shall be designed to perform the safety functions by itself as set out in this section, even when actions are ordered by using a remote supervisory function.</u>	
Annex III, 3, point (3.3)(3.3.1), introductory part		
3.3.1. Control devices	3.3.1. <del>–</del> Control devices	3.3.1. Control devices
Annex III, 3, point (3.3)(3.3.1), first paragraph		
The driver shall be able to actuate all control devices required to operate the machinery from the driving position,	The driver <del>shall</del> <b>must</b> be able to actuate all control devices required to operate the machinery from the driving position,	The driver must be able to actuate all control devices required to operate the machinery from the driving position,

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>except for functions, which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely.</p>	<p>except for functions, which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely.</p>	<p>except for functions which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely.</p>
<p>Annex III, 3, point (3.3)(3.3.1), second paragraph</p>		
<p>Where there are pedals, they shall be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They shall have a slip-resistant surface and be easy to clean.</p>	<p>Where there are pedals, they <del>shall</del><b>must</b> be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They <del>shall</del><b>must</b> have a slip-resistant surface and be easy to clean.</p>	<p>Where there are pedals, they must be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They must have a slip-resistant surface and be easy to clean.</p>
<p>Annex III, 3, point (3.3)(3.3.1), third paragraph</p>		
<p>Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with pre-set positions, shall return to the neutral position as soon as they are released by the operator.</p>	<p>Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with <del>pre-set</del><b>preset</b> positions, <del>shall</del><b>must</b> return to the neutral position as soon as they are released by the operator.</p>	<p>Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with preset positions, must return to the neutral position as soon as they are released by the operator.</p>
<p>Annex III, 3, point (3.3)(3.3.1), fourth paragraph</p>		
<p>In the case of wheeled machinery, the steering system shall be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels.</p>	<p>In the case of wheeled machinery, the steering system <del>shall</del><b>must</b> be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels.</p>	<p>In the case of wheeled machinery, the steering system must be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels.</p>
<p>Annex III, 3, point (3.3)(3.3.1), fifth paragraph</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Any control that locks the differential shall be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.	Any control that locks the differential <del>shall</del> <b>must</b> be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.	Any control that locks the differential must be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.
Annex III, 3, point (3.3)(3.3.1), sixth paragraph		
The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.	The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.	The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.
Annex III, 3, point (3.3)(3.3.2), introductory part		
3.3.2. Starting/moving	3.3.2. <del>Starting/moving</del>	3.3.2. Starting/moving
Annex III, 3, point (3.3)(3.3.2), first paragraph		
All travel movements of self-propelled machinery with a ride-on driver shall be possible only if the driver is at the controls.	All travel movements of self-propelled machinery with a ride-on driver <del>shall</del> <b>must</b> be possible only if the driver is at the controls.	All travel movements of self-propelled machinery with a ride-on driver must be possible only if the driver is at the controls.
Annex III, 3, point (3.3)(3.3.2), second paragraph		
Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g. stabilisers, jib, etc.), the driver shall be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.	Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g. stabilisers, jib, etc.), the driver <del>shall</del> <b>must</b> be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.	Where, for operating purposes, machinery is fitted with devices which exceed its normal clearance zone (e.g. stabilisers, jib, etc.), the driver must be provided with the means of checking easily, before moving the machinery, that such devices are in a particular position which allows safe movement.
Annex III, 3, point (3.3)(3.3.2), third paragraph		
This also applies to all other parts which; to allow safe movement, have to be in particular positions, locked if necessary.	This also applies to all other parts which; <sup>17</sup> to allow safe movement, have to be in particular positions, locked if necessary.	This also applies to all other parts which, to allow safe movement, have to be in particular positions, locked if necessary.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 3, point (3.3)(3.3.2), fourth paragraph		
Where it does not give rise to other risks, movement of the machinery shall depend on safe positioning of the aforementioned parts.	Where it does not give rise to other risks, movement of the machinery <del>shall</del> <b>must</b> depend on safe positioning of the aforementioned parts.	Where it does not give rise to other risks, movement of the machinery must depend on safe positioning of the aforementioned parts.
Annex III, 3, point (3.3)(3.3.2), fifth paragraph		
It shall not be possible for unintentional movement of the machinery to occur while the engine is being started.	It <del>shall</del> <b>must</b> not be possible for unintentional movement of the machinery to occur while the engine is being started.	It must not be possible for unintentional movement of the machinery to occur while the engine is being started.
Annex III, 3, point (3.3)(3.3.2), sixth paragraph		
The movement of an autonomous mobile machinery shall take into account the risks related to the area where it is intended to move and work.	<u>The movement of an autonomous mobile machinery shall take into account the risks related to the area where it is intended to move and work.</u>	
Annex III, 3, point (3.3)(3.3.3), introductory part		
3.3.3. Travelling function	3.3.3. <del>Travelling function</del>	3.3.3. Travelling function
Annex III, 3, point (3.3)(3.3.3), first paragraph		
Without prejudice to road traffic regulations, self-propelled machinery and its trailers shall meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.	Without prejudice to road traffic regulations, self-propelled machinery and its trailers <del>shall</del> <b>must</b> meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.	Without prejudice to road traffic regulations, self-propelled machinery and its trailers must meet the requirements for slowing down, stopping, braking and immobilisation so as to ensure safety under all the operating, load, speed, ground and gradient conditions allowed for.
Annex III, 3, point (3.3)(3.3.3), second paragraph		
The driver shall be able to slow down and stop self-propelled machinery by means	The driver <del>shall</del> <b>must</b> be able to slow down and stop self-propelled machinery	The driver must be able to slow down and stop self-propelled machinery by

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device shall be provided for slowing down and stopping.</p>	<p>by means of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device <del>shall</del><b>must</b> be provided for slowing down and stopping.</p>	<p>means of a main device. Where safety so requires, in the event of a failure of the main device, or in the absence of the energy supply needed to actuate the main device, an emergency device with a fully independent and easily accessible control device must be provided for slowing down and stopping.</p>
<p>Annex III, 3, point (3.3)(3.3.3), third paragraph</p>		
<p>Where safety so requires, a parking device shall be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, if it is purely mechanical.</p>	<p>Where safety so requires, a parking device <del>shall</del><b>must</b> be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, <del>if provided that</del> it is purely mechanical.</p>	<p>Where safety so requires, a parking device must be provided to render stationary machinery immobile. This device may be combined with one of the devices referred to in the second paragraph, provided that it is purely mechanical.</p>
<p>Annex III, 3, point (3.3)(3.3.3), fourth paragraph, introductory part</p>		
<p>(i) Remote-controlled machinery shall be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:</p>	<p>(i) Remote-controlled machinery <del>shall</del><b>must</b> be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:</p>	<p>Remote-controlled machinery must be equipped with devices for stopping operation automatically and immediately and for preventing potentially dangerous operation in the following situations:</p>
<p>Annex III, 3, point (3.3)(3.3.3), fourth paragraph(a)</p>		
<p>(a) if the driver loses control;</p>	<p><del>(a)</del>— if the driver loses control;<sup>7</sup></p>	<p>— if the driver loses control,</p>
<p>Annex III, 3, point (3.3)(3.3.3), fourth paragraph(b)</p>		
<p>(b) if it receives a stop signal;</p>	<p><del>(b)</del>— if it receives a stop signal;<sup>7</sup></p>	<p>— if it receives a stop signal,</p>
<p>Annex III, 3, point (3.3)(3.3.3), fourth paragraph(c)</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(c) if a fault is detected in a safety-related part of the system;	<del>(c)</del> — if a fault is detected in a safety-related part of the system; <sup>7</sup>	— if a fault is detected in a safety-related part of the system,
Annex III, 3, point (3.3)(3.3.3), fourth paragraph(d)		
(d) if no validation signal is detected within a specified time.	<del>(d)</del> — if no validation signal is detected within a specified time.	— if no validation signal is detected within a specified time.
Annex III, 3, point (3.3)(3.3.3), fifth paragraph		
Section 1.2.4 does not apply to the travelling function.	Section 1.2.4 does not apply to the travelling function.	Section 1.2.4 does not apply to the travelling function.
Annex III, 3, point (3.3)(3.3.3), sixth paragraph, introductory part		
(ii) Autonomous mobile machinery or related product shall comply, with one or both where necessary according to the risk assessment, of the following conditions:	<u>(ii) Autonomous mobile machinery or related product shall comply, with one or both where necessary according to the risk assessment, of the following conditions:</u>	
Annex III, 3, point (3.3)(3.3.3), sixth paragraph(a)		
(a) it shall move and operate in an enclosed zone fitted with a peripheral protection system comprising guards or protective devices;	<u>(a) it shall move and operate in an enclosed zone fitted with a peripheral protection system comprising guards or protective devices;</u>	
Annex III, 3, point (3.3)(3.3.3), sixth paragraph(b)		
(b) it shall be equipped with devices intended to detect any human, domestic animal or any other obstacle in its vicinity, where those obstacles could give rise to a risk to health and safety of persons or of domestic animals or to safe operation of the machinery or related product.	<u>(b) it shall be equipped with devices intended to detect any human, domestic animal or any other obstacle in its vicinity, where those obstacles could give rise to a risk to health and safety of persons or of domestic animals or to safe operation of the machinery or related product.</u>	
Annex III, 3, point (3.3)(3.3.3), seventh paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>The movements of mobile machinery or related product connected with one or more trailers or towed equipment, including autonomous mobile machinery or related product, connected with one or more trailers or towed equipment, shall not give rise to risks for persons, domestic animals or any other obstacle in the danger zone of such machinery or related product and trailers or towed equipment.</p>	<p><u>The movements of mobile machinery or related product connected with one or more trailers or towed equipment, including autonomous mobile machinery or related product, connected with one or more trailers or towed equipment, shall not give rise to risks for persons, domestic animals or any other obstacle in the danger zone of such machinery or related product and trailers or towed equipment.</u></p>	
<p>Annex III, 3, point (3.3)(3.3.4), introductory part</p>		
<p>3.3.4. Movement of pedestrian-controlled machinery</p>	<p>3.3.4. <del>–</del>Movement of pedestrian-controlled machinery</p>	<p>3.3.4. Movement of pedestrian-controlled machinery</p>
<p>Annex III, 3, point (3.3)(3.3.4), first paragraph, introductory part</p>		
<p>Movement of pedestrian-controlled self-propelled machinery shall be possible only through sustained action on the relevant control device by the driver. In particular, it shall not be possible for movement to occur while the engine is being started. The control systems for pedestrian-controlled machinery shall be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular:</p>	<p>Movement of pedestrian-controlled self-propelled machinery <del>shall</del><b>must</b> be possible only through sustained action on the relevant control device by the driver. In particular, it <del>shall</del><b>must</b> not be possible for movement to occur while the engine is being started. The control systems for pedestrian-controlled machinery <del>shall</del><b>must</b> be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular:</p>	<p>Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control device by the driver. In particular, it must not be possible for movement to occur while the engine is being started. The control systems for pedestrian-controlled machinery must be designed in such a way as to minimise the risks arising from inadvertent movement of the machine towards the driver, in particular:</p>
<p>Annex III, 3, point (3.3)(3.3.4), first paragraph(a)</p>		
<p>(a) Crushing;</p>	<p>(a) Crushing; <del>— crushing,</del></p>	<p>— crushing,</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 3, point (3.3)(3.3.4), first paragraph(b)		
(b) injury from rotating tools.	<del>(b)</del> — injury from rotating tools.	— injury from rotating tools.
Annex III, 3, point (3.3)(3.3.4), second paragraph		
The speed of travel of the machinery shall be compatible with the pace of a driver on foot.	The speed of travel of the machinery <del>shall</del> <b>must</b> be compatible with the pace of a driver on foot.	The speed of travel of the machinery must be compatible with the pace of a driver on foot.
Annex III, 3, point (3.3)(3.3.4), third paragraph		
In the case of machinery on which a rotary tool may be fitted, it shall not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In the latter case, the reversing speed shall be such that it does not endanger the driver.	In the case of machinery on which a rotary tool may be fitted, it <del>shall</del> <b>must</b> not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In the latter case, the reversing speed <del>shall</del> <b>must</b> be such that it does not endanger the driver.	In the case of machinery on which a rotary tool may be fitted, it must not be possible to actuate the tool when the reverse control is engaged, except where the movement of the machinery results from movement of the tool. In the latter case, the reversing speed must be such that it does not endanger the driver.
Annex III, 3, point (3.3)(3.3.5), introductory part		
3.3.5. Control circuit failure	3.3.5. <del>—</del> Control circuit failure	3.3.5. Control circuit failure
Annex III, 3, point (3.3)(3.3.5), first paragraph		
A failure in the power supply to the power-assisted steering, where fitted, shall not prevent machinery from being steered during the time required to stop it.	A failure in the power supply to the power-assisted steering, where fitted, <del>shall</del> <b>must</b> not prevent machinery from being steered during the time required to stop it.	A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.
Annex III, 3, point (3.3)(3.3.5), second paragraph		
For autonomous mobile machinery, a failure in the steering system shall not have an impact on the safety of the machinery.	<u>For autonomous mobile machinery, a failure in the steering system shall not have an impact on the safety of the machinery.</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 3, point (3.4), introductory part		
3.4. PROTECTION AGAINST MECHANICAL RISKS	3.4. –PROTECTION AGAINST MECHANICAL <del>RISKS</del> HAZARDS	3.4. PROTECTION AGAINST MECHANICAL HAZARDS
Annex III, 3, point (3.4)(3.4.1), introductory part		
3.4.1. Uncontrolled movements	3.4.1. –Uncontrolled movements	3.4.1. Uncontrolled movements
Annex III, 3, point (3.4)(3.4.1), first paragraph		
A machinery or related product shall be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.	<u>A machinery or related product shall</u> <del>Machinery must</del> be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.	Machinery must be designed, constructed and where appropriate placed on its mobile support in such a way as to ensure that, when moved, uncontrolled oscillations of its centre of gravity do not affect its stability or exert excessive strain on its structure.
Annex III, 3, point (3.4)(3.4.2), introductory part		
3.4.2. Moving transmission parts	3.4.2. –Moving transmission parts	3.4.2. Moving transmission parts
Annex III, 3, point (3.4)(3.4.2), first paragraph		
By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.	By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.	By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.
Annex III, 3, point (3.4)(3.4.3), introductory part		
3.4.3. Roll-over and tip-over	3.4.3. –Roll-over and tip-over	3.4.3. Roll-over and tip-over

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 3, point (3.4)(3.4.3), first paragraph		
Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery shall be fitted with an appropriate protective structure, unless this increases the risk.	Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery <del>shall</del> <b>must</b> be fitted with an appropriate protective structure, unless this increases the risk.	Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk of rolling or tipping over, the machinery must be fitted with an appropriate protective structure, unless this increases the risk.
Annex III, 3, point (3.4)(3.4.3), second paragraph		
This structure shall be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.	This structure <del>shall</del> <b>must</b> be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.	This structure must be such that in the event of rolling or tipping over it affords the ride-on person(s) an adequate deflection-limiting volume.
Annex III, 3, point (3.4)(3.4.3), third paragraph		
In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer shall, for each type of structure concerned, perform appropriate tests or have such tests performed.	In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer <del>shall or his authorised representative must</del> <b>must</b> , for each type of structure concerned, perform appropriate tests or have such tests performed.	In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.
Annex III, 3, point (3.4)(3.4.4), introductory part		
3.4.4. Falling objects	3.4.4. –Falling objects	3.4.4. Falling objects
Annex III, 3, point (3.4)(3.4.4), first paragraph		
Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery shall be designed and	Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery <del>shall</del> <b>must</b> be designed and	Where, in the case of self-propelled machinery with a ride-on driver, operator(s) or other person(s), there is a risk due to falling objects or material, the machinery must be designed and

DRAFT Machinery Regulation	Comparison	Machinery Directive
constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure.	constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure.	constructed in such a way as to take account of this risk and fitted, if its size allows, with an appropriate protective structure.
Annex III, 3, point (3.4)(3.4.4), second paragraph		
This structure shall be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume.	This structure <del>shall</del> <b>must</b> be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume.	This structure must be such that, in the event of falling objects or material, it guarantees the ride-on person(s) an adequate deflection-limiting volume.
Annex III, 3, point (3.4)(3.4.4), third paragraph		
In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer shall, for each type of structure concerned, perform appropriate tests or have such tests performed.	In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer <del>shall</del> <b>or his authorised representative must</b> , for each type of structure concerned, perform appropriate tests or have such tests performed.	In order to verify that the structure complies with the requirement laid down in the second paragraph, the manufacturer or his authorised representative must, for each type of structure concerned, perform appropriate tests or have such tests performed.
Annex III, 3, point (3.4)(3.4.5), introductory part		
3.4.5. Means of access	3.4.5. <del>Means of access</del>	3.4.5. Means of access
Annex III, 3, point (3.4)(3.4.5), first paragraph		
Handholds and steps shall be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.	Handholds and steps <del>shall</del> <b>must</b> be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.	Handholds and steps must be designed, constructed and arranged in such a way that the operators use them instinctively and do not use the control devices to assist access.
Annex III, 3, point (3.4)(3.4.6), introductory part		
3.4.6. Towing devices	3.4.6. <del>Towing devices</del>	3.4.6. Towing devices
Annex III, 3, point (3.4)(3.4.6), first paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>All machinery used to tow or to be towed shall be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use.</p>	<p>All machinery used to tow or to be towed <del>shall</del><b>must</b> be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection and to prevent accidental disconnection during use.</p>	<p>All machinery used to tow or to be towed must be fitted with towing or coupling devices designed, constructed and arranged in such a way as to ensure easy and secure connection and disconnection during use.</p>
<p>Annex III, 3, point (3.4)(3.4.6), second paragraph</p>		
<p>Insofar as the tow bar load so requires, such machinery shall be equipped with a support with a bearing surface suited to the load and the ground.</p>	<p>Insofar as the tow bar load so requires, such machinery <del>shall</del><b>must</b> be equipped with a support with a bearing surface suited to the load and the ground.</p>	<p>Insofar as the tow bar load so requires, such machinery must be equipped with a support with a bearing surface suited to the load and the ground.</p>
<p>Annex III, 3, point (3.4)(3.4.7), introductory part</p>		
<p>3.4.7. Transmission of power between self-propelled machinery (or tractor) and recipient machinery</p>	<p>3.4.7.– Transmission of power between self-propelled machinery (or tractor) and recipient machinery</p>	<p>3.4.7. Transmission of power between self-propelled machinery (or tractor) and recipient machinery</p>
<p>Annex III, 3, point (3.4)(3.4.7), first paragraph</p>		
<p>Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery shall be designed and constructed in such a way that any part that moves during operation is protected over its whole length.</p>	<p>Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery <del>shall</del><b>must</b> be designed and constructed in such a way that any part that moves during operation is protected over its whole length.</p>	<p>Removable mechanical transmission devices linking self-propelled machinery (or a tractor) to the first fixed bearing of recipient machinery must be designed and constructed in such a way that any part that moves during operation is protected over its whole length.</p>
<p>Annex III, 3, point (3.4)(3.4.7), second paragraph</p>		
<p>On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached shall be protected either by a guard fixed and</p>	<p>On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached <del>shall</del><b>must</b> be protected either by a guard fixed and</p>	<p>On the side of the self-propelled machinery (or tractor), the power take-off to which the removable mechanical transmission device is attached must be protected either by a guard fixed and</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.	linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.	linked to the self-propelled machinery (or tractor) or by any other device offering equivalent protection.
Annex III, 3, point (3.4)(3.4.7), third paragraph		
It shall be possible to open this guard for access to the removable transmission device. Once it is in place, there shall be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.	It <del>shall</del> <b>must</b> be possible to open this guard for access to the removable transmission device. Once it is in place, there <del>shall</del> <b>must</b> be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.	It must be possible to open this guard for access to the removable transmission device. Once it is in place, there must be enough room to prevent the drive shaft damaging the guard when the machinery (or the tractor) is moving.
Annex III, 3, point (3.4)(3.4.7), fourth paragraph		
On the recipient machinery side, the input shaft shall be enclosed in a protective casing fixed to the machinery.	On the recipient machinery side, the input shaft <del>shall</del> <b>must</b> be enclosed in a protective casing fixed to the machinery.	On the recipient machinery side, the input shaft must be enclosed in a protective casing fixed to the machinery.
Annex III, 3, point (3.4)(3.4.7), fifth paragraph		
Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device shall be marked accordingly.	Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device <del>shall</del> <b>must</b> be marked accordingly.	Torque limiters or freewheels may be fitted to universal joint transmissions only on the side adjoining the driven machinery. The removable mechanical transmission device must be marked accordingly.
Annex III, 3, point (3.4)(3.4.7), sixth paragraph		
All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), shall have a system for attaching the removable mechanical transmission device so that, when the machinery is	All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), <del>shall</del> <b>must</b> have a system for attaching the removable mechanical transmission device so that, when the machinery is	All recipient machinery, the operation of which requires a removable mechanical transmission device to connect it to self-propelled machinery (or a tractor), must have a system for attaching the removable mechanical transmission device so that, when the machinery is

DRAFT Machinery Regulation	Comparison	Machinery Directive
uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery.	uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery.	uncoupled, the removable mechanical transmission device and its guard are not damaged by contact with the ground or part of the machinery.
Annex III, 3, point (3.4)(3.4.7), seventh paragraph		
The outside parts of the guard shall be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard shall cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.	The outside parts of the guard <del>shall</del> <b>must</b> be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard <del>shall</del> <b>must</b> cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.	The outside parts of the guard must be so designed, constructed and arranged that they cannot turn with the removable mechanical transmission device. The guard must cover the transmission to the ends of the inner jaws in the case of simple universal joints and at least to the centre of the outer joint or joints in the case of wide-angle universal joints.
Annex III, 3, point (3.4)(3.4.7), eighth paragraph		
If means of access to working positions are provided near to the removable mechanical transmission device, they shall be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.	If means of access to working positions are provided near to the removable mechanical transmission device, they <del>shall</del> <b>must</b> be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.	If means of access to working positions are provided near to the removable mechanical transmission device, they must be designed and constructed in such a way that the shaft guards cannot be used as steps, unless designed and constructed for that purpose.
Annex III, 3, point (3.5), introductory part		
3.5. PROTECTION AGAINST OTHER RISKS	3.5. <del>PROTECTION AGAINST OTHER RISKS</del> <b>HAZARDS</b>	3.5. PROTECTION AGAINST OTHER HAZARDS
Annex III, 3, point (3.5)(3.5.1), introductory part		
3.5.1. Batteries	3.5.1. <del>Batteries</del>	3.5.1. Batteries
Annex III, 3, point (3.5)(3.5.1), first paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>The battery housing shall be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tip over and to avoid the accumulation of vapours in places occupied by operators.</p>	<p>The battery housing <del>shall</del><b>must</b> be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or <del>tip over</del><b>tipover</b> and to avoid the accumulation of vapours in places occupied by operators.</p>	<p>The battery housing must be designed and constructed in such a way as to prevent the electrolyte being ejected on to the operator in the event of rollover or tipover and to avoid the accumulation of vapours in places occupied by operators.</p>
<p>Annex III, 3, point (3.5)(3.5.1), second paragraph</p>		
<p>A machinery or related product shall be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.</p>	<p><u>A machinery or related product shall</u><del>Machinery must</del> be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.</p>	<p>Machinery must be designed and constructed in such a way that the battery can be disconnected with the aid of an easily accessible device provided for that purpose.</p>
<p>Annex III, 3, point (3.5)(3.5.1), third paragraph</p>		
<p>The batteries with automatic charging for mobile machinery, including autonomous mobile machinery or related product, shall be designed to prevent hazards referred to in sections 1.3.8.2. and 1.5.1., including the risks of contact or collision of the machinery or related product with a person or another machinery or related product when the machinery or related product moves autonomously to the charging station.</p>	<p><u>The batteries with automatic charging for mobile machinery, including autonomous mobile machinery or related product, shall be designed to prevent hazards referred to in sections 1.3.8.2. and 1.5.1., including the risks of contact or collision of the machinery or related product with a person or another machinery or related product when the machinery or related product moves autonomously to the charging station.</u></p>	
<p>Annex III, 3, point (3.5)(3.5.2), introductory part</p>		
<p>3.5.2. Fire</p>	<p>3.5.2. <del>Fire</del></p>	<p>3.5.2. Fire</p>
<p>Annex III, 3, point (3.5)(3.5.2), first paragraph, introductory part</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Depending on the hazards anticipated by the manufacturer, machinery shall, where its size permits:	Depending on the hazards anticipated by the manufacturer, machinery <del>shall</del> <b>must</b> , where its size permits:	Depending on the hazards anticipated by the manufacturer, machinery must, where its size permits:
Annex III, 3, point (3.5)(3.5.2), first paragraph(a)		
(a) either allow easily accessible fire extinguishers to be fitted, or	<del>(a)</del> — either allow easily accessible fire extinguishers to be fitted, or	— either allow easily accessible fire extinguishers to be fitted, or
Annex III, 3, point (3.5)(3.5.2), first paragraph(b)		
(b) be provided with built-in extinguisher systems.	<del>(b)</del> — be provided with built-in extinguisher systems.	— be provided with built-in extinguisher systems.
Annex III, 3, point (3.5)(3.5.3), introductory part		
3.5.3. Emissions of hazardous substances	3.5.3. <del>—</del> Emissions of hazardous substances	3.5.3. Emissions of hazardous substances
Annex III, 3, point (3.5)(3.5.3), first paragraph		
The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the application of hazardous substances. However, the operator shall be protected against the risk of exposure to such hazardous emissions.	The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the <del>application</del> <b>spraying</b> of <del>hazardous substances</del> <b>products</b> . However, the operator <del>shall</del> <b>must</b> be protected against the risk of exposure to such hazardous emissions.	The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.
Annex III, 3, point (3.5)(3.5.3), second paragraph		
Ride-on mobile machinery having application of hazardous substances as the main function shall be equipped with filtration cabs or equivalent safety measures.	<del>Ride-on mobile machinery having application of hazardous substances as the main function shall be equipped with filtration cabs or equivalent safety measures.</del>	
Annex III, 3, point (3.5)(3.5.4), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
3.5.4. Risk of contact with live overhead power lines	<u>3.5.4. Risk of contact with live overhead power lines</u>	
Annex III, 3, point (3.5)(3.5.4), first paragraph		
Depending on its height, mobile machinery or related product shall, where relevant, be designed, constructed and equipped, so as to prevent the risk of contact with an energised overhead power line or the risk of creating an electric arc between any part of the machinery or an operator driving the machinery and an energised overhead power line.	<u>Depending on its height, mobile machinery or related product shall, where relevant, be designed, constructed and equipped, so as to prevent the risk of contact with an energised overhead power line or the risk of creating an electric arc between any part of the machinery or an operator driving the machinery and an energised overhead power line.</u>	
Annex III, 3, point (3.5)(3.5.4), second paragraph		
When the risk to the persons operating machinery incurred by the contact with an energised overhead power line cannot be fully avoided, mobile machinery or related product shall be designed, constructed and equipped so as to prevent any electrical hazards.	<u>When the risk to the persons operating machinery incurred by the contact with an energised overhead power line cannot be fully avoided, mobile machinery or related product shall be designed, constructed and equipped so as to prevent any electrical hazards.</u>	
Annex III, 3, point (3.6), introductory part		
3.6. INFORMATION AND INDICATIONS	3.6. –INFORMATION AND INDICATIONS	3.6. INFORMATION AND INDICATIONS
Annex III, 3, point (3.6)(3.6.1), introductory part		
3.6.1. Signs, signals and warnings	3.6.1. –Signs, signals and warnings	3.6.1. Signs, signals and warnings
Annex III, 3, point (3.6)(3.6.1), first paragraph		
All machinery or related product shall have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as	All machinery <u>or related product shall</u> <del>must</del> have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as	All machinery must have signs and/or instruction plates concerning use, adjustment and maintenance, wherever necessary, so as to ensure the health and

DRAFT Machinery Regulation	Comparison	Machinery Directive
to ensure the health and safety of persons. They shall be chosen, designed and constructed in such a way as to be clearly visible and indelible.	to ensure the health and safety of persons. They <del>shall</del> <b>must</b> be chosen, designed and constructed in such a way as to be clearly visible and indelible.	safety of persons. They must be chosen, designed and constructed in such a way as to be clearly visible and indelible.
Annex III, 3, point (3.6)(3.6.1), second paragraph, introductory part		
Without prejudice to the provisions of road traffic regulations, machinery or related product with a ride-on driver shall have the following equipment:	Without prejudice to the provisions of road traffic regulations, machinery <u>or related product</u> with a ride-on driver <del>shall</del> <b>must</b> have the following equipment:	Without prejudice to the provisions of road traffic regulations, machinery with a ride-on driver must have the following equipment:
Annex III, 3, point (3.6)(3.6.1), second paragraph(a)		
(a) an acoustic warning device to alert persons;	<u>(a)</u> — an acoustic warning device to alert persons; <del>;</del>	— an acoustic warning device to alert persons,
Annex III, 3, point (3.6)(3.6.1), second paragraph(b)		
(b) a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery or related product intended solely for underground working and having no electrical power;	<u>(b)</u> — a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery <u>or related product</u> intended solely for underground working and having no electrical power; <del>;</del>	— a system of light signals relevant to the intended conditions of use; the latter requirement does not apply to machinery intended solely for underground working and having no electrical power,
Annex III, 3, point (3.6)(3.6.1), second paragraph(c)		
(c) where necessary, there shall be an appropriate connection between a trailer and the machinery or related product for the operation of signals.	<u>(c)</u> — where necessary, there <del>shall</del> <b>must</b> be an appropriate connection between a trailer and the machinery <u>or related product</u> for the operation of signals.	— where necessary, there must be an appropriate connection between a trailer and the machinery for the operation of signals.
Annex III, 3, point (3.6)(3.6.1), third paragraph		
Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing shall be fitted with appropriate means to	Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing <del>shall</del> <b>must</b> be fitted with appropriate	Remote-controlled machinery which, under normal conditions of use, exposes persons to the risk of impact or crushing must be fitted with appropriate means to

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>signal its movements or with means to protect persons against such risks. The same applies to machinery or related product, which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver.</p>	<p>means to signal its movements or with means to protect persons against such risks. The same applies to machinery <u>or related product</u>, which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver.</p>	<p>signal its movements or with means to protect persons against such risks. The same applies to machinery which involves, when in use, the constant repetition of a forward and backward movement on a single axis where the area to the rear of the machine is not directly visible to the driver.</p>
<p>Annex III, 3, point (3.6)(3.6.1), fourth paragraph</p>		
<p>Machinery or related product shall be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices shall be provided with the means to check that they are in good working order and their failure shall be made apparent to the operator.</p>	<p>Machinery <u>or related product</u> shall <del>must</del> be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices shall <del>must</del> be provided with the means to check that they are in good working order and their failure shall <del>must</del> be made apparent to the operator.</p>	<p>Machinery must be constructed in such a way that the warning and signalling devices cannot be disabled unintentionally. Where it is essential for safety, such devices must be provided with the means to check that they are in good working order and their failure must be made apparent to the operator.</p>
<p>Annex III, 3, point (3.6)(3.6.1), fifth paragraph</p>		
<p>Where the movement of machinery or its tools is particularly hazardous, signs on the machinery shall be provided to warn against approaching the machinery while it is working; the signs shall be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.</p>	<p>Where the movement of machinery or its tools is particularly hazardous, signs on the machinery shall <del>must</del> be provided to warn against approaching the machinery while it is working; the signs shall <del>must</del> be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.</p>	<p>Where the movement of machinery or its tools is particularly hazardous, signs on the machinery must be provided to warn against approaching the machinery while it is working; the signs must be legible at a sufficient distance to ensure the safety of persons who have to be in the vicinity.</p>
<p>Annex III, 3, point (3.6)(3.6.2), introductory part</p>		
<p>3.6.2. Marking</p>	<p>3.6.2. –Marking</p>	<p>3.6.2. Marking</p>
<p>Annex III, 3, point (3.6)(3.6.2), first paragraph, introductory part</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(i) The following shall be shown legibly and indelibly on all Machinery or related products:	(i) The following <del>shall</del> <b>must</b> be shown legibly and indelibly on all <u>Machinery or related products</u> <del>machinery</del> :	The following must be shown legibly and indelibly on all machinery:
Annex III, 3, point (3.6)(3.6.2), first paragraph(a)		
(a) nominal power expressed in kilowatts (kW);	(a) — nominal power expressed in kilowatts (kW); <del>;</del>	— nominal power expressed in kilowatts (kW),
Annex III, 3, point (3.6)(3.6.2), first paragraph(b)		
(b) mass of the most usual configuration, in kilograms (kg);	(b) — mass of the most usual configuration, in kilograms (kg);	— mass of the most usual configuration, in kilograms (kg);
Annex III, 3, point (3.6)(3.6.2), second paragraph, introductory part		
(ii) and, where appropriate:	(ii) and, where appropriate:	and, where appropriate:
Annex III, 3, point (3.6)(3.6.2), second paragraph(a)		
(a) maximum drawbar pull provided for at the coupling hook, in Newtons (N);	(a) — maximum drawbar pull provided for at the coupling hook, in Newtons (N); <del>;</del>	— maximum drawbar pull provided for at the coupling hook, in Newtons (N),
Annex III, 3, point (3.6)(3.6.2), second paragraph(b)		
(b) maximum vertical load provided for on the coupling hook, in Newtons (N).	(b) — maximum vertical load provided for on the coupling hook, in Newtons (N).	— maximum vertical load provided for on the coupling hook, in Newtons (N).
Annex III, 3, point (3.6)(3.6.3), introductory part		
3.6.3. Instructions for use	3.6.3. <del>Instructions for use</del>	3.6.3. Instructions
Annex III, 3, point (3.6)(3.6.3)(3.6.3.1), introductory part		
3.6.3.1. Vibrations	3.6.3.1. <del>Vibrations</del>	3.6.3.1. Vibrations
Annex III, 3, point (3.6)(3.6.3)(3.6.3.1), first paragraph, introductory part		
The instructions for use shall give the following information concerning vibrations, expressed as acceleration	The instructions <u>for use shall</u> <del>must</del> give the following information concerning vibrations, <u>expressed as acceleration</u>	The instructions must give the following information concerning vibrations

DRAFT Machinery Regulation	Comparison	Machinery Directive
(m/s <sup>2</sup> ), transmitted by the machinery or related products to the hand-arm system or to the whole body:	<u>(m/s<sup>2</sup>)</u> , transmitted by the machinery <u>or related products</u> to the hand-arm system or to the whole body:	transmitted by the machinery to the hand-arm system or to the whole body:
Annex III, 3, point (3.6)(3.6.3)(3.6.3.1), first paragraph(a)		
(a) the vibration total value from continuous vibrations to which the hand-arm system is subjected;	<u>(a)</u> — the vibration total value <u>from continuous vibrations</u> to which the hand-arm system is subjected; <del>if it exceeds 2,5 m/s<sup>2</sup>. Where this value does not exceed 2,5 m/s<sup>2</sup>, this must be mentioned;</del>	— the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s <sup>2</sup> . Where this value does not exceed 2,5 m/s <sup>2</sup> , this must be mentioned,
Annex III, 3, point (3.6)(3.6.3)(3.6.3.1), first paragraph(b)		
(b) the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected;	<u>(b)</u> the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected;	
Annex III, 3, point (3.6)(3.6.3)(3.6.3.1), first paragraph(c)		
(c) the highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0, 5 m/s <sup>2</sup> . Where this value does not exceed 0, 5 m/s <sup>2</sup> , this shall be mentioned;	<u>(c)</u> — the highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0, 5 m/s <sup>2</sup> . Where this value does not exceed 0, 5 m/s <sup>2</sup> , this <del>shall</del> <u>must</u> be mentioned;	— the highest root mean square value of weighted acceleration to which the whole body is subjected, if it exceeds 0,5 m/s <sup>2</sup> . Where this value does not exceed 0,5 m/s <sup>2</sup> , this must be mentioned,
Annex III, 3, point (3.6)(3.6.3)(3.6.3.1), first paragraph(d)		
(d) the uncertainty of measurements.	<u>(d)</u> — the uncertainty of <del>measurements</del> <u>measurement</u> .	— the uncertainty of measurement.
Annex III, 3, point (3.6)(3.6.3)(3.6.3.1), second paragraph		
These values shall be either those actually measured for the machinery or related products in question or those established on the basis of	These values <del>shall</del> <u>must</u> be either those actually measured for the machinery <u>or related products</u> in question or those established on the basis of	These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>measurements taken for technically comparable machinery or related products, which is representative of the machinery or related products to be produced.</p>	<p>measurements taken for technically comparable machinery <u>or related products</u>, which is representative of the machinery <u>or related products</u> to be produced.</p>	<p>technically comparable machinery which is representative of the machinery to be produced.</p>
<p>Annex III, 3, point (3.6)(3.6.3)(3.6.3.1), third paragraph</p>		
<p>Where harmonised standards or common specifications adopted by the Commission in accordance with Article 17(3) cannot be applied, the vibration shall be measured using the most appropriate measurement code for the machinery or related products concerned.</p>	<p>Where harmonised standards <u>or common specifications adopted by the Commission in accordance with Article 17(3) cannot be</u><del>are not</del> applied, the vibration <del>shall</del><b>must</b> be measured using the most appropriate measurement code for the machinery <u>or related products</u> concerned.</p>	<p>Where harmonised standards are not applied, the vibration must be measured using the most appropriate measurement code for the machinery concerned.</p>
<p>Annex III, 3, point (3.6)(3.6.3)(3.6.3.1), fourth paragraph</p>		
<p>The operating conditions during measurement and the measurement codes used shall be described.</p>	<p>The operating conditions during measurement and the measurement codes used <del>shall</del><b>must</b> be described.</p>	<p>The operating conditions during measurement and the measurement codes used must be described.</p>
<p>Annex III, 3, point (3.6)(3.6.3)(3.6.3.2), introductory part</p>		
<p>3.6.3.2. Multiple uses</p>	<p>3.6.3.2. <del>–</del>Multiple uses</p>	<p>3.6.3.2. Multiple uses</p>
<p>Annex III, 3, point (3.6)(3.6.3)(3.6.3.2), first paragraph</p>		
<p>The instructions for use for a machinery or related product allowing several uses depending on the equipment used and the instructions for use for the interchangeable equipment shall contain the information necessary for safe assembly and use of the basic machinery or related product and the</p>	<p>The instructions for <u>use for a machinery or related product</u> allowing several uses depending on the equipment used and the instructions for <u>use for the interchangeable equipment</u> <del>shall</del><b>must</b> contain the information necessary for safe assembly and use of the basic machinery <u>or related product</u> and the</p>	<p>The instructions for machinery allowing several uses depending on the equipment used and the instructions for the interchangeable equipment must contain the information necessary for safe assembly and use of the basic machinery and the interchangeable equipment that can be fitted.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
interchangeable equipment that can be fitted.	interchangeable equipment that can be fitted.	
Annex III, 3, point (3.6)(3.6.3)(3.6.3.3), introductory part		
3.6.3.3. Autonomous mobile machinery or related products	<u>3.6.3.3. Autonomous mobile machinery or related products</u>	
Annex III, 3, point (3.6)(3.6.3)(3.6.3.3), first paragraph		
The instructions for use of autonomous mobile machinery or related products shall specify the characteristics of its intended travel, working areas and danger zones.	<u>The instructions for use of autonomous mobile machinery or related products shall specify the characteristics of its intended travel, working areas and danger zones.</u>	
Annex III, 4		
4 SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS	4.— SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS	4. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS TO OFFSET HAZARDS DUE TO LIFTING OPERATIONS
Annex III, 4, first paragraph		
Machinery or related product presenting hazards due to lifting operations shall meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).	Machinery <u>or related product</u> presenting hazards due to lifting operations <u>shall</u> <del>must</del> meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).	Machinery presenting hazards due to lifting operations must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).
Annex III, 4, point (4.1), introductory part		
4.1. GENERAL	4.1. —GENERAL	4.1. GENERAL
Annex III, 4, point (4.1)(4.1.1), introductory part		
4.1.1. Definitions	4.1.1. —Definitions	4.1.1. Definitions
Annex III, 4, point (4.1)(4.1.1)(a)		
(a) 'Lifting operation' means a movement of unit loads consisting of goods and/or	(a) 'Lifting operation' means a movement of unit loads consisting of goods and/or	(a) 'Lifting operation' means a movement of unit loads consisting of goods and/or

DRAFT Machinery Regulation	Comparison	Machinery Directive
persons necessitating, at a given moment, a change of level;	persons necessitating, at a given moment, a change of level <del>;</del>	persons necessitating, at a given moment, a change of level.
Annex III, 4, point (4.1)(4.1.1)(b)		
(b) 'Guided load' means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points;	(b) 'Guided load' means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points <del>;</del>	(b) 'Guided load' means a load where the total movement is made along rigid or flexible guides whose position is determined by fixed points.
Annex III, 4, point (4.1)(4.1.1)(c)		
(c) 'Working coefficient' means the arithmetic ratio between the load guaranteed by the manufacturer up to which a component is able to hold it and the maximum working load marked on the component;	(c) 'Working coefficient' means the arithmetic ratio between the load guaranteed by the manufacturer <del>or his authorised representative</del> up to which a component is able to hold it and the maximum working load marked on the component <del>;</del>	(c) 'Working coefficient' means the arithmetic ratio between the load guaranteed by the manufacturer or his authorised representative up to which a component is able to hold it and the maximum working load marked on the component.
Annex III, 4, point (4.1)(4.1.1)(d)		
(d) 'Test coefficient' means the arithmetic ratio between the load used to carry out the static or dynamic tests on the machinery or lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory;	(d) 'Test coefficient' means the arithmetic ratio between the load used to carry out the static or dynamic tests on <del>the</del> <del>lifting</del> machinery or <del>a</del> lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory <del>;</del>	(d) 'Test coefficient' means the arithmetic ratio between the load used to carry out the static or dynamic tests on lifting machinery or a lifting accessory and the maximum working load marked on the lifting machinery or lifting accessory.
Annex III, 4, point (4.1)(4.1.1)(e)		
(e) 'Static test' means the test during which machinery or lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred;	(e) 'Static test' means the test during which <del>lifting</del> machinery or <del>a</del> lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred <del>;</del>	(e) 'Static test' means the test during which lifting machinery or a lifting accessory is first inspected and subjected to a force corresponding to the maximum working load multiplied by the appropriate static test coefficient and then re-inspected once the said load has been released to ensure that no damage has occurred.
Annex III, 4, point (4.1)(4.1.1)(f)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(f) 'Dynamic test' means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly;	(f) 'Dynamic test' means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly;	(f) 'Dynamic test' means the test during which lifting machinery is operated in all its possible configurations at the maximum working load multiplied by the appropriate dynamic test coefficient with account being taken of the dynamic behaviour of the lifting machinery in order to check that it functions properly.
Annex III, 4, point (4.1)(4.1.1)(g)		
(g) 'Carrier' means a part of the machinery or related product on or in which persons and/or goods are supported in order to be lifted.	(g) 'Carrier' means a part of the machinery <u>or related product</u> on or in which persons and/or goods are supported in order to be lifted.	(g) 'Carrier' means a part of the machinery on or in which persons and/or goods are supported in order to be lifted.
Annex III, 4, point (4.1)(4.1.2), introductory part		
4.1.2. Protection against mechanical risks	4.1.2. <del>Protection against mechanical risks</del> <del>hazards</del>	4.1.2. Protection against mechanical hazards
Annex III, 4, point (4.1)(4.1.2)(4.1.2.1), introductory part		
4.1.2.1. Risks due to lack of stability	4.1.2.1. <del>Risks due to lack of stability</del>	4.1.2.1. Risks due to lack of stability
Annex III, 4, point (4.1)(4.1.2)(4.1.2.1), first paragraph		
Machinery or related products shall be designed and constructed in such a way that the stability required by section 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instructions for use. To that end, the manufacturer shall use the appropriate verification methods.	Machinery <u>or related products shall</u> <del>must</del> be designed and constructed in such a way that the stability required by section 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the <u>instructions for use</u> . <del>instruction handbook</del> . To that end, the manufacturer <u>shall</u> <del>or his authorised</del>	Machinery must be designed and constructed in such a way that the stability required by section 1.3.1 is maintained both in service and out of service, including all stages of transportation, assembly and dismantling, during foreseeable component failures and also during the tests carried out in accordance with the instruction handbook. To that end, the manufacturer or his authorised representative must use the appropriate verification methods.

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>representative must</del> use the appropriate verification methods.	
Annex III, 4, point (4.1)(4.1.2)(4.1.2.2), introductory part		
4.1.2.2. Machinery running on guide rails and rail tracks	4.1.2.2. <del>–</del> Machinery running on guide rails and rail tracks	4.1.2.2. Machinery running on guide rails and rail tracks
Annex III, 4, point (4.1)(4.1.2)(4.1.2.2), first paragraph		
Machinery shall be provided with devices, which act on the guide rails or tracks to prevent derailment.	Machinery <del>shall</del> <u>must</u> be provided with devices, which act on the guide rails or tracks to prevent derailment.	Machinery must be provided with devices which act on the guide rails or tracks to prevent derailment.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.2), second paragraph		
If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices shall be provided which prevent the equipment, component or load from falling or the machinery from overturning.	If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices <del>shall</del> <u>must</u> be provided which prevent the equipment, component or load from falling or the machinery from overturning.	If, despite such devices, there remains a risk of derailment or of failure of a rail or of a running component, devices must be provided which prevent the equipment, component or load from falling or the machinery from overturning.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.3), introductory part		
4.1.2.3. Mechanical strength	4.1.2.3. <del>–</del> Mechanical strength	4.1.2.3. Mechanical strength
Annex III, 4, point (4.1)(4.1.2)(4.1.2.3), first paragraph		
Machinery or lifting accessories and their components shall be capable of withstanding the stresses to which they are subjected during their lifetime, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons.	Machinery <del>or</del> , lifting accessories and their components <del>shall</del> <u>must</u> be capable of withstanding the stresses to which they are subjected <u>during their lifetime</u> , both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons.	Machinery, lifting accessories and their components must be capable of withstanding the stresses to which they are subjected, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons.

DRAFT Machinery Regulation	Comparison	Machinery Directive
This requirement shall also be satisfied during transport, assembly and dismantling.	This requirement <del>shall</del> <b>must</b> also be satisfied during transport, assembly and dismantling.	This requirement must also be satisfied during transport, assembly and dismantling.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.3), second paragraph		
Machinery or lifting accessories shall be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use and any reasonably foreseeable misuse.	Machinery <del>or</del> <b>and</b> lifting accessories <del>shall</del> <b>must</b> be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use <u>and any reasonably foreseeable misuse.</u>	Machinery and lifting accessories must be designed and constructed in such a way as to prevent failure from fatigue and wear, taking due account of their intended use.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.3), third paragraph		
The materials used shall be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness, radiation and ageing.	The materials used <del>shall</del> <b>must</b> be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness, <u>radiation</u> and ageing.	The materials used must be chosen on the basis of the intended working environments, with particular regard to corrosion, abrasion, impacts, extreme temperatures, fatigue, brittleness and ageing.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.3), fourth paragraph, introductory part		
Machinery or lifting accessories shall be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations shall take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values:	Machinery <del>or</del> <b>and</b> lifting accessories <del>shall</del> <b>must</b> be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations <del>shall</del> <b>must</b> take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values:	Machinery and lifting accessories must be designed and constructed in such a way as to withstand the overload in the static tests without permanent deformation or patent defect. Strength calculations must take account of the value of the static test coefficient chosen to guarantee an adequate level of safety. That coefficient has, as a general rule, the following values:
Annex III, 4, point (4.1)(4.1.2)(4.1.2.3), fourth paragraph(a)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(a) manually-operated machinery or lifting accessories: 1, 5;	(a) manually-operated machinery <del>or</del> and lifting accessories: 1, 5;	(a) manually-operated machinery and lifting accessories: 1,5;
Annex III, 4, point (4.1)(4.1.2)(4.1.2.3), fourth paragraph(b)		
(b) other machinery or related products: 1,25.	(b) other machinery <u>or related products</u> : 1,25.	(b) other machinery: 1,25.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.3), fifth paragraph		
Machinery shall be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1,1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests shall be carried out under the least favourable conditions, as a general rule by combining the movements concerned.	Machinery <del>shall</del> must be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1,1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests <del>shall</del> must be carried out under the least favourable conditions, as a general rule by combining the movements concerned.	Machinery must be designed and constructed in such a way as to undergo, without failure, the dynamic tests carried out using the maximum working load multiplied by the dynamic test coefficient. This dynamic test coefficient is chosen so as to guarantee an adequate level of safety: the coefficient is, as a general rule, equal to 1,1. As a general rule, the tests will be performed at the nominal speeds provided for. Should the control circuit of the machinery allow for a number of simultaneous movements, the tests must be carried out under the least favourable conditions, as a general rule by combining the movements concerned.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.4), introductory part		
4.1.2.4. Pulleys, drums, wheels, ropes and chains	4.1.2.4. –Pulleys, drums, wheels, ropes and chains	4.1.2.4. Pulleys, drums, wheels, ropes and chains
Annex III, 4, point (4.1)(4.1.2)(4.1.2.4), first paragraph		
Pulleys, drums and wheels shall have a diameter commensurate with the size of	Pulleys, drums and wheels <del>shall</del> must have a diameter commensurate with the	Pulleys, drums and wheels must have a diameter commensurate with the size of

DRAFT Machinery Regulation	Comparison	Machinery Directive
the ropes or chains with which they can be fitted.	size of the ropes or chains with which they can be fitted.	the ropes or chains with which they can be fitted.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.4), second paragraph		
Drums and wheels shall be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.	Drums and wheels <del>shall</del> <b>must</b> be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.	Drums and wheels must be designed, constructed and installed in such a way that the ropes or chains with which they are equipped can be wound without coming off.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.4), third paragraph		
Ropes used directly for lifting or supporting the load shall not include any splicing other than at their ends. Splicings are, however, tolerated in installations, which are intended by design to be modified regularly according to needs of use.	Ropes used directly for lifting or supporting the load <del>shall</del> <b>must</b> not include any splicing other than at their ends. Splicings are, however, tolerated in installations, which are intended by design to be modified regularly according to needs of use.	Ropes used directly for lifting or supporting the load must not include any splicing other than at their ends. Splicings are, however, tolerated in installations which are intended by design to be modified regularly according to needs of use.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.4), fourth paragraph		
Complete ropes and their endings shall have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5.	Complete ropes and their endings <del>shall</del> <b>must</b> have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5.	Complete ropes and their endings must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 5.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.4), fifth paragraph		
Lifting chains shall have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4.	Lifting chains <del>shall</del> <b>must</b> have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4.	Lifting chains must have a working coefficient chosen in such a way as to guarantee an adequate level of safety. As a general rule, this coefficient is equal to 4.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.4), sixth paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>In order to verify that an adequate working coefficient has been attained, the manufacturer shall, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.</p>	<p>In order to verify that an adequate working coefficient has been attained, the manufacturer <del>shall or his authorised representative must</del>, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.</p>	<p>In order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of chain and rope used directly for lifting the load and for the rope ends, perform the appropriate tests or have such tests performed.</p>
<p>Annex III, 4, point (4.1)(4.1.2)(4.1.2.5), introductory part</p>		
<p>4.1.2.5. Lifting accessories and their components</p>	<p>4.1.2.5. <del>–</del>Lifting accessories and their components</p>	<p>4.1.2.5. Lifting accessories and their components</p>
<p>Annex III, 4, point (4.1)(4.1.2)(4.1.2.5), first paragraph</p>		
<p>Lifting accessories and their components shall be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application.</p>	<p>Lifting accessories and their components <del>shall</del><b>must</b> be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application.</p>	<p>Lifting accessories and their components must be sized with due regard to fatigue and ageing processes for a number of operating cycles consistent with their expected life-span as specified in the operating conditions for a given application.</p>
<p>Annex III, 4, point (4.1)(4.1.2)(4.1.2.5), second paragraph, introductory part</p>		
<p>Moreover:</p>	<p>Moreover:</p>	<p>Moreover:</p>
<p>Annex III, 4, point (4.1)(4.1.2)(4.1.2.5), second paragraph(a)</p>		
<p>(a) the working coefficient of wire-rope/rope-end combinations shall be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes shall not comprise any splices or loops other than at their ends;</p>	<p>(a) the working coefficient of wire-rope/rope-end combinations <del>shall</del><b>must</b> be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes <del>shall</del><b>must</b> not comprise any splices or loops other than at their ends;</p>	<p>(a) the working coefficient of wire-rope/rope-end combinations must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 5. Ropes must not comprise any splices or loops other than at their ends;</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 4, point (4.1)(4.1.2)(4.1.2.5), second paragraph(b)		
<p>(b) where chains with welded links are used, they shall be of the short-link type. The working coefficient of chains shall be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;</p>	<p>(b) where chains with welded links are used, they <del>shall</del><b>must</b> be of the short-link type. The working coefficient of chains <del>shall</del><b>must</b> be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;</p>	<p>(b) where chains with welded links are used, they must be of the short-link type. The working coefficient of chains must be chosen in such a way as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;</p>
Annex III, 4, point (4.1)(4.1.2)(4.1.2.5), second paragraph(c)		
<p>(c) the working coefficient for textile ropes, slings or webbing is dependent on the material, method of manufacture, dimensions and use. This coefficient shall be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes, slings or webbings shall not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;</p>	<p>(c) the working coefficient for textile ropes, <del>slings</del> or <del>webbing</del><b>slings</b> is dependent on the material, method of manufacture, dimensions and use. This coefficient <del>shall</del><b>must</b> be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes, <del>and</del> slings or webbings <del>shall</del><b>must</b> not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;</p>	<p>(c) the working coefficient for textile ropes or slings is dependent on the material, method of manufacture, dimensions and use. This coefficient must be chosen in such a way as to guarantee an adequate level of safety; it is, as a general rule, equal to 7, provided the materials used are shown to be of very good quality and the method of manufacture is appropriate to the intended use. Should this not be the case, the coefficient is, as a general rule, set at a higher level in order to secure an equivalent level of safety. Textile ropes and slings must not include any knots, connections or splicing other than at the ends of the sling, except in the case of an endless sling;</p>
Annex III, 4, point (4.1)(4.1.2)(4.1.2.5), second paragraph(d)		
<p>(d) all metallic components making up, or used with, a sling shall have a working coefficient chosen in such a way as to</p>	<p>(d) all metallic components making up, or used with, a sling <del>shall</del><b>must</b> have a working coefficient chosen in such a way</p>	<p>(d) all metallic components making up, or used with, a sling must have a working coefficient chosen in such a way as to</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;	as to guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;	guarantee an adequate level of safety; this coefficient is, as a general rule, equal to 4;
Annex III, 4, point (4.1)(4.1.2)(4.1.2.5), second paragraph(e)		
(e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;	(e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;	(e) the maximum working load of a multilegged sling is determined on the basis of the working coefficient of the weakest leg, the number of legs and a reduction factor which depends on the slinging configuration;
Annex III, 4, point (4.1)(4.1.2)(4.1.2.5), second paragraph(f)		
(f) in order to verify that an adequate working coefficient has been attained, the manufacturer shall, for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.	(f) in order to verify that an adequate working coefficient has been attained, the manufacturer <del>shall</del> <del>or his authorised representative must</del> , for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.	(f) in order to verify that an adequate working coefficient has been attained, the manufacturer or his authorised representative must, for each type of component referred to in (a), (b), (c) and (d), perform the appropriate tests or have such tests performed.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.6), introductory part		
4.1.2.6. Control of movements	4.1.2.6. –Control of movements	4.1.2.6. Control of movements
Annex III, 4, point (4.1)(4.1.2)(4.1.2.6), first paragraph, introductory part		
Devices for controlling movements shall act in such a way that the machinery or related product on which they are installed is kept safe.	Devices for controlling movements <del>shall</del> <del>must</del> act in such a way that the machinery <del>or related product</del> on which they are installed is kept safe.	Devices for controlling movements must act in such a way that the machinery on which they are installed is kept safe.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.6), first paragraph(a)		
(a) Machinery or related product shall be designed and constructed or fitted with devices in such a way that the amplitude	(a) Machinery <del>or related product</del> <del>shall</del> <del>must</del> be designed and constructed or fitted with devices in such a way that	(a) Machinery must be designed and constructed or fitted with devices in such a way that the amplitude of movement of

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>of movement of its components is kept within the specified limits. The operation of such devices shall, where appropriate, be preceded by a warning.</p>	<p>the amplitude of movement of its components is kept within the specified limits. The operation of such devices <del>shall</del><b>must</b>, where appropriate, be preceded by a warning.</p>	<p>its components is kept within the specified limits. The operation of such devices must, where appropriate, be preceded by a warning.</p>
<p>Annex III, 4, point (4.1)(4.1.2)(4.1.2.6), first paragraph(b)</p>		
<p>(b) Where several fixed or rail-mounted machinery or related product can be manoeuvred simultaneously in the same place, with risks of collision, such machinery shall be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided.</p>	<p>(b) Where several fixed or rail-mounted <u>machinery or related product</u><del>machines</del> can be manoeuvred simultaneously in the same place, with risks of collision, such machinery <del>shall</del><b>must</b> be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided.</p>	<p>(b) Where several fixed or rail-mounted machines can be manoeuvred simultaneously in the same place, with risks of collision, such machinery must be designed and constructed in such a way as to make it possible to fit systems enabling these risks to be avoided.</p>
<p>Annex III, 4, point (4.1)(4.1.2)(4.1.2.6), first paragraph(c)</p>		
<p>(c) Machinery or related product shall be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine.</p>	<p>(c) Machinery <u>or related product</u> <del>shall</del><b>must</b> be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine.</p>	<p>(c) Machinery must be designed and constructed in such a way that the loads cannot creep dangerously or fall freely and unexpectedly, even in the event of partial or total failure of the power supply or when the operator stops operating the machine.</p>
<p>Annex III, 4, point (4.1)(4.1.2)(4.1.2.6), first paragraph(d)</p>		
<p>(d) It shall not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery or related product whose function requires it to operate in that way.</p>	<p>(d) It <del>shall</del><b>must</b> not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery <u>or related product</u> whose function requires it to operate in that way.</p>	<p>(d) It must not be possible, under normal operating conditions, to lower the load solely by friction brake, except in the case of machinery whose function requires it to operate in that way.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 4, point (4.1)(4.1.2)(4.1.2.6), first paragraph(e)		
(e) Holding devices shall be designed and constructed in such a way that inadvertent dropping of the loads is avoided.	(e) Holding devices <del>shall</del> <b>must</b> be designed and constructed in such a way that inadvertent dropping of the loads is avoided.	(e) Holding devices must be designed and constructed in such a way that inadvertent dropping of the loads is avoided.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.7), introductory part		
4.1.2.7. Movements of loads during handling	4.1.2.7. <del>–</del> Movements of loads during handling	4.1.2.7. Movements of loads during handling
Annex III, 4, point (4.1)(4.1.2)(4.1.2.7), first paragraph		
The operating position of machinery shall be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery, which might be manoeuvring at the same time and liable to constitute a hazard.	The operating position of machinery <del>shall</del> <b>must</b> be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery, which might be manoeuvring at the same time and liable to constitute a hazard.	The operating position of machinery must be located in such a way as to ensure the widest possible view of trajectories of the moving parts, in order to avoid possible collisions with persons, equipment or other machinery which might be manoeuvring at the same time and liable to constitute a hazard.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.7), second paragraph		
Machinery with guided loads shall be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.	Machinery with guided loads <del>shall</del> <b>must</b> be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.	Machinery with guided loads must be designed and constructed in such a way as to prevent persons from being injured by movement of the load, the carrier or the counterweights, if any.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8), introductory part		
4.1.2.8. Machinery serving fixed landings	4.1.2.8. <del>–</del> Machinery serving fixed landings	4.1.2.8. Machinery serving fixed landings
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.1), introductory part		
4.1.2.8.1. Movements of the carrier	4.1.2.8.1. <del>–</del> Movements of the carrier	4.1.2.8.1. Movements of the carrier

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.1), first paragraph		
The movement of the carrier of machinery serving fixed landings shall be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.	The movement of the carrier of machinery serving fixed landings shall <del>must</del> be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.	The movement of the carrier of machinery serving fixed landings must be rigidly guided to and at the landings. Scissor systems are also regarded as rigid guidance.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.2), introductory part		
4.1.2.8.2. Access to the carrier	4.1.2.8.2. <del>–</del> Access to the carrier	4.1.2.8.2. Access to the carrier
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.2), first paragraph		
Where persons have access to the carrier, the machinery shall be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded.	Where persons have access to the carrier, the machinery shall <del>must</del> be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded.	Where persons have access to the carrier, the machinery must be designed and constructed in such a way as to ensure that the carrier remains stationary during access, in particular while it is being loaded or unloaded.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.2), second paragraph		
The machinery shall be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.	The machinery shall <del>must</del> be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.	The machinery must be designed and constructed in such a way as to ensure that the difference in level between the carrier and the landing being served does not create a risk of tripping.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.3), introductory part		
4.1.2.8.3. Risks due to contact with the moving carrier	4.1.2.8.3. <del>–</del> Risks due to contact with the moving carrier	4.1.2.8.3. Risks due to contact with the moving carrier

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.3), first paragraph		
Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone shall be rendered inaccessible during normal operation.	Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone <del>shall</del> <b>must</b> be rendered inaccessible during normal operation.	Where necessary in order to fulfil the requirement expressed in the second paragraph of section 4.1.2.7, the travel zone must be rendered inaccessible during normal operation.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.3), second paragraph		
When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space shall be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.	When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space <del>shall</del> <b>must</b> be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.	When, during inspection or maintenance, there is a risk that persons situated under or above the carrier may be crushed between the carrier and any fixed parts, sufficient free space must be provided either by means of physical refuges or by means of mechanical devices blocking the movement of the carrier.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.4), introductory part		
4.1.2.8.4. Risk due to the load falling off the carrier	4.1.2.8.4. <del>–</del> Risk due to the load falling off the carrier	4.1.2.8.4. Risk due to the load falling off the carrier
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.4), first paragraph		
Where there is a risk due to the load falling off the carrier, the machinery shall be designed and constructed in such a way as to prevent this risk.	Where there is a risk due to the load falling off the carrier, the machinery <del>shall</del> <b>must</b> be designed and constructed in such a way as to prevent this risk.	Where there is a risk due to the load falling off the carrier, the machinery must be designed and constructed in such a way as to prevent this risk.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.5), introductory part		
4.1.2.8.5. Landings	4.1.2.8.5. –Landings	4.1.2.8.5. Landings
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.5), first paragraph		
Risks due to contact of persons at landings with the moving carrier or other moving parts shall be prevented.	Risks due to contact of persons at landings with the moving carrier or other moving parts <del>shall</del> <b>must</b> be prevented.	Risks due to contact of persons at landings with the moving carrier or other moving parts must be prevented.
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.5), second paragraph, introductory part		
Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards shall be fitted in order to prevent this risk. Such guards shall not open in the direction of the travel zone. They shall be fitted with an interlocking device controlled by the position of the carrier that prevents:	Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards <del>shall</del> <b>must</b> be fitted in order to prevent this risk. Such guards <del>shall</del> <b>must</b> not open in the direction of the travel zone. They <del>shall</del> <b>must</b> be fitted with an interlocking device controlled by the position of the carrier that prevents:	Where there is a risk due to persons falling into the travel zone when the carrier is not present at the landings, guards must be fitted in order to prevent this risk. Such guards must not open in the direction of the travel zone. They must be fitted with an interlocking device controlled by the position of the carrier that prevents:
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.5), second paragraph(a)		
(a) hazardous movements of the carrier until the guards are closed and locked;	<u>(a)</u> — hazardous movements of the carrier until the guards are closed and locked; <sup>7</sup>	— hazardous movements of the carrier until the guards are closed and locked,
Annex III, 4, point (4.1)(4.1.2)(4.1.2.8)(4.1.2.8.5), second paragraph(b)		
(b) hazardous opening of a guard until the carrier has stopped at the corresponding landing.	<u>(b)</u> — hazardous opening of a guard until the carrier has stopped at the corresponding landing.	— hazardous opening of a guard until the carrier has stopped at the corresponding landing.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 4, point (4.1)(4.1.3), introductory part		
4.1.3. Fitness for purpose	4.1.3. <del>–</del> Fitness for purpose	4.1.3. Fitness for purpose
Annex III, 4, point (4.1)(4.1.3), first paragraph		
<p>When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer shall ensure, by taking appropriate measures or having them taken, that the machinery or lifting accessories which are ready for use — whether manually or power-operated — can fulfil their specified functions safely.</p>	<p>When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer <del>shall</del><del>or his authorised representative must</del> ensure, by taking appropriate measures or having them taken, that the machinery or <del>the</del> lifting accessories which are ready for use — whether manually or power-operated — can fulfil their specified functions safely.</p>	<p>When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer or his authorised representative must ensure, by taking appropriate measures or having them taken, that the machinery or the lifting accessories which are ready for use — whether manually or power-operated — can fulfil their specified functions safely.</p>
Annex III, 4, point (4.1)(4.1.3), second paragraph		
<p>The static and dynamic tests referred to in section 4.1.2.3 shall be performed on all lifting machinery ready to be put into service.</p>	<p>The static and dynamic tests referred to in section 4.1.2.3 <del>shall</del><del>must</del> be performed on all lifting machinery ready to be put into service.</p>	<p>The static and dynamic tests referred to in section 4.1.2.3 must be performed on all lifting machinery ready to be put into service.</p>
Annex III, 4, point (4.1)(4.1.3), third paragraph		
<p>Where the machinery cannot be assembled in the manufacturer's premises, the appropriate measures shall be taken at the place of use by the manufacturer. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.</p>	<p>Where the machinery cannot be assembled in the manufacturer's premises <del>or in the premises of his authorised representative</del>, the appropriate measures <del>shall</del><del>must</del> be taken at the place of use <u>by the manufacturer.</u> Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.</p>	<p>Where the machinery cannot be assembled in the manufacturer's premises or in the premises of his authorised representative, the appropriate measures must be taken at the place of use. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.</p>
Annex III, 4, point (4.2), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
4.2. REQUIREMENTS FOR MACHINERY OR RELATED PRODUCTS WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT	4.2. <del>REQUIREMENTS</del> FOR MACHINERY <u>OR RELATED PRODUCTS</u> WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT	4.2. REQUIREMENTS FOR MACHINERY WHOSE POWER SOURCE IS OTHER THAN MANUAL EFFORT
Annex III, 4, point (4.2)(4.2.1), introductory part		
4.2.1. Control of movements	4.2.1. <del>Control of movements</del>	4.2.1. Control of movements
Annex III, 4, point (4.2)(4.2.1), first paragraph		
Hold-to-run control devices shall be used to control the movements of the machinery or related product or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery or related product colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.	Hold-to-run control devices <del>shall</del> <b>must</b> be used to control the movements of the machinery <u>or related product</u> or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery <u>or related product</u> colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.	Hold-to-run control devices must be used to control the movements of the machinery or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.
Annex III, 4, point (4.2)(4.2.2), introductory part		
4.2.2. Loading control	4.2.2. <del>Loading control</del>	4.2.2. Loading control
Annex III, 4, point (4.2)(4.2.2), first paragraph, introductory part		
Machinery or related product with a maximum working load of not less than 1 000 kilograms or an overturning moment of not less than 40 000 Nm shall be fitted with devices to warn the driver and prevent dangerous movements in the event:	Machinery <u>or related product</u> with a maximum working load of not less than 1 000 kilograms or an overturning moment of not less than 40 000 Nm <del>shall</del> <b>must</b> be fitted with devices to warn the driver and prevent dangerous movements in the event:	Machinery with a maximum working load of not less than 1 000 kilograms or an overturning moment of not less than 40 000 Nm must be fitted with devices to warn the driver and prevent dangerous movements in the event:
Annex III, 4, point (4.2)(4.2.2), first paragraph(a)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(a) of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded, or	(a) — of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded, or	— of overloading, either as a result of the maximum working load or the maximum working moment due to the load being exceeded, or
Annex III, 4, point (4.2)(4.2.2), first paragraph(b)		
(b) of the overturning moment being exceeded.	(b) — of the overturning moment being exceeded.	— of the overturning moment being exceeded.
Annex III, 4, point (4.2)(4.2.3), introductory part		
4.2.3. Installations guided by ropes	4.2.3. —Installations guided by ropes	4.2.3. Installations guided by ropes
Annex III, 4, point (4.2)(4.2.3), first paragraph		
Rope carriers, tractors or tractor carriers shall be held by counterweights or by a device allowing permanent control of the tension.	Rope carriers, tractors or tractor carriers shall <del>must</del> be held by counterweights or by a device allowing permanent control of the tension.	Rope carriers, tractors or tractor carriers must be held by counterweights or by a device allowing permanent control of the tension.
Annex III, 4, point (4.3), introductory part		
4.3. INFORMATION AND MARKINGS	4.3. —INFORMATION AND MARKINGS	4.3. INFORMATION AND MARKINGS
Annex III, 4, point (4.3)(4.3.1), introductory part		
4.3.1. Chains, ropes and webbing	4.3.1. —Chains, ropes and webbing	4.3.1. Chains, ropes and webbing
Annex III, 4, point (4.3)(4.3.1), first paragraph		
Each length of lifting chain, rope or webbing not forming part of an assembly shall bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer and the identifying reference of the relevant certificate.	Each length of lifting chain, rope or webbing not forming part of an assembly shall <del>must</del> bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer <del>or his authorised representative</del> and the identifying reference of the relevant certificate.	Each length of lifting chain, rope or webbing not forming part of an assembly must bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his authorised representative and the identifying reference of the relevant certificate.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 4, point (4.3)(4.3.1), second paragraph, introductory part		
The certificate mentioned above shall show at least the following information:	The certificate mentioned above <del>shall</del> <b>must</b> show at least the following information:	The certificate mentioned above must show at least the following information:
Annex III, 4, point (4.3)(4.3.1), second paragraph(a)		
(a) the name and address of the manufacturer;	(a) the name and address of the manufacturer <del>and, if appropriate, his authorised representative;</del>	(a) the name and address of the manufacturer and, if appropriate, his authorised representative;
Annex III, 4, point (4.3)(4.3.1), second paragraph(b), introductory part		
(b) a description of the chain or rope, which includes:	(b) a description of the chain or rope, which includes:	(b) a description of the chain or rope which includes:
Annex III, 4, point (4.3)(4.3.1), second paragraph(b)(i)		
i. its nominal size,	<del>i.</del> — its nominal size,	— its nominal size,
Annex III, 4, point (4.3)(4.3.1), second paragraph(b)(ii)		
ii. its construction,	<del>ii.</del> — its construction,	— its construction,
Annex III, 4, point (4.3)(4.3.1), second paragraph(b)(iii)		
iii. the material from which it is made, and	<del>iii.</del> — the material from which it is made, and	— the material from which it is made, and
Annex III, 4, point (4.3)(4.3.1), second paragraph(b)(iv)		
iv. any special metallurgical treatment applied to the material;	<del>iv.</del> — any special metallurgical treatment applied to the material;	— any special metallurgical treatment applied to the material;
Annex III, 4, point (4.3)(4.3.1), second paragraph(c)		
(c) the test method used;	(c) the test method used;	(c) the test method used;
Annex III, 4, point (4.3)(4.3.1), second paragraph(d)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.	(d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.	(d) the maximum load to which the chain or rope should be subjected in service. A range of values may be given on the basis of the intended applications.
Annex III, 4, point (4.3)(4.3.2), introductory part		
4.3.2. Lifting accessories	4.3.2. <del>—</del> Lifting accessories	4.3.2. Lifting accessories
Annex III, 4, point (4.3)(4.3.2), first paragraph, introductory part		
Lifting accessories shall show the following particulars:	Lifting accessories <del>shall</del> <b>must</b> show the following particulars:	Lifting accessories must show the following particulars:
Annex III, 4, point (4.3)(4.3.2), first paragraph(i)		
i. identification of the material where this information is needed for safe use;	i. <del>—</del> identification of the material where this information is needed for safe use <del>;</del> ;	— identification of the material where this information is needed for safe use,
Annex III, 4, point (4.3)(4.3.2), first paragraph(ii)		
ii. the maximum working load.	ii. <del>—</del> the maximum working load.	— the maximum working load.
Annex III, 4, point (4.3)(4.3.2), second paragraph		
In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph shall be displayed on a plate or other equivalent means and securely affixed to the accessory.	In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph <del>shall</del> <b>must</b> be displayed on a plate or other equivalent means and securely affixed to the accessory.	In the case of lifting accessories on which marking is physically impossible, the particulars referred to in the first paragraph must be displayed on a plate or other equivalent means and securely affixed to the accessory.
Annex III, 4, point (4.3)(4.3.2), third paragraph		
The particulars shall be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.	The particulars <del>shall</del> <b>must</b> be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.	The particulars must be legible and located in a place where they are not liable to disappear as a result of wear or jeopardise the strength of the accessory.

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 4, point (4.3)(4.3.3), introductory part		
4.3.3. Lifting machinery	4.3.3. <del>Lifting</del> machinery	4.3.3. Lifting machinery
Annex III, 4, point (4.3)(4.3.3), first paragraph		
The maximum working load shall be prominently marked on the lifting machinery. This marking shall be legible, indelible and in an un-coded form.	The maximum working load <del>shall</del> <b>must</b> be prominently marked on the <u>lifting</u> machinery. This marking <del>shall</del> <b>must</b> be legible, indelible and in an un-coded form.	The maximum working load must be prominently marked on the machinery. This marking must be legible, indelible and in an un-coded form.
Annex III, 4, point (4.3)(4.3.3), second paragraph		
Where the maximum working load depends on the configuration of the lifting machinery, each operating position shall be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration.	Where the maximum working load depends on the configuration of the <u>lifting</u> machinery, each operating position <del>shall</del> <b>must</b> be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration.	Where the maximum working load depends on the configuration of the machinery, each operating position must be provided with a load plate indicating, preferably in diagrammatic form or by means of tables, the working load permitted for each configuration.
Annex III, 4, point (4.3)(4.3.3), third paragraph		
Machinery intended for lifting goods only, equipped with a carrier, which allows access to persons, shall bear a clear and indelible warning prohibiting the lifting of persons. This warning shall be visible at each place where access is possible.	Machinery intended for lifting goods only, equipped with a carrier, which allows access to persons, <del>shall</del> <b>must</b> bear a clear and indelible warning prohibiting the lifting of persons. This warning <del>shall</del> <b>must</b> be visible at each place where access is possible.	Machinery intended for lifting goods only, equipped with a carrier which allows access to persons, must bear a clear and indelible warning prohibiting the lifting of persons. This warning must be visible at each place where access is possible.
Annex III, 4, point (4.4), introductory part		
4.4. INSTRUCTIONS FOR USE	4.4. <del>INSTRUCTIONS FOR USE</del>	4.4. INSTRUCTIONS
Annex III, 4, point (4.4)(4.4.1), introductory part		
4.4.1. Lifting accessories	4.4.1. <del>Lifting</del> accessories	4.4.1. Lifting accessories

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 4, point (4.4)(4.4.1), first paragraph, introductory part		
Each lifting accessory or each commercially indivisible batch of lifting accessories shall be accompanied by instructions setting out at least the following particulars:	Each lifting accessory or each commercially indivisible batch of lifting accessories <del>shall</del> <b>must</b> be accompanied by instructions setting out at least the following particulars:	Each lifting accessory or each commercially indivisible batch of lifting accessories must be accompanied by instructions setting out at least the following particulars:
Annex III, 4, point (4.4)(4.4.1), first paragraph(a)		
(a) the intended use;	(a) the intended use;	(a) the intended use;
Annex III, 4, point (4.4)(4.4.1), first paragraph(b)		
(b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e));	(b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e));	(b) the limits of use (particularly for lifting accessories such as magnetic or vacuum pads which do not fully comply with section 4.1.2.6(e));
Annex III, 4, point (4.4)(4.4.1), first paragraph(c)		
(c) instructions for assembly, use and maintenance;	(c) instructions for assembly, use and maintenance;	(c) instructions for assembly, use and maintenance;
Annex III, 4, point (4.4)(4.4.1), first paragraph(d)		
(d) the static test coefficient used.	(d) the static test coefficient used.	(d) the static test coefficient used.
Annex III, 4, point (4.4)(4.4.2), introductory part		
4.4.2. Lifting machinery	4.4.2. <del>Lifting machinery</del>	4.4.2. Lifting machinery
Annex III, 4, point (4.4)(4.4.2), first paragraph, introductory part		
Lifting machinery shall be accompanied by instructions for use containing information on:	Lifting machinery <del>shall</del> <b>must</b> be accompanied by instructions <u>for use</u> containing information on:	Lifting machinery must be accompanied by instructions containing information on:
Annex III, 4, point (4.4)(4.4.2), first paragraph(a), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(a) the technical characteristics of the lifting machinery, and in particular:	(a) the technical characteristics of the <u>lifting</u> machinery, and in particular:	(a) the technical characteristics of the machinery, and in particular:
Annex III, 4, point (4.4)(4.4.2), first paragraph(a)(i)		
i. the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3,	i.— the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3,	— the maximum working load and, where appropriate, a copy of the load plate or load table described in the second paragraph of section 4.3.3,
Annex III, 4, point (4.4)(4.4.2), first paragraph(a)(ii)		
ii. the reactions at the supports or anchors and, where appropriate, characteristics of the tracks,	ii.— the reactions at the supports or anchors and, where appropriate, characteristics of the tracks,	— the reactions at the supports or anchors and, where appropriate, characteristics of the tracks,
Annex III, 4, point (4.4)(4.4.2), first paragraph(a)(iii)		
iii. where appropriate, the definition and the means of installation of the ballast;	iii.— where appropriate, the definition and the means of installation of the ballast;	— where appropriate, the definition and the means of installation of the ballast;
Annex III, 4, point (4.4)(4.4.2), first paragraph(b)		
(b) the contents of the logbook, if the latter is not supplied with the lifting machinery;	(b) the contents of the logbook, if the latter is not supplied with the <u>lifting</u> machinery;	(b) the contents of the logbook, if the latter is not supplied with the machinery;
Annex III, 4, point (4.4)(4.4.2), first paragraph(c)		
(c) advice for use, particularly to offset the lack of direct vision of the load by the operator;	(c) advice for use, particularly to offset the lack of direct vision of the load by the operator;	(c) advice for use, particularly to offset the lack of direct vision of the load by the operator;
Annex III, 4, point (4.4)(4.4.2), first paragraph(d)		
(d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer ;	(d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer <del>;</del> <b>his authorised representative;</b>	(d) where appropriate, a test report detailing the static and dynamic tests carried out by or for the manufacturer or his authorised representative;

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 4, point (4.4)(4.4.2), first paragraph(e)		
(e) for lifting machinery, which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before it is first put into service.	(e) for <u>lifting</u> machinery, which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before it is first put into service.	(e) for machinery which is not assembled on the premises of the manufacturer in the form in which it is to be used, the necessary instructions for performing the measures referred to in section 4.1.3 before it is first put into service.
Annex III, 5		
5 SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY OR RELATED PRODUCTS INTENDED FOR UNDERGROUND WORK	5— SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY <u>OR RELATED PRODUCTS</u> INTENDED FOR UNDERGROUND WORK	5. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY INTENDED FOR UNDERGROUND WORK
Annex III, 5, first paragraph		
Machinery or related product intended for underground work shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).	Machinery <u>or related product</u> intended for underground work <del>shall</del> <b>must</b> meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).	Machinery intended for underground work must meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).
Annex III, 5, point (5.1), introductory part		
5.1. RISKS DUE TO LACK OF STABILITY	5.1. <del>—</del> RISKS DUE TO LACK OF STABILITY	5.1. RISKS DUE TO LACK OF STABILITY
Annex III, 5, point (5.1), first paragraph		
Powered roof supports shall be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They shall be equipped with anchorages for the top plates of the individual hydraulic props.	Powered roof supports <del>shall</del> <b>must</b> be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They <del>shall</del> <b>must</b> be equipped with anchorages for the top plates of the individual hydraulic props.	Powered roof supports must be designed and constructed in such a way as to maintain a given direction when moving and not slip before and while they come under load and after the load has been removed. They must be equipped with anchorages for the top plates of the individual hydraulic props.
Annex III, 5, point (5.2), introductory part		
5.2. MOVEMENT	5.2. <del>—</del> MOVEMENT	5.2. MOVEMENT

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 5, point (5.2), first paragraph		
Powered roof supports shall allow for unhindered movement of persons.	Powered roof supports <del>shall</del> <b>must</b> allow for unhindered movement of persons.	Powered roof supports must allow for unhindered movement of persons.
Annex III, 5, point (5.3), introductory part		
5.3. CONTROL DEVICES	5.3. <del>-</del> CONTROL DEVICES	5.3. CONTROL DEVICES
Annex III, 5, point (5.3), first paragraph		
The accelerator and brake controls for movement of machinery running on rails shall be hand-operated. However, enabling devices may be foot-operated.	The accelerator and brake controls for movement of machinery running on rails <del>shall</del> <b>must</b> be hand-operated. However, enabling devices may be foot-operated.	The accelerator and brake controls for movement of machinery running on rails must be hand-operated. However, enabling devices may be foot-operated.
Annex III, 5, point (5.3), second paragraph		
The control devices of powered roof supports shall be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices shall be protected against any accidental release.	The control devices of powered roof supports <del>shall</del> <b>must</b> be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices <del>shall</del> <b>must</b> be protected against any accidental release.	The control devices of powered roof supports must be designed and positioned in such a way that, during displacement operations, operators are sheltered by a support in place. The control devices must be protected against any accidental release.
Annex III, 5, point (5.4), introductory part		
5.4. STOPPING	5.4. <del>-</del> STOPPING	5.4. STOPPING
Annex III, 5, point (5.4), first paragraph		
Self-propelled machinery running on rails for use in underground work shall be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement.	Self-propelled machinery running on rails for use in underground work <del>shall</del> <b>must</b> be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement.	Self-propelled machinery running on rails for use in underground work must be equipped with an enabling device acting on the circuit controlling the movement of the machinery such that movement is stopped if the driver is no longer in control of the movement.
Annex III, 5, point (5.5), introductory part		
5.5. FIRE	5.5. <del>-</del> FIRE	5.5. FIRE
Annex III, 5, point (5.5), first paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
Section 3.5.2 (b) is mandatory in respect of machinery or related product, which comprises highly flammable parts.	<del>Section</del> The second indent of section 3.5.2 (b) is mandatory in respect of machinery <u>or related product</u> , which comprises highly flammable parts.	The second indent of section 3.5.2 is mandatory in respect of machinery which comprises highly flammable parts.
Annex III, 5, point (5.5), second paragraph		
The braking system of machinery or related product intended for use in underground workings shall be designed and constructed in such a way that it does not produce sparks or cause fires.	The braking system of machinery <u>or related product</u> intended for use in underground workings <del>shall</del> <b>must</b> be designed and constructed in such a way that it does not produce sparks or cause fires.	The braking system of machinery intended for use in underground workings must be designed and constructed in such a way that it does not produce sparks or cause fires.
Annex III, 5, point (5.5), third paragraph		
Machinery or related product with internal combustion engines for use in underground workings shall be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.	Machinery <u>or related product</u> with internal combustion engines for use in underground workings <del>shall</del> <b>must</b> be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.	Machinery with internal combustion engines for use in underground workings must be fitted only with engines using fuel with a low vaporising pressure and which exclude any spark of electrical origin.
Annex III, 5, point (5.6), introductory part		
5.6. EXHAUST EMISSIONS	5.6. <del>EXHAUST EMISSIONS</del>	5.6. EXHAUST EMISSIONS
Annex III, 5, point (5.6), first paragraph		
Exhaust emissions from internal combustion engines shall not be discharged upwards.	Exhaust emissions from internal combustion engines <del>shall</del> <b>must</b> not be discharged upwards.	Exhaust emissions from internal combustion engines must not be discharged upwards.
Annex III, 6		
6 SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY OR RELATED PRODUCTS PRESENTING PARTICULAR RISKS DUE TO THE LIFTING OF PERSONS	<del>6</del> SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY <u>OR RELATED PRODUCTS</u> PRESENTING PARTICULAR <del>RISKS</del> <b>HAZARDS</b> DUE TO THE LIFTING OF PERSONS	6. SUPPLEMENTARY ESSENTIAL HEALTH AND SAFETY REQUIREMENTS FOR MACHINERY PRESENTING PARTICULAR HAZARDS DUE TO THE LIFTING OF PERSONS
Annex III, 6, first paragraph		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Machinery or related product presenting risks due to the lifting of persons shall meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).</p>	<p>Machinery <u>or related product</u> presenting <del>risks</del><del>hazards</del> due to the lifting of persons <u>shall</u><del>must</del> meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).</p>	<p>Machinery presenting hazards due to the lifting of persons must meet all the relevant essential health and safety requirements described in this chapter (see General Principles, point 4).</p>
<p>Annex III, 6, point (6.1), introductory part</p>		
<p>6.1. GENERAL</p>	<p>6.1. –GENERAL</p>	<p>6.1. GENERAL</p>
<p>Annex III, 6, point (6.1)(6.1.1), introductory part</p>		
<p>6.1.1. Mechanical strength</p>	<p>6.1.1. –Mechanical strength</p>	<p>6.1.1. Mechanical strength</p>
<p>Annex III, 6, point (6.1)(6.1.1), first paragraph</p>		
<p>The carrier, including any trapdoors, shall be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.</p>	<p>The carrier, including any trapdoors, <u>shall</u><del>must</del> be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.</p>	<p>The carrier, including any trapdoors, must be designed and constructed in such a way as to offer the space and strength corresponding to the maximum number of persons permitted on the carrier and the maximum working load.</p>
<p>Annex III, 6, point (6.1)(6.1.1), second paragraph</p>		
<p>The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery or related product intended for the lifting of persons and shall, as a general rule, be doubled. Machinery or related product intended for lifting persons or persons and goods shall be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.</p>	<p>The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery <u>or related product</u> intended for the lifting of persons and <u>shall</u><del>must</del>, as a general rule, be doubled. Machinery <u>or related product</u> intended for lifting persons or persons and goods <u>shall</u><del>must</del> be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.</p>	<p>The working coefficients for components set out in sections 4.1.2.4 and 4.1.2.5 are inadequate for machinery intended for the lifting of persons and must, as a general rule, be doubled. Machinery intended for lifting persons or persons and goods must be fitted with a suspension or supporting system for the carrier designed and constructed in such a way as to ensure an adequate overall level of safety and to prevent the risk of the carrier falling.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 6, point (6.1)(6.1.1), third paragraph		
If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.	If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.	If ropes or chains are used to suspend the carrier, as a general rule, at least two independent ropes or chains are required, each with its own anchorage.
Annex III, 6, point (6.1)(6.1.2), introductory part		
6.1.2. Loading control for machinery or related products moved by power other than human strength	6.1.2. <del>–</del> Loading control for machinery <u>or related products</u> moved by power other than human strength	6.1.2. Loading control for machinery moved by power other than human strength
Annex III, 6, point (6.1)(6.1.2), first paragraph		
The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.	The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.	The requirements of section 4.2.2 apply regardless of the maximum working load and overturning moment, unless the manufacturer can demonstrate that there is no risk of overloading or overturning.
Annex III, 6, point (6.2), introductory part		
6.2. CONTROL DEVICES	6.2. <del>–</del> CONTROL DEVICES	6.2. CONTROL DEVICES
Annex III, 6, point (6.2), first paragraph		
Where safety requirements do not impose other solutions, the carrier shall, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.	Where safety requirements do not impose other solutions, the carrier <del>shall</del> <b>must</b> , as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.	Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.
Annex III, 6, point (6.2), second paragraph		
In operation, those control devices shall override any other devices controlling the same movement with the exception of emergency stop devices.	In operation, those control devices <del>shall</del> <b>must</b> override any other devices controlling the same movement with the exception of emergency stop devices.	In operation, those control devices must override any other devices controlling the same movement with the exception of emergency stop devices.

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Annex III, 6, point (6.2), third paragraph</p> <p>The control devices for the movements referred to in the first paragraph shall be of the hold-to-run type except where the carrier is completely enclosed. If there is no risk of persons or objects on the carrier colliding or falling and no other risks due to the upward and downward movements of the carrier, control devices authorising automatic stops at preselected positions may be used instead of hold-to-run type control devices</p>	<p>The control devices for <del>the</del><u>these</u> movements <u>referred to in the first paragraph shall</u><del>must</del> be of the hold-to-run type except where the carrier <del>itself</del> is completely enclosed. <u>If there is no risk of persons or objects on the carrier colliding or falling and no other risks due to the upward and downward movements of the carrier, control devices authorising automatic stops at preselected positions may be used instead of hold-to-run type control devices</u></p>	<p>The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed.</p>
<p>Annex III, 6, point (6.3), introductory part</p>		
<p>6.3. RISKS TO PERSONS IN OR ON THE CARRIER</p>	<p>6.3. <del>–</del>RISKS TO PERSONS IN OR ON THE CARRIER</p>	<p>6.3. RISKS TO PERSONS IN OR ON THE CARRIER</p>
<p>Annex III, 6, point (6.3)(6.3.1), introductory part</p>		
<p>6.3.1. Risks due to movements of the carrier</p>	<p>6.3.1. <del>–</del>Risks due to movements of the carrier</p>	<p>6.3.1. Risks due to movements of the carrier</p>
<p>Annex III, 6, point (6.3)(6.3.1), first paragraph</p>		
<p>Machinery or related product for lifting persons shall be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.</p>	<p>Machinery <u>or related product</u> for lifting persons <del>shall</del><u>must</u> be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.</p>	<p>Machinery for lifting persons must be designed, constructed or equipped in such a way that the acceleration or deceleration of the carrier does not engender risks for persons.</p>
<p>Annex III, 6, point (6.3)(6.3.2), introductory part</p>		
<p>6.3.2. Risk of persons falling from the carrier</p>	<p>6.3.2. <del>–</del>Risk of persons falling from the carrier</p>	<p>6.3.2. Risk of persons falling from the carrier</p>
<p>Annex III, 6, point (6.3)(6.3.2), first paragraph</p>		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>The carrier shall not tilt to an extent, which creates a risk of the occupants falling, including when the machinery or related product and carrier are moving.</p>	<p>The carrier <del>shall</del><b>must</b> not tilt to an extent, which creates a risk of the occupants falling, including when the machinery <u>or related product</u> and carrier are moving.</p>	<p>The carrier must not tilt to an extent which creates a risk of the occupants falling, including when the machinery and carrier are moving.</p>
<p>Annex III, 6, point (6.3)(6.3.2), second paragraph</p>		
<p>Where the carrier is designed as a workstation, provision shall be made to ensure stability and to prevent hazardous movements.</p>	<p>Where the carrier is designed as a <del>workstation</del><b>work station</b>, provision <del>shall</del><b>must</b> be made to ensure stability and to prevent hazardous movements.</p>	<p>Where the carrier is designed as a work station, provision must be made to ensure stability and to prevent hazardous movements.</p>
<p>Annex III, 6, point (6.3)(6.3.2), third paragraph</p>		
<p>If the measures referred to in section 1.5.15 are not adequate, carriers shall be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points shall be strong enough for the use of personal protective equipment against falls from a height.</p>	<p>If the measures referred to in section 1.5.15 are not adequate, carriers <del>shall</del><b>must</b> be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points <del>shall</del><b>must</b> be strong enough for the use of personal protective equipment against falls from a height.</p>	<p>If the measures referred to in section 1.5.15 are not adequate, carriers must be fitted with a sufficient number of suitable anchorage points for the number of persons permitted on the carrier. The anchorage points must be strong enough for the use of personal protective equipment against falls from a height.</p>
<p>Annex III, 6, point (6.3)(6.3.2), fourth paragraph</p>		
<p>Any trapdoor in floors or ceilings or side doors shall be designed and constructed in such a way as to prevent inadvertent opening and shall open in a direction that obviates any risk of falling, should they open unexpectedly.</p>	<p>Any trapdoor in floors or ceilings or side doors <del>shall</del><b>must</b> be designed and constructed in such a way as to prevent inadvertent opening and <del>shall</del><b>must</b> open in a direction that obviates any risk of falling, should they open unexpectedly.</p>	<p>Any trapdoor in floors or ceilings or side doors must be designed and constructed in such a way as to prevent inadvertent opening and must open in a direction that obviates any risk of falling, should they open unexpectedly.</p>
<p>Annex III, 6, point (6.3)(6.3.3), introductory part</p>		
<p>6.3.3. Risk due to objects falling on the carrier</p>	<p>6.3.3. <del>–</del>Risk due to objects falling on the carrier</p>	<p>6.3.3. Risk due to objects falling on the carrier</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex III, 6, point (6.3)(6.3.3), first paragraph		
Where there is a risk of objects falling on the carrier and endangering persons, the carrier shall be equipped with a protective roof.	Where there is a risk of objects falling on the carrier and endangering persons, the carrier <del>shall</del> <b>must</b> be equipped with a protective roof.	Where there is a risk of objects falling on the carrier and endangering persons, the carrier must be equipped with a protective roof.
Annex III, 6, point (6.4), introductory part		
6.4. MACHINERY OR RELATED PRODUCTS SERVING FIXED LANDINGS	6.4. <del>MACHINERY OR RELATED PRODUCTS SERVING FIXED LANDINGS</del>	6.4. MACHINERY SERVING FIXED LANDINGS
Annex III, 6, point (6.4)(6.4.1), introductory part		
6.4.1. Risks to persons in or on the carrier	6.4.1. <del>Risks to persons in or on the carrier</del>	6.4.1. Risks to persons in or on the carrier
Annex III, 6, point (6.4)(6.4.1), first paragraph		
The carrier shall be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself shall be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors shall remain closed if the carrier stops between landings where there is a risk of falling from the carrier.	The carrier <del>shall</del> <b>must</b> be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself <del>shall</del> <b>must</b> be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors <del>shall</del> <b>must</b> remain closed if the carrier stops between landings where there is a risk of falling from the carrier.	The carrier must be designed and constructed in such a way as to prevent risks due to contact between persons and/or objects in or on the carrier with any fixed or moving elements. Where necessary in order to fulfil this requirement, the carrier itself must be completely enclosed with doors fitted with an interlocking device that prevents hazardous movements of the carrier unless the doors are closed. The doors must remain closed if the carrier stops between landings where there is a risk of falling from the carrier.
Annex III, 6, point (6.4)(6.4.1), second paragraph		
Machinery or related product shall be designed, constructed and, where necessary, equipped with devices in such	<del>Machinery or related product shall</del> <b>The machinery must</b> be designed, constructed and, where necessary,	The machinery must be designed, constructed and, where necessary, equipped with devices in such a way as

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>a way as to prevent uncontrolled upward or downward movement of the carrier. These devices shall be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.</p>	<p>equipped with devices in such a way as to prevent uncontrolled upward or downward movement of the carrier. These devices <del>shall</del><b>must</b> be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.</p>	<p>to prevent uncontrolled upward or downward movement of the carrier. These devices must be able to stop the carrier at its maximum working load and at the foreseeable maximum speed.</p>
<p>Annex III, 6, point (6.4)(6.4.1), third paragraph</p>		
<p>The stopping action shall not cause deceleration harmful to the occupants, whatever the load conditions.</p>	<p>The stopping action <del>shall</del><b>must</b> not cause deceleration harmful to the occupants, whatever the load conditions.</p>	<p>The stopping action must not cause deceleration harmful to the occupants, whatever the load conditions.</p>
<p>Annex III, 6, point (6.4)(6.4.2), introductory part</p>		
<p>6.4.2. Controls at landings</p>	<p>6.4.2. <del>—</del>Controls at landings</p>	<p>6.4.2. Controls at landings</p>
<p>Annex III, 6, point (6.4)(6.4.2), first paragraph, introductory part</p>		
<p>Controls, other than those for emergency use, at landings shall not initiate movements of the carrier when:</p>	<p>Controls, other than those for emergency use, at landings <del>shall</del><b>must</b> not initiate movements of the carrier when:</p>	<p>Controls, other than those for emergency use, at landings must not initiate movements of the carrier when:</p>
<p>Annex III, 6, point (6.4)(6.4.2), first paragraph(a)</p>		
<p>(a) the control devices in the carrier are being operated,</p>	<p><del>(a)</del>— the control devices in the carrier are being operated,</p>	<p>— the control devices in the carrier are being operated,</p>
<p>Annex III, 6, point (6.4)(6.4.2), first paragraph(b)</p>		
<p>(b) the carrier is not at a landing.</p>	<p><del>(b)</del>— the carrier is not at a landing.</p>	<p>— the carrier is not at a landing.</p>
<p>Annex III, 6, point (6.4)(6.4.3), introductory part</p>		
<p>6.4.3. Access to the carrier</p>	<p>6.4.3. <del>—</del>Access to the carrier</p>	<p>6.4.3. Access to the carrier</p>
<p>Annex III, 6, point (6.4)(6.4.3), first paragraph</p>		
<p>The guards at the landings and on the carrier shall be designed and constructed</p>	<p>The guards at the landings and on the carrier <del>shall</del><b>must</b> be designed and</p>	<p>The guards at the landings and on the carrier must be designed and constructed</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.	constructed in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.	in such a way as to ensure safe transfer to and from the carrier, taking into consideration the foreseeable range of goods and persons to be lifted.
Annex III, 6, point (6.5), introductory part		
6.5. MARKINGS	6.5. <del>MARKINGS</del>	6.5. MARKINGS
Annex III, 6, point (6.5), first paragraph, introductory part		
The carrier shall bear the information necessary to ensure safety including:	The carrier <del>shall</del> <b>must</b> bear the information necessary to ensure safety including:	The carrier must bear the information necessary to ensure safety including:
Annex III, 6, point (6.5), first paragraph(a)		
(a) the number of persons permitted on the carrier,	<del>(a)</del> — the number of persons permitted on the carrier,	— the number of persons permitted on the carrier,
Annex III, 6, point (6.5), first paragraph(b)		
(b) the maximum working load.	<del>(b)</del> — the maximum working load.	— the maximum working load.

## Annex IV: Technical Documentation for machinery and related products

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex IV, A		Annex VII
Annex IV A TECHNICAL DOCUMENTATION	<u>Annex IV A TECHNICAL DOCUMENTATION</u> <del>ANNEX VII</del>	ANNEX VII
		Annex VII, A
TECHNICAL DOCUMENTATION FOR MACHINERY AND RELATED PRODUCTS	<u>TECHNICAL DOCUMENTATION FOR MACHINERY AND RELATED PRODUCTS</u> <del>A. Technical file for machinery</del>	A. Technical file for machinery
Annex IV, Annex IV, A, first paragraph		Annex VII, A, preamble
The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the machinery or related product with the applicable essential health and safety requirements set out in Annex III.	<u>The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the machinery or related product with the applicable essential health and safety requirements set out in Annex III.</u> <del>This part describes the procedure for compiling a technical file. The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. The technical file must be compiled in one or more official Community languages, except for the instructions for the machinery, for which the special provisions of Annex I, section 1.7.4.1 apply.</del>	This part describes the procedure for compiling a technical file. The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, manufacture and operation of the machinery to the extent necessary for this assessment. The technical file must be compiled in one or more official Community languages, except for the instructions for the machinery, for which the special provisions of Annex I, section 1.7.4.1 apply.
Annex IV, Annex IV, A, second paragraph, introductory part		Annex VII, A, (1)
The technical documentation shall include at least the following elements:	<del>1.</del> The technical <u>documentation</u> <del>file</del> shall <u>include at least</u> <del>comprise</del> the following elements:	1. The technical file shall comprise the following:

DRAFT Machinery Regulation	Comparison	Machinery Directive
		Annex VII, A, (1)(a)
	<del>(a) a construction file including:</del>	(a) a construction file including:
Annex IV, Annex IV, A, second paragraph, point (a)		Annex VII, A, (1)(a), dash 1
(a) a complete description of the machinery or related product and of its intended use;	<del>(—) a complete-general</del> description of the machinery <u>or related product and of its intended use;</u>	— a general description of the machinery,
Annex IV, Annex IV, A, second paragraph, point (ba)		Annex VII, A, (1)(a), dash 4
(b) the documentation on risk assessment demonstrating the procedure carried out, including:	<del>(b)—</del> the documentation on risk assessment demonstrating the procedure <u>carried out</u> <del>followed</del> , including:	— the documentation on risk assessment demonstrating the procedure followed, including:
Annex IV, Annex IV, A, second paragraph, point (bb)		Annex VII, A, (1)(a), dash 4(i)
(i) a list of the essential health and safety requirements that are applicable to the machinery or related product,	(i) a list of the essential health and safety requirements <u>that are applicable</u> <del>which apply</del> to the machinery <u>or related product</u> ,	(i) a list of the essential health and safety requirements which apply to the machinery,
Annex IV, Annex IV, A, second paragraph, point (bc)		Annex VII, A, (1)(a), dash 4(ii)
(ii) the description of the protective measures implemented to meet each applicable essential health and safety requirement and, when appropriate, the indication of the residual risks associated with the machinery or related product,	(ii) the description of the protective measures implemented to <u>meet each applicable essential health and safety requirement</u> <del>eliminate identified hazards or to reduce risks</del> and, when appropriate, the indication of the residual risks associated with the machinery <u>or related product</u> ,	(ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, when appropriate, the indication of the residual risks associated with the machinery,
Annex IV, Annex IV, A, second paragraph, point (c)		
(c) deleted	<del>(c) deleted</del>	
Annex IV, Annex IV, A, second paragraph, point (d)		Annex VII, A, (1)(a), dash 2

DRAFT Machinery Regulation	Comparison	Machinery Directive
(d) design and manufacturing drawings and schemes of the machinery or related product and of its components, sub-assemblies and circuits;	<u>(d) design and manufacturing drawings and schemes</u> <del>— the overall drawing</del> of the machinery <u>or related product and drawings</u> of <u>its components, sub-assemblies and</u> <del>the control</del> circuits; <del>as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,</del>	— the overall drawing of the machinery and drawings of the control circuits, as well as the pertinent descriptions and explanations necessary for understanding the operation of the machinery,
	<del>— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,</del>	Annex VII, A, (1)(a), dash 3 — full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the machinery with the essential health and safety requirements,
Annex IV, Annex IV, A, second paragraph, point (e)		
(e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the machinery or related product;	<u>(e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the machinery or related product;</u> <del>[see above]</del>	[see above]
Annex IV, Annex IV, A, second paragraph, point (f)		Annex VII, A, (1)(a), dash 5
(f) the references of the harmonised standards referred to in Article 17(1) or common specifications adopted by the Commission in accordance with Article 17(3) that have been applied for the design and manufacture of the machinery or related product. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts, which have been applied;	<u>(f) the references of the harmonised standards referred to in Article 17(1) or common specifications adopted by the Commission in accordance with Article 17(3) that have been applied for the design and manufacture of the machinery or related product. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts,</u> <del>which have been applied;</del> <del>— the</del>	— the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,</del>	
Annex IV, Annex IV, A, second paragraph, point (g)		
(g) where harmonised standards or common specifications have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to meet each applicable essential health and safety requirements;	<u>(g) where harmonised standards or common specifications have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to meet each applicable essential health and safety requirements;</u> <del>[see above]</del>	[see above]
Annex IV, Annex IV, A, second paragraph, point (h)		Annex VII, A, (1)(a), dash 6
(h) reports and/or results of the design calculations, tests, inspections and examinations carried out to verify the conformity of the machinery or related product with the applicable essential health and safety requirements;	<u>(h) reports and/or</u> <del>— any technical report giving the results of the</del> <u>design calculations, tests, inspections and examinations carried out to verify the conformity of either by the machinery or related product with</u> <del>manufacturer or by a body chosen by the</del> <u>applicable essential health and safety requirements;</u> <del>manufacturer or his authorised representative,</del>	— any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
Annex IV, Annex IV, A, second paragraph, point (i)		
(i) deleted	<u>(i) deleted</u>	
Annex IV, Annex IV, A, second paragraph, point (j)		
(j) a description of the means used by the manufacturer during the production of the machinery or related product to	<u>(j) a description of the means used by the manufacturer during the production of the machinery or related product to</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
ensure the conformity of the machinery or related product produced with the design specifications;	<u>ensure the conformity of the machinery or related product produced with the design specifications;</u>	
Annex IV, Annex IV, A, second paragraph, point (k)		Annex VII, A, (1)(a), dash 7
(k) a copy of the manufacturer's instructions for use and the information set out in section 1.7.4 of Annex III;	<u>(k)— a copy of the manufacturer's instructions for use and the information set out in section 1.7.4 of Annex III;</u> <del>machinery;</del>	— a copy of the instructions for the machinery,
Annex IV, Annex IV, A, second paragraph, point (l)		Annex VII, A, (1)(a), dash 8
(l) where appropriate, the declaration of incorporation for partly completed machinery set out in Annex V and the relevant assembly instructions for such machinery;	<u>(l)— where appropriate, the declaration of incorporation for <del>included</del> partly completed machinery set out in Annex V and the relevant assembly instructions for such machinery;</u>	— where appropriate, the declaration of incorporation for included partly completed machinery and the relevant assembly instructions for such machinery,
Annex IV, Annex IV, A, second paragraph, point (la)		Annex VII, A, (1)(a), dash 9
(la) where appropriate, copies of the EU declaration of conformity of machinery or related products as well as any product covered by other EU harmonisation legislations incorporated into the machinery or related product;	<u>(la)— where appropriate, copies of the <del>EU</del>EC declaration of conformity of machinery or <del>related other</del> products as well as any product covered by other EU harmonisation legislations incorporated into the machinery or related product;</u>	— where appropriate, copies of the EC declaration of conformity of machinery or other products incorporated into the machinery,
		Annex VII, A, (1)(a), dash 10
	<del>— a copy of the EC declaration of conformity;</del>	— a copy of the EC declaration of conformity;
Annex IV, Annex IV, A, second paragraph, point (m)		Annex VII, A, (1)(b)
(m) for machinery or related products produced in series, the internal measures that will be implemented to ensure that the machinery or related product remains in conformity with this Regulation;	<u>(m)</u> <del>b</del> for <u>machinery or related products produced in series</u> <del>manufacture</del> , the internal measures that will be implemented to ensure that the machinery or related product remains in	(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive.

DRAFT Machinery Regulation	Comparison	Machinery Directive
	conformity with <del>the provisions of this Regulation;</del> <del>Directive.</del>	
Annex IV, Annex IV, A, second paragraph, point (n)		
(n) the source code or programming logic of the safety related software to demonstrate the conformity of the machinery or related product with this Regulation further to a reasoned request from a competent national authority provided that is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III;	<u>(n) the source code or programming logic of the safety related software to demonstrate the conformity of the machinery or related product with this Regulation further to a reasoned request from a competent national authority provided that is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III;</u>	
Annex IV, Annex IV, A, second paragraph, point (o)		
(o) for sensor-fed, remotely-driven, or autonomous machinery or related product, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used;	<u>(o) for sensor-fed, remotely-driven, or autonomous machinery or related product, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used;</u>	
Annex IV, Annex IV, A, second paragraph, point (p)		Annex VII, A, (1), second paragraph
(p) the results of research and tests on components, fittings or the machinery or related product carried out by the manufacturer to determine whether by its design or construction it is capable of being assembled and put into service safely.	<u>(p) the results of</u> <del>The manufacturer must carry out necessary</del> research and tests on components, fittings or the <del>completed</del> <u>machinery or related product carried out by the manufacturer</u> to determine whether by its design or construction it is capable of being assembled and put into	The manufacturer must carry out necessary research and tests on components, fittings or the completed machinery to determine whether by its design or construction it is capable of being assembled and put into service

DRAFT Machinery Regulation	Comparison	Machinery Directive
	service safely. <del>The relevant reports and results shall be included in the technical file.</del>	safely. The relevant reports and results shall be included in the technical file.
Annex IV, B		Annex VII, B
B RELEVANT TECHNICAL DOCUMENTATION FOR PARTLY COMPLETED MACHINERY	<u>B RELEVANT TECHNICAL DOCUMENTATION FOR PARTLY COMPLETED MACHINERY</u> <del>B. Relevant technical documentation for partly completed machinery</del>	B. Relevant technical documentation for partly completed machinery
Annex IV, B, first paragraph		Annex VII, B, first paragraph
The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the partly completed machinery with the applicable essential health and safety requirements set out in Annex III.	<del>The This part describes the procedure for compiling relevant</del> technical documentation <u>shall specify the means used by.</u> <del>The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the manufacturer to ensure the conformity design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the applicable essential health and safety requirements set out</del> <u>applied.</u> <del>The documentation must be compiled in Annex III</del> <u>one or more official Community languages.</u>	This part describes the procedure for compiling relevant technical documentation. The documentation must show which requirements of this Directive are applied and fulfilled. It must cover the design, manufacture and operation of the partly completed machinery to the extent necessary for the assessment of conformity with the essential health and safety requirements applied. The documentation must be compiled in one or more official Community languages.
Annex IV, B, second paragraph, introductory part		Annex VII, B, second paragraph
The technical documentation shall include at least the following elements:	<u>The technical documentation</u> <del>it</del> shall <u>include at least</u> <del>comprise</del> the following elements:	It shall comprise the following:
		Annex VII, B, (a)
	<del>(a) a construction file including:</del>	(a) a construction file including:
Annex IV, B, second paragraph, point (a)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(a) a complete description of the partly completed machinery and of its intended function when incorporated into or assembled with machinery or other partly completed machinery or equipment;	<u>(a) a complete description of the partly completed machinery and of its intended function when incorporated into or assembled with machinery or other partly completed machinery or equipment;</u>	
Annex IV, B, second paragraph, point (b)		
(b) deleted	<u>(b) deleted</u>	
Annex IV, B, second paragraph, point (ba)		Annex VII, B, (a), dash 3
(b) the risk assessment documentation showing the procedure carried out, including:	<u>(b)— the risk assessment documentation showing the procedure carried out</u> <del>followed</del> , including:	— the risk assessment documentation showing the procedure followed, including:
Annex IV, B, second paragraph, point (bb)		Annex VII, B, (a), dash 3(i)
i) a list of the essential health and safety requirements which apply to the partly completed machinery,	<del>(i)</del> a list of the essential health and safety requirements <u>which apply to the partly completed machinery</u> <del>applied and fulfilled</del> ,	(i) a list of the essential health and safety requirements applied and fulfilled,
Annex IV, B, second paragraph, point (bc)		Annex VII, B, (a), dash 3(ii)
ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,	<del>(ii)</del> the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,	(ii) the description of the protective measures implemented to eliminate identified hazards or to reduce risks and, where appropriate, the indication of the residual risks,
Annex IV, B, second paragraph, point (c)		Annex VII, B, (a), dash 1
(c) design and manufacturing drawings and schemes of the partly completed machinery and of its components, sub-assemblies and circuits;	<u>(c) design and manufacturing drawings and schemes</u> <del>— the overall drawing</del> of the partly completed machinery and <del>drawings</del> of <u>its components, sub-assemblies and</u> <del>the control</del> circuits; ;	— the overall drawing of the partly completed machinery and drawings of the control circuits,
		Annex VII, B, (a), dash 2
	<del>— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed</del>	— full detailed drawings, accompanied by any calculation notes, test results, certificates, etc., required to check the conformity of the partly completed

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>machinery with the applied essential health and safety requirements;</del>	machinery with the applied essential health and safety requirements,
Annex IV, B, second paragraph, point (d) (d) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (c) and of the operation of the partly completed machinery;	<u>(d) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (c) and of the operation of the partly completed machinery;</u> <del>[see above]</del>	[see above]
Annex IV, B, second paragraph, point (e) (e) the references of the harmonised standards referred to in Article 17(1) or common specifications adopted by the Commission in accordance with Article 17(3) that have been applied for the design and manufacture of the partly completed machinery. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts, which have been applied;	<u>(e) the references of the harmonised standards referred to in Article 17(1) or common specifications adopted by the Commission in accordance with Article 17(3) that have been applied for the design and manufacture of the partly completed machinery. In the event of partial application of harmonised standards or common specifications, the documentation shall specify the parts, which have been applied;</u> <del>(iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards;</del>	Annex VII, B, (a), dash 3(iii) (iii) the standards and other technical specifications used, indicating the essential health and safety requirements covered by these standards,
Annex IV, B, second paragraph, point (f) (f) where harmonised standards or common specifications have not been applied or have been only partially applied, description of the other technical specifications that have been applied in order to meet each applicable essential health and safety requirements;	<u>(f) where harmonised standards or common specifications have not been applied or have been only partially applied, description of the other technical specifications that have been applied in order to meet each applicable essential health and safety requirements;</u> <del>[see above]</del>	[see above]
Annex IV, B, second paragraph, point (g)		Annex VII, B, (a), dash 3(iv)

DRAFT Machinery Regulation	Comparison	Machinery Directive
(g) reports and/or results of the design calculations, tests, inspections and examinations carried out to verify the conformity of the partly completed machinery with the applicable essential health and safety requirements;	<del>(g) reports and/or iv) any technical report giving the results of the design calculations, tests, inspections and examinations carried out to verify the conformity of either by the partly completed machinery with manufacturer or by a body chosen by the applicable essential health and safety requirements; manufacturer or his authorised representative;</del>	(iv) any technical report giving the results of the tests carried out either by the manufacturer or by a body chosen by the manufacturer or his authorised representative,
Annex IV, B, second paragraph, point (h)		
(h) deleted	<del>(h) deleted</del>	
Annex IV, B, second paragraph, point (i)		
(i) a description of the means used by the manufacturer during the production of the partly completed machinery to ensure the conformity of the partly completed machinery produced with the design specifications;	<del>(i) a description of the means used by the manufacturer during the production of the partly completed machinery to ensure the conformity of the partly completed machinery produced with the design specifications;</del>	
Annex IV, B, second paragraph, point (j)		Annex VII, B, (a), dash 3(v)
(j) a copy of the assembly instructions for the partly completed machinery set out in Annex X;	<del>(jv) a copy of the assembly instructions for the partly completed machinery set out in Annex X;</del>	(v) a copy of the assembly instructions for the partly completed machinery;
Annex IV, B, second paragraph, point (k)		Annex VII, B, (b)
(k) for partly completed machinery produced in series, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied;	<del>(kb) for partly completed machinery produced in series-manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied;:-</del>	(b) for series manufacture, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied.
Annex IV, B, second paragraph, point (l)		
(l) the source code or programming logic of the safety related software upon a	<del>(l) the source code or programming logic of the safety related software upon a</del>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>reasoned request from a competent national authority provided that is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III:</p>	<p><u>reasoned request from a competent national authority provided that is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III:</u></p>	
<p>Annex IV, B, second paragraph, point (m)</p>		
<p>(m) for sensor-fed, remotely-driven, or autonomous partly completed machinery, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used;</p>	<p><u>(m) for sensor-fed, remotely-driven, or autonomous partly completed machinery, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used;</u></p>	
<p>Annex IV, B, second paragraph, point (n)</p>		<p>Annex VII, B, third paragraph</p>
<p>(n) the results of research and tests on components, fittings or the partly completed machinery carried out by the manufacturer to determine whether by its design or construction it is capable of being assembled and incorporated safely.</p>	<p><u>(n) the results of</u><del>The manufacturer must carry out necessary</del> research and tests on components, fittings or the partly completed machinery <u>carried out by the manufacturer</u> to determine whether by its design or construction it is capable of being assembled and <u>incorporated</u><del>used</del> safely.<del>The relevant reports and results shall be included in the technical file.</del></p>	<p>The manufacturer must carry out necessary research and tests on components, fittings or the partly completed machinery to determine whether by its design or construction it is capable of being assembled and used safely. The relevant reports and results shall be included in the technical file.</p>

## Annex V: EU Declaration of Conformity and Incorporation

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex V		Annex II
ANNEX V	ANNEX V#	ANNEX II
Annex V first heading		
EU DECLARATION OF CONFORMITY AND INCORPORATION	<u>EU DECLARATION OF CONFORMITY AND INCORPORATION</u> Declarations	Declarations
Annex V, first heading		Annex II, 1, A
A. EU DECLARATION OF CONFORMITY OF MACHINERY AND RELATED PRODUCT No...1	A. <u>EU-EC</u> DECLARATION OF CONFORMITY OF <del>THE</del> MACHINERY <u>AND RELATED PRODUCT No...1</u>	A. EC DECLARATION OF CONFORMITY OF THE MACHINERY
1. It is optional for the manufacturer to assign a number to the declaration of conformity.	<u>1. It is optional for the manufacturer to assign a number to the declaration of conformity.</u>	
		Annex II, 1, A, first paragraph
	<del>This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.</del>	This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex I, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.
		Annex II, 1, A, second paragraph
	<del>This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.</del>	This declaration relates exclusively to the machinery in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user.
Annex V, first paragraph a		Annex II, 1, A, third paragraph
The EU declaration of conformity shall contain the following particulars:	The <u>EU-EC</u> declaration of conformity <del>shall</del> <u>must</u> contain the following particulars:	The EC declaration of conformity must contain the following particulars:
Annex V, point (1)		Annex II, 1, A, (3)

DRAFT Machinery Regulation	Comparison	Machinery Directive
1. The machinery or related product (product, type, model, batch or serial number):	<del>1. The</del> <del>3. description and identification of the machinery or related product (product, type, ,including generic denomination, function, model, batch or type, serial number):</del> <del>and commercial name;</del>	3. description and identification of the machinery, including generic denomination, function, model, type, serial number and commercial name;
Annex V, point (1a)		
(1a) Where applicable: substantially modified machinery:	<u>(1a) Where applicable: substantially modified machinery:</u>	
Annex V, point (2)		Annex II, 1, A, (1)
2. Name and address of the manufacturer and, where applicable, his or her authorised representative:	<u>2. Name</u> <del>1. business name</del> and <u>full</u> address of the manufacturer and, where <u>applicable</u> <del>appropriate</del> , his <u>or her</u> authorised representative <del>;</del>	1. business name and full address of the manufacturer and, where appropriate, his authorised representative;
		Annex II, 1, A, (2)
	<del>2. name and address of the person authorised to compile the technical file, who must be established in the Community;</del>	2. name and address of the person authorised to compile the technical file, who must be established in the Community;
Annex V, point (3)		
3. For lifting machinery which is intended to be permanently installed in a building or a structure and which cannot be assembled in the manufacturer's premises but can only be assembled at the place of use, the address of that place:	<u>3. For lifting machinery which is intended to be permanently installed in a building or a structure and which cannot be assembled in the manufacturer's premises but can only be assembled at the place of use, the address of that place:</u>	
Annex V, point (4)		
4. This declaration of conformity is issued under the sole responsibility of the manufacturer:	<u>4. This declaration of conformity is issued under the sole responsibility of the manufacturer:</u>	
Annex V, point (5)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>5. Object of the declaration (identification of machinery or related product allowing traceability; where necessary for the identification of the machinery or related product, a colour image of sufficient clarity may be included):</p>	<p><u>5. Object of the declaration (identification of machinery or related product allowing traceability; where necessary for the identification of the machinery or related product, a colour image of sufficient clarity may be included):</u></p>	
<p>Annex V, point (6)</p>		<p>Annex II, 1, A, (4)</p>
<p>6. The object of the declaration described in point 5 is in conformity with the relevant Union harmonisation legislation:</p>	<p><u>6. The object of the declaration described in point 5 is in conformity with the relevant Union harmonisation legislation:</u>  <del>4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the Official Journal of the European Union;</del></p>	<p>4. a sentence expressly declaring that the machinery fulfils all the relevant provisions of this Directive and where appropriate, a similar sentence declaring the conformity with other Directives and/or relevant provisions with which the machinery complies. These references must be those of the texts published in the Official Journal of the European Union;</p>
<p>Annex V, point (7)</p>		<p>Annex II, 1, A, (7)</p>
<p>7. References to the harmonised standards referred to in Article 17(1) or common specifications adopted by the Commission in accordance with Article 17(3) that have been applied, including the date of the standard or of the common specification, or references to the other technical specifications, including their date, in relation to which conformity is declared. In the event of partial application of harmonised standards or common specifications, the</p>	<p><u>7. References to the harmonised standards referred to in Article 17(1) or common specifications adopted by the Commission in accordance with Article 17(3) that have been applied, including the date of the standard or of the common specification, or references to the other technical specifications, including their date, in relation to which conformity is declared. In the event of partial application of harmonised standards or common specifications, the EU declaration of conformity shall specify</u></p>	<p>7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2);</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
EU declaration of conformity shall specify the parts, which have been applied:	<u>the parts, which have been applied:</u> <del>7. where appropriate, a reference to the harmonised standards used, as referred to in Article 7(2);</del>	
		Annex II, 1, A, (8)
	<del>8. where appropriate, the reference to other technical standards and specifications used;</del>	8. where appropriate, the reference to other technical standards and specifications used;
Annex V, point (8)		Annex II, 1, A, (5)
8. Where applicable, the notified body ... (name, number) ... performed the EU type-examination (Module B) and issued the EU type-examination certificate ... (reference to that certificate), followed by conformity to type based on internal production control (module C) or the conformity based on unit verification (module G) or full quality assurance (module H):	<u>8. Where applicable</u> <del>5. where appropriate, the name, address and identification number of the notified body ... (name, number) ... performed</del> the <u>EU</u> <del>EC</del> type-examination (Module B) <del>referred to in Annex IX</del> and <u>issued the EU</u> <del>number of the EC</del> type-examination certificate ... (reference to that certificate), followed by conformity to type based on internal production control (module C) or the conformity based on unit verification (module G) or full quality assurance (module H):;	5. where appropriate, the name, address and identification number of the notified body which carried out the EC type-examination referred to in Annex IX and the number of the EC type-examination certificate;
		Annex II, 1, A, (6)
	<del>6. where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in Annex X;</del>	6. where appropriate, the name, address and identification number of the notified body which approved the full quality assurance system referred to in Annex X;
Annex V, point (9)		
9. Where applicable, the machinery or related product is subject to the conformity assessment procedure based on internal production control (Module A):	<u>9. Where applicable, the machinery or related product is subject to the conformity assessment procedure based on internal production control (Module A):</u>	
Annex V, point (10), introductory part		
10. Additional information:	<u>10. Additional information:</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex V, point (10), first paragraph		
Signed for and on behalf of: ...	<u>Signed for and on behalf of: ...</u>	
Annex V, point (10), second paragraph		Annex II, 1, A, (9)
(place and date of issue):	<del>(9. the</del> place and date of <u>issue</u> ): <del>the declaration;</del>	9. the place and date of the declaration;
Annex V, point (10), third paragraph		Annex II, 1, A, (10)
(name, function) (signature):	<u>(name, function) (signature)</u> : <del>10. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.</del>	10. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.
Annex V, thirteenth heading		Annex II, 1, B
B. EU DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY No...1	B. <u>EU</u> - DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY <u>No...1</u>	B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY
1. It is optional to assign a number to the declaration of conformity.	<u>1. It is optional to assign a number to the declaration of conformity.</u>	
		Annex II, 1, B, first paragraph
	<del>This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.</del>	This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.
Annex V, second paragraph, introductory part		Annex II, 1, B, second paragraph
The declaration of incorporation shall contain the following particulars:	The declaration of incorporation <del>shall</del> <u>must</u> contain the following particulars:	The declaration of incorporation must contain the following particulars:
Annex V, second paragraph, point (1)		Annex II, 1, B, (3)#
1. Partly Completed Machinery (product, type, batch or serial number):	<u>1. Partly Completed Machinery (product, type, batch or serial number)</u> : <del>3.</del>	3. description and identification of the partly completed machinery including

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>description and identification of the partly completed machinery including generic denomination, function, model, type, serial number and commercial name;</del>	generic denomination, function, model, type, serial number and commercial name;
Annex V, second paragraph, point (2)		Annex II, 1, B, (1)
2. Name and address of the manufacturer and, where applicable, his or her authorised representative:	<del>2. Name</del> <u>1. business name</u> and full address of the manufacturer <del>of the partly completed machinery</del> and, where applicable <del>appropriate</del> , his <u>or her</u> authorised representative.;	1. business name and full address of the manufacturer of the partly completed machinery and, where appropriate, his authorised representative;
		Annex II, 1, B, (2)
	<del>2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community;</del>	2. name and address of the person authorised to compile the relevant technical documentation, who must be established in the Community;
Annex V, second paragraph, point (3)		
3. This declaration of incorporation is issued under the sole responsibility of the manufacturer:	<u>3. This declaration of incorporation is issued under the sole responsibility of the manufacturer:</u>	
Annex V, second paragraph, point (4)		
4. Object of the declaration (identification of partly completed machinery allowing traceability; where necessary for the identification of the partly completed machinery, a colour image of sufficient clarity may be included):	<u>4. Object of the declaration (identification of partly completed machinery allowing traceability; where necessary for the identification of the partly completed machinery, a colour image of sufficient clarity may be included):</u>	
Annex V, second paragraph, point (5)		Annex II, 1, B, (4)
5. A sentence declaring which essential requirements of Regulation (EU) .../..... of the European Parliament and of the Council+1 are applied and fulfilled and that the relevant technical documentation was drawn-up in accordance with part B of Annex IV, and, where appropriate, a	<del>5. A</del> <u>4. a</u> sentence declaring which essential requirements of <u>Regulation (EU) .../..... of the European Parliament and of the Council+1</u> <del>this Directive</del> are applied and fulfilled and that the relevant technical documentation <u>was drawn-up</u> <del>is compiled</del> in accordance with part B of	4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>sentence declaring the conformity of the partly completed machinery with other relevant Union harmonisation legislation:</p>	<p>Annex <del>IV</del><sup>VH</sup>, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant <u>Union harmonisation legislation</u>:<del>Directives. These references must be those of the texts published in the Official Journal of the European Union;</del></p>	<p>machinery with other relevant Directives. These references must be those of the texts published in the Official Journal of the European Union;</p>
<p>1. OJ: Please insert in the text the number of the Regulation contained in document ...and insert the number, date, title and OJ reference of that Regulation in the footnote</p>	<p><u>1. OJ: Please insert in the text the number of the Regulation contained in document ...and insert the number, date, title and OJ reference of that Regulation in the footnote</u></p>	
<p>Annex V, second paragraph, point (6)</p>		
<p>6. References to the harmonised standards referred to in Article 17(1) or common specifications adopted by the Commission in accordance with Article 17(3) that have been applied, including the date of the standard or of the common specification, or references to the other technical specifications, including their date, in relation to which conformity is declared. In the event of partial application of harmonised standards or common specifications, the declaration of incorporation shall specify the parts, which have been applied:</p>	<p><u>6. References to the harmonised standards referred to in Article 17(1) or common specifications adopted by the Commission in accordance with Article 17(3) that have been applied, including the date of the standard or of the common specification, or references to the other technical specifications, including their date, in relation to which conformity is declared. In the event of partial application of harmonised standards or common specifications, the declaration of incorporation shall specify the parts, which have been applied:</u></p>	
<p>Annex V, second paragraph, point (7)</p>		<p>Annex II, 1, B, (5)</p>
<p>7. An undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall</p>	<p><del>5. an</del> <u>7. An</u> undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This</p>	<p>5. an undertaking to transmit, in response to a reasoned request by the national authorities, relevant information on the partly completed machinery. This shall</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery:	shall include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery.;	include the method of transmission and shall be without prejudice to the intellectual property rights of the manufacturer of the partly completed machinery;
Annex V, second paragraph, point (8)		Annex II, 1, B, (6)
8. A statement that the partly completed machinery shall not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with this Regulation:	8. <del>A 6. a</del> statement that the partly completed machinery <del>shall</del> <b>must</b> not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with <u>this Regulation</u> : <del>the provisions of this Directive, where appropriate;</del>	6. a statement that the partly completed machinery must not be put into service until the final machinery into which it is to be incorporated has been declared in conformity with the provisions of this Directive, where appropriate;
Annex V, second paragraph, point (9), introductory part		
9. Additional information:	<u>9. Additional information:</u>	
Annex V, second paragraph, point (9), first paragraph		
Signed for and on behalf of: ...	<u>Signed for and on behalf of: ...</u>	
Annex V, second paragraph, point (9), second paragraph		Annex II, 1, B, (7)
(place and date of issue):	<del>(7. the</del> place and date of <u>issue</u> ): <del>the declaration;</del>	7. the place and date of the declaration;
Annex V, second paragraph, point (9), third paragraph		Annex II, 1, B, (8)
(name, function) (signature):	<u>(name, function) (signature)</u> : <del>8. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.</del>	8. the identity and signature of the person empowered to draw up the declaration on behalf of the manufacturer or his authorised representative.

## Annex VI: Modul A – Internal production control

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex VI		Annex VIII
ANNEX VI	ANNEX <del>VI</del> <sup>VIII</sup>	ANNEX VIII
Annex VI, first heading		
INTERNAL PRODUCTION CONTROL	<u>INTERNAL PRODUCTION CONTROL</u> <del>Assessment of conformity with internal checks on the manufacture of machinery</del>	Assessment of conformity with internal checks on the manufacture of machinery
Annex VI, second heading		
(Module A)	<u>(Module A)</u>	
Annex VI, point (1)		Annex VIII, (1)
1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his or her sole responsibility that the machinery or related product concerned satisfies the applicable requirements of this Regulation.	1. <u>Internal production control is</u> <del>This Annex describes</del> the <u>conformity assessment procedure whereby</u> <del>by which</del> the manufacturer <u>fulfils</u> <del>or his authorised representative, who carries out</del> the obligations laid down in points <u>2, 3 and 4,</u> <del>and 3,</del> ensures and declares <u>on his or her sole responsibility</u> that the machinery <u>or related product</u> concerned satisfies the <u>applicable</u> <del>relevant</del> requirements of this Regulation <del>Directive</del> .	1. This Annex describes the procedure by which the manufacturer or his authorised representative, who carries out the obligations laid down in points 2 and 3, ensures and declares that the machinery concerned satisfies the relevant requirements of this Directive.
Annex VI, point (2), introductory part		
2. Technical documentation	<u>2. Technical documentation</u>	
Annex VI, point (2), first paragraph		Annex VIII, (2)
The manufacturer shall draw up the technical documentation described in Annex IV, Part A.	<del>The</del> <u>2. For each representative type of the series in question, the</u> manufacturer <del>or his authorised representative</del> shall draw up the technical <u>documentation</u> <del>described</del> <u>file referred to</u> in Annex <u>IV,</u> <del>Part VII, part</del> A.	2. For each representative type of the series in question, the manufacturer or his authorised representative shall draw up the technical file referred to in Annex VII, part A.
Annex VI, point (3), introductory part		
3. Manufacturing	<u>3. Manufacturing</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Annex VI, point (3), first paragraph</p> <p>The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured machinery or related product with the technical documentation referred to in point 2 and with the applicable requirements of this Regulation.</p>	<p><del>3.</del>The manufacturer <del>shall</del><del>must</del> take all measures necessary <del>so in order</del> that the manufacturing process <u>and its monitoring ensure</u><del>ensures</del> compliance of the manufactured machinery <u>or related product</u> with the technical <u>documentation</u><del>file</del> referred to in <u>point 2</u><del>Annex VII, part A,</del> and with the <u>applicable</u> requirements of this <u>Regulation</u><del>Directive</del>.</p>	<p>Annex VIII, (3)</p> <p>3. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and with the requirements of this Directive.</p>
<p>Annex VI, point (4), introductory part</p> <p>4. CE marking and EU declaration of conformity</p>	<p><u>4. CE marking and EU declaration of conformity</u></p>	
<p>Annex VI, point (4)(4.1)</p> <p>4.1. The manufacturer shall affix the CE marking to each individual machinery or related product that satisfies the applicable requirements of this Regulation.</p>	<p><u>4.1. The manufacturer shall affix the CE marking to each individual machinery or related product that satisfies the applicable requirements of this Regulation.</u></p>	
<p>Annex VI, point (4)(4.2)</p> <p>4.2. The manufacturer shall draw up an EU declaration of conformity for each machinery or related product model in accordance with Article 18 and keep it, together with the technical documentation, at the disposal of the national authorities for ten years after the machinery or related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery or related product for which it has been drawn up.</p>	<p><u>4.2. The manufacturer shall draw up an EU declaration of conformity for each machinery or related product model in accordance with Article 18 and keep it, together with the technical documentation, at the disposal of the national authorities for ten years after the machinery or related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery or related product for which it has been drawn up.</u></p>	
<p>Annex VI, point (4), first paragraph</p>		

<b>DRAFT Machinery Regulation</b>	<b>Comparison</b>	<b>Machinery Directive</b>
A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.	<u>A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.</u>	
Annex VI, point (5), introductory part		
5. Authorised representative	<u>5. Authorised representative</u>	
Annex VI, point (5), first paragraph		
The manufacturer's obligations set out in point 4 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.	<u>The manufacturer's obligations set out in point 4 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.</u>	

## Annex VII: Modul B – EU Type-Examination

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex VII		
ANNEX VII	<u>ANNEX VII</u>	
Annex VII, first heading		Annex IX
EU TYPE-EXAMINATION	<u>EU TYPE-EXAMINATION</u> <del>ANNEX IX</del>	ANNEX IX
Annex VII, second heading		
(Module B)	<u>(Module B)</u>	
Annex VII, point (1)		Annex IX, introduction
1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a machinery or related product and verifies and attests that the technical design of the machinery or related product meets the applicable requirements of this Regulation.	1. <del>EU</del> <u>EG</u> type-examination is the <u>part of a conformity assessment procedure in which</u> <del>whereby</del> a notified body <u>examines the technical design of a machinery or related product</u> <del>ascertains and verifies and attests</del> <del>certifies that a representative model of machinery referred to in Annex IV (hereafter named the type) satisfies the technical design of the machinery or related product</del> meets the applicable requirements <del>provisions</del> of this Regulation <del>Directive</del> .	EC type-examination is the procedure whereby a notified body ascertains and certifies that a representative model of machinery referred to in Annex IV (hereafter named the type) satisfies the provisions of this Directive.
		Annex IX, (1)
	<del>1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred to in Annex VII, part A.</del>	1. The manufacturer or his authorised representative must, for each type, draw up the technical file referred to in Annex VII, part A.
Annex VII, point (2)		
2. EU type-examination shall be carried out by assessment of the adequacy of the technical design of the machinery or related product through examination of the technical documentation, plus examination of a specimen of the machinery or related product that is	<u>2. EU type-examination shall be carried out by assessment of the adequacy of the technical design of the machinery or related product through examination of the technical documentation, plus examination of a specimen of the machinery or related product that is</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
representative of the production envisaged (production type).	<u>representative of the production envisaged (production type).</u>	
Annex VII, point (3), introductory part		
3. Application for EU type-examination	<u>3. Application for EU type-examination</u>	
Annex VII, point (3), first paragraph		Annex IX, (2), first paragraph
The manufacturer shall lodge an application for EU type-examination with a single notified body of his or her choice.	The manufacturer shall lodge an <del>2. For each type, the</del> application for <del>EU</del> an EC type-examination <del>with</del> <u>shall be submitted by the manufacturer or his authorised representative to</u> a <u>single</u> notified body of his <u>or her</u> choice.	2. For each type, the application for an EC type-examination shall be submitted by the manufacturer or his authorised representative to a notified body of his choice.
Annex VII, point (3), second paragraph, introductory part		Annex IX, (2), second paragraph
The application shall include:	The application shall include:	The application shall include:
Annex VII, point (3), second paragraph(a)		Annex IX, (2), second paragraph, dash 1
(a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;	<u>(a)— the name and address of the manufacturer and, if the application is lodged by an</u> <del>where appropriate, his</del> authorised representative, <u>the name and address of that authorised representative;</u>	— the name and address of the manufacturer and, where appropriate, his authorised representative,
Annex VII, point (3), second paragraph(b)		Annex IX, (2), second paragraph, dash 2
(b) a written declaration that the same application has not been lodged with any other notified body;	<u>(b)— a written declaration that the same application has not been lodged with any other</u> <del>submitted to another</del> notified body;	— a written declaration that the application has not been submitted to another notified body,
Annex VII, point (3), second paragraph(c)		Annex IX, (2), second paragraph, dash 3
(c) the technical documentation described in Annex IV;	<u>(c)— the technical documentation described in Annex IV;</u> <del>file.</del>	— the technical file.
Annex VII, point (3), second paragraph(d)		Annex IX, (2), third paragraph
(d) the access to the specimen(s) of the machinery or related product representative of the production envisaged. The notified body may	<u>(d) the access to the specimen(s) of the machinery or related product representative of the production envisaged. The notified body may</u>	Moreover, the applicant shall place at the disposal of the notified body a sample of the type. The notified body may ask for

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>request further specimens if needed for carrying out the test programme. For machinery or related products produced in series where each item is adapted to fit an individual user, specimens shall be provided that are representative of the range of different users, while machinery or related products produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided.</p>	<p><u>request further specimens if needed for carrying out the test programme. For machinery or related products produced in series where each item is adapted to fit an individual user, specimens shall be provided that are representative of the range of different users, while machinery or related products produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided.</u> <del>Moreover, the applicant shall place at the disposal of the notified body a sample of the type. The notified body may ask for further samples if the test programme so requires.</del></p>	<p>further samples if the test programme so requires.</p>
<p>Annex VII, point (4), introductory part</p>		
<p>4. EU type-examination</p>	<p><u>4. EU type-examination</u></p>	
<p>Annex VII, point (4), first paragraph, introductory part</p>		<p>Annex IX, (3)</p>
<p>The notified body shall:</p>	<p><del>3.</del>The notified body shall:</p>	<p>3. The notified body shall:</p>
<p>Annex VII, point (4), first paragraph(a)</p>		
<p>(a) examine the technical documentation to assess the adequacy of the technical design of the machinery or related product. In conducting such an examination, Annex IV, second subparagraph, point (j), need not be taken into account;</p>	<p><u>(a) examine the technical documentation to assess the adequacy of the technical design of the machinery or related product. In conducting such an examination, Annex IV, second subparagraph, point (j), need not be taken into account;</u></p>	
<p>Annex VII, point (4), first paragraph(b)</p>		
<p>(b) for machinery or related products produced in series where each item is adapted to fit an individual user, examine the description of the measures to assess their adequacy;</p>	<p><u>(b) for machinery or related products produced in series where each item is adapted to fit an individual user, examine the description of the measures to assess their adequacy;</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Annex VII, point (4), first paragraph(c)</p> <p>(c) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements that have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications adopted by the Commission in accordance with Article 17(3), as well as the elements that have been designed in accordance with other technical specifications;</p>	<p><del>(c) verify</del><u>3.1. examine the technical file,</u> <del>check</del> that the <u>specimen(s) have been</u><del>type was</del> manufactured in <u>conformity</u><del>accordance</del> with <u>the technical documentation,</u><del>it</del> and <u>identify</u> the<del>establish which</del> elements <u>that have been designed in accordance with the applicable</u><del>relevant</del> provisions of the <u>relevant harmonised standards or common specifications adopted by the Commission</u><del>referred to in accordance with Article 17(3), as well as the</del><u>7(2), and</u> <del>those</del> elements <u>that have been designed in accordance with other technical specifications</u><del>whose design is not based on the relevant provisions of those standards;</del></p>	<p>Annex IX, (3.1)</p> <p>3.1. examine the technical file, check that the type was manufactured in accordance with it and establish which elements have been designed in accordance with the relevant provisions of the standards referred to in Article 7(2), and those elements whose design is not based on the relevant provisions of those standards;</p>
<p>Annex VII, point (4), first paragraph(d)</p> <p>(d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, or common specifications adopted by the Commission in accordance with Article 17(3), those have been applied correctly;</p>	<p><del>(d)</del><u>3.3. where harmonised standards referred to in Article 7(2) were used,</u> <del>carry out or have carried out</del> appropriate <u>examinations</u><del>inspections, measurements</del> and tests, <u>or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, or common specifications adopted by the Commission in accordance with Article 17(3),</u><del>verify that</del> those <u>have been</u><del>standards were actually</del> applied correctly;</p>	<p>Annex IX, (3.3)</p> <p>3.3. where harmonised standards referred to in Article 7(2) were used, carry out or have carried out appropriate inspections, measurements and tests to verify that those standards were actually applied;</p>
<p>Annex VII, point (4), first paragraph(e)</p>		<p>Annex IX, (3.2)</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications adopted by the Commission in accordance with Article 17(3) have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly</p>	<p><del>(e)3.2.</del> carry out <u>appropriate examinations and tests</u>, or have <u>them</u> carried out, <del>appropriate inspections, measurements and tests</del> to <del>check</del><u>ascertain</u> whether, <u>where</u> the solutions <u>in the relevant harmonised standards or common specifications</u> adopted <u>by the Commission in accordance with Article 17(3)</u> have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding <del>satisfy the</del> essential health and safety requirements <u>and have been applied correctly</u><del>of this Directive, where the standards referred to in Article 7(2) were not applied;</del></p>	<p>3.2. carry out or have carried out appropriate inspections, measurements and tests to ascertain whether the solutions adopted satisfy the essential health and safety requirements of this Directive, where the standards referred to in Article 7(2) were not applied;</p>
		Annex IX, (3.4)
	<p><del>3.4. agree with the applicant as to the place where the check that the type was manufactured in accordance with the examined technical file and the necessary inspections, measurements and tests will be carried out.</del></p>	<p>3.4. agree with the applicant as to the place where the check that the type was manufactured in accordance with the examined technical file and the necessary inspections, measurements and tests will be carried out.</p>
Annex VII, point (5), introductory part		
5. Evaluation report	<u>5. Evaluation report</u>	
Annex VII, point (5), first paragraph		
<p>The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in</p>	<p><u>The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
full or in part, only with the agreement of the manufacturer.	<u>full or in part, only with the agreement of the manufacturer.</u>	
Annex VII, point (6), introductory part		
6. EU type-examination certificate	<u>6. EU type-examination certificate</u>	
Annex VII, point (6)(6.1), introductory part		Annex IX, (4), first paragraph, first sentence
6.1. Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU type-examination certificate to the manufacturer.	<del>6.1. Where</del> <u>4. If the type meets</u> <del>satisfies</del> the <u>applicable essential health and safety requirements</u> <del>provisions of this Directive,</del> the notified body shall issue <del>the applicant</del> <u>with an EU</u> <del>EC</del> type-examination certificate <u>to the manufacturer.</u>	4. If the type satisfies the provisions of this Directive, the notified body shall issue the applicant with an EC type-examination certificate.
Annex VII, point (6)(6.1), first paragraph		Annex IX, (9.3), first paragraph
The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.	<del>9.3.-</del> The <u>period</u> <del>manufacturer shall request from the notified body the review of the validity of a newly issued</del> <u>the EC type-examination certificate and, where appropriate, of a renewed certificate shall not exceed</u> <del>every</del> five years.	9.3. The manufacturer shall request from the notified body the review of the validity of the EC type-examination certificate every five years.
Annex VII, point (6)(6.2), introductory part		Annex IX, (4), first paragraph, second sentence
6.2. The EU type-examination certificate shall contain at least the following information:	<u>6.2. The EU type-examination certificate shall contain at least the following information:</u> <del>The certificate shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.</del>	The certificate shall include the name and address of the manufacturer and his authorised representative, the data necessary for identifying the approved type, the conclusions of the examination and the conditions to which its issue may be subject.
Annex VII, point (6)(6.2)(a)		
(a) the name and identification number of the notified body;	<u>(a) the name and identification number of the notified body;</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex VII, point (6)(6.2)(b) (b) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;	<u>(b) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;</u> <del>[see above]</del>	[see above]
Annex VII, point (6)(6.2)(c) (c) an identification of the machinery or related product covered by the certificate (type number);	<u>(c) an identification of the machinery or related product covered by the certificate (type number);</u> <del>[see above]</del>	[see above]
Annex VII, point (6)(6.2)(d) (d) a statement that the machinery or related product type complies with the applicable essential health and safety requirements;	<u>(d) a statement that the machinery or related product type complies with the applicable essential health and safety requirements;</u> <del>[see above]</del>	[see above]
Annex VII, point (6)(6.2)(e) (e) where harmonised standards or common specifications adopted by the Commission in accordance with Article 17(3) have been fully or partially applied, the references of those standards or common specifications or parts thereof;	<u>(e) where harmonised standards or common specifications adopted by the Commission in accordance with Article 17(3) have been fully or partially applied, the references of those standards or common specifications or parts thereof;</u>	
Annex VII, point (6)(6.2)(f) (f) where other technical specifications have been applied, the references of those technical specifications;	<u>(f) where other technical specifications have been applied, the references of those technical specifications;</u>	
Annex VII, point (6)(6.2)(g) (g) deleted	<u>(g) deleted</u>	
Annex VII, point (6)(6.2)(h) (h) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal;	<u>(h) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal;</u>	
Annex VII, point (6)(6.2)(i)		

DRAFT Machinery Regulation	Comparison	Machinery Directive
(i) any conditions attached to the issuing of the certificate.	<u>(i) any conditions attached to the issuing of the certificate.</u> <del>[see above]</del>	[see above]
Annex VII, point (6)(6.3)		
6.3. The EU type-examination certificate may have one or more annexes attached.	<u>6.3. The EU type-examination certificate may have one or more annexes attached.</u>	
Annex VII, point (6)(6.4)		
6.4. Where the type does not satisfy the applicable essential health and safety requirements, the notified body shall refuse to issue an EU type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.	<u>6.4. Where the type does not satisfy the applicable essential health and safety requirements, the notified body shall refuse to issue an EU type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.</u>	
Annex VII, point (7), introductory part		
7. Review of the EU type-examination certificate	<u>7. Review of the EU type-examination certificate</u>	
Annex VII, point (7)(7.1)		Annex IX, (9.1)
7.1. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art, which indicate that the approved type may no longer comply with the applicable essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.	<del>7.1. The notified body shall keep itself apprised</del> <u>has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. It shall inform the manufacturer of any major changes in the generally acknowledged state of the art, which indicate that the approved type may no longer comply with</u> <del>would have an implication on</del> <u>the applicable essential health and safety requirements, and shall determine whether such changes require further investigation. If so,</u> <del>validity of the certificate. The notified body shall inform the manufacturer accordingly</del> <u>withdraw certificates which are no longer valid.</u>	9.1. The notified body has the ongoing responsibility of ensuring that the EC type-examination certificate remains valid. It shall inform the manufacturer of any major changes which would have an implication on the validity of the certificate. The notified body shall withdraw certificates which are no longer valid.
Annex VII, point (7)(7.2)		Annex IX, (6)

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type-examination certificate of all modifications to the approved type and of all modifications to the technical documentation that may affect the conformity of the machinery or related product with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.</p>	<p><del>7.26.</del> The <del>manufacturer</del><u>applicant</u> shall inform the notified body <del>that holds</del><u>which retains</u> the technical <del>documentation</del><u>file</u> relating to the <del>EU</del><u>EC</u> type-examination certificate of all modifications to the approved type <del>and of all.</del><u>The notified body shall examine these modifications to and shall then either confirm the technical documentation that may affect validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity of the machinery or related product with the applicable essential health and safety requirements or the intended working conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate</u><del>of the type.</del></p>	<p>6. The applicant shall inform the notified body which retains the technical file relating to the EC type-examination certificate of all modifications to the approved type. The notified body shall examine these modifications and shall then either confirm the validity of the existing EC type-examination certificate or issue a new one if the modifications are liable to compromise conformity with the essential health and safety requirements or the intended working conditions of the type.</p>
<p>Annex VII, point (7)(7.3)</p>		<p>Annex IX, (9.2)</p>
<p>7.3. The manufacturer shall ensure that the machinery or related product continues to fulfil the applicable essential health and safety requirements in light of the state of the art.</p>	<p><del>7.39.2.</del> The manufacturer <del>shall ensure that</del><u>of the machinery or related product continues to fulfil</u><del>concerned has</del> the <u>applicable essential health and safety requirements in light of the ongoing responsibility of ensuring that the said machinery meets the corresponding</u> state of the art.</p>	<p>9.2. The manufacturer of the machinery concerned has the ongoing responsibility of ensuring that the said machinery meets the corresponding state of the art.</p>
<p>Annex VII, point (7)(7.4), introductory part</p>		
<p>7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate either:</p>	<p><u>7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate either:</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex VII, point (7)(7.4)(a) (a) in the case of a modification to the approved type referred to in point 7.2;	<u>(a) in the case of a modification to the approved type referred to in point 7.2;</u> <del>{see point 7.2}</del>	[see point 7.2]
Annex VII, point (7)(7.4)(b) (b) in the case of a change in the state of the art referred to in point 7.3;	<u>(b) in the case of a change in the state of the art referred to in point 7.3;</u> <del>{see point 7.3}</del>	[see point 7.3]
Annex VII, point (7)(7.4)(c) (c) at the latest, before the date of expiry of the certificate. In this case, the review may lead to a renewal of the EU type certificate only when the application is submitted by the manufacturer at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate. Otherwise, the review may lead only to an approval in the form of an addition to the original EU type-examination certificate and the expiry date of the certificate shall be the one of the original certificate.	<u>(c) at the latest, before the date of expiry of the certificate. In this case, the review may lead to a renewal of the EU type certificate only when the application is submitted by the manufacturer at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate. Otherwise, the review may lead only to an approval in the form of an addition to the original EU type-examination certificate and the expiry date of the certificate shall be the one of the original certificate.</u> <del>{compare point 6.1}</del>	[compare point 6.1]
Annex VII, point (7)(7.5) 7.5. The notified body shall examine the machinery or related product type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential health and safety requirements. If the notified body is satisfied that the approved type continues to fulfil the applicable essential health and safety	<u>7.5. The notified body shall examine the machinery or related product type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential health and safety requirements. If the notified body is satisfied that the approved type continues to fulfil the applicable essential health and safety</u>	Annex IX, (9.3), second paragraph If the notified body finds that the certificate remains valid, taking into account the state of the art, it shall renew the certificate for a further five years.

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>requirements, it shall renew the EU type-examination certificate. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.</p>	<p><u>requirements, it shall renew the EU type-examination certificate. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.</u>  <del>If the notified body finds that the certificate remains valid, taking into account the state of the art, it shall renew the certificate for a further five years.</del></p>	
<p>Annex VII, point (7)(7.6), introductory part</p>		
<p>7.6. Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply the notified body with the following:</p>	<p><u>7.6. Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply the notified body with the following:</u></p>	
<p>Annex VII, point (7)(7.6)(a)</p>		
<p>(a) His or her name and address and data identifying the EU type-examination certificate concerned;</p>	<p><u>(a) His or her name and address and data identifying the EU type-examination certificate concerned;</u></p>	
<p>Annex VII, point (7)(7.6)(b)</p>		
<p>(b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or common specifications adopted by the Commission in accordance with Article 17(3) or other technical specifications applied;</p>	<p><u>(b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or common specifications adopted by the Commission in accordance with Article 17(3) or other technical specifications applied;</u></p>	
<p>Annex VII, point (7)(7.6)(c)</p>		
<p>(c) confirmation that there has been no change in the state of the art as referred to in point 7.3; and</p>	<p><u>(c) confirmation that there has been no change in the state of the art as referred to in point 7.3; and</u></p>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex VII, point (7)(7.6)(d)		
(d) where not already supplied, copies of current product drawings and photographs, product marking and information;	<u>(d) where not already supplied, copies of current product drawings and photographs, product marking and information;</u>	
Annex VII, point (7)(7.6), first paragraph		
Where the notified body has confirmed that no modification to the approved type referred to in point 7.2 and no change in the state of the art referred to in point 7.3 has occurred, the simplified review procedure shall be applied and the examinations and tests referred to in point 7.5 shall not be carried out. In that case, the notified body shall renew the EU type-examination certificate.	<u>Where the notified body has confirmed that no modification to the approved type referred to in point 7.2 and no change in the state of the art referred to in point 7.3 has occurred, the simplified review procedure shall be applied and the examinations and tests referred to in point 7.5 shall not be carried out. In that case, the notified body shall renew the EU type-examination certificate.</u>	
Annex VII, point (7)(7.6), second paragraph		
The costs associated with that renewal shall be proportionate to the administrative burden of the simplified procedure.	<u>The costs associated with that renewal shall be proportionate to the administrative burden of the simplified procedure.</u>	
Annex VII, point (7)(7.6), third paragraph		
If the notified body finds that a change in the state of the art referred to in point 7.3 has occurred, the procedure set out in point 7.5 shall apply.	<u>If the notified body finds that a change in the state of the art referred to in point 7.3 has occurred, the procedure set out in point 7.5 shall apply.</u>	
Annex VII, point (7)(7.7)		Annex IX, (9.4)
7.7. If, following the review, the notified body concludes that the EU type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the machinery or related product concerned.	<u>7.7. If, following</u> <del>9.4. In</del> <u>the review, the notified body concludes</u> <del>event</del> <u>that the EU validity of the EC-type</u> <del>-</del> <u>examination certificate is no longer valid, the body shall withdraw it and</u> <del>not renewed</del> <u>, the manufacturer shall cease the placing on</u>	9.4. In the event that the validity of the EC-type examination certificate is not renewed, the manufacturer shall cease the placing on the market of the machinery concerned.

DRAFT Machinery Regulation	Comparison	Machinery Directive
	the market of the machinery <u>or related product</u> concerned.	
Annex VII, point (8), introductory part		
8. Each notified body shall inform its notifying authority concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.	<u>8. Each notified body shall inform its notifying authority concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.</u>	
Annex VII, point (8), first paragraph		Annex IX, (5)
Each notified body shall inform the other notified bodies concerning the EU type-examination certificates and/or any additions thereto, which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the EU type-examination certificates and/or additions thereto which it has issued.	<del>Each 5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies concerning the EU type-examination certificates and/or any additions thereto, the Member State which notified it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the EU type-examination certificates and/or additions thereto which it has issued. An appeal procedure must be available.</del>	5. If the type does not satisfy the provisions of this Directive, the notified body shall refuse to issue the applicant with an EC type-examination certificate, giving detailed reasons for its refusal. It shall inform the applicant, the other notified bodies and the Member State which notified it. An appeal procedure must be available.
Annex VII, point (8), second paragraph		Annex IX, (7)
The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type-examination certificates and/or additions thereto. On request, the Commission and the Member	<del>7.</del> The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the <del>EU</del> EC type-examination certificates <u>and/or additions thereto.</u> <del>On.</del> <del>On reasoned</del> request, the	7. The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC type-examination certificates. On reasoned request, the Commission and the Member

DRAFT Machinery Regulation	Comparison	Machinery Directive
States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.	Commission and the Member States may obtain a copy of the technical <u>documentation</u> <del>file</del> and the results of the examinations carried out by the notified body.	States may obtain a copy of the technical file and the results of the examinations carried out by the notified body.
Annex VII, point (8), third paragraph		Annex IX, (4), second paragraph
The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, for a period of five years after the expiry of the validity of that certificate.	The <del>manufacturer and the</del> notified body shall <del>keep</del> <u>retain</u> a copy of <u>the EU type-examination</u> <del>this</del> certificate, <u>its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, and all relevant documents</u> for a period of <del>five</del> <u>15</u> years <del>after</del> <u>from</u> the <del>expiry</del> <u>date</u> of the <del>validity</del> <u>issue</u> of <del>that</del> <u>the</u> certificate.	The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.
		Annex IX, (9.3), third paragraph
	<del>The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.</del>	The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.
Annex VII, point (9)		Annex IX, (4), second paragraph
9. The manufacturer shall keep a copy of the EU type-examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities, for 10 years after the machinery or related product has been placed on the market or put into service.	<del>9. The manufacturer and the notified body</del> shall <del>keep</del> <u>retain</u> a copy of <u>the EU type-examination</u> <del>this</del> certificate, <u>its annexes and additions, together with the technical documentation at</u> <del>file and all relevant documents for a period of 15 years from the</del> <u>disposal</u> <del>date of issue of the</del> <u>national authorities, for 10 years after the machinery or related product has been placed on the market or put into service</u> <del>certificate</del> .	The manufacturer and the notified body shall retain a copy of this certificate, the technical file and all relevant documents for a period of 15 years from the date of issue of the certificate.
		Annex IX, (9.3), third paragraph

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.</del></p>	<p>The manufacturer and the notified body shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.</p>
Annex VII, point (10)		
<p>10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7.2, 7.4 and 9, provided that they are specified in the mandate.</p>	<p><u>10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7.2, 7.4 and 9, provided that they are specified in the mandate.</u></p>	
		Annex IX, (8)
	<p><del>8. Files and correspondence referring to the EC type-examination procedures shall be written in the official Community language(s) of the Member State where the notified body is established or in any other official Community language acceptable to the notified body.</del></p>	<p>8. Files and correspondence referring to the EC type-examination procedures shall be written in the official Community language(s) of the Member State where the notified body is established or in any other official Community language acceptable to the notified body.</p>

**Annex VIII: Modul C – Conformity to type based on internal production control**

<b>DRAFT Machinery Regulation</b>	<b>Comparison</b>	<b>Machinery Directive</b>
Annex VIII		
ANNEX VIII	<u>ANNEX VIII</u>	
Annex VIII, first heading		
CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (Module C)	<u>CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL (Module C)</u>	
Annex VIII, point (1)		
1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares under his or her sole responsibility that the machinery or related product concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.	<u>1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares under his or her sole responsibility that the machinery or related product concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.</u>	
Annex VIII, point (2), introductory part		
2. Manufacturing	<u>2. Manufacturing</u>	
Annex VIII, point (2), first paragraph		
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured machinery or related product with the type described in the EU type-examination certificate and with the applicable requirements of this Regulation.	<u>The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured machinery or related product with the type described in the EU type-examination certificate and with the applicable requirements of this Regulation.</u>	
Annex VIII, point (3), introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
3. CE marking and EU declaration of conformity	<u>3. CE marking and EU declaration of conformity</u>	
Annex VIII, point (3)(3.1)		
3.1. The manufacturer shall affix the CE marking to each individual machinery or related product that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.	<u>3.1. The manufacturer shall affix the CE marking to each individual machinery or related product that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.</u>	
Annex VIII, point (3)(3.2)		
3.2. The manufacturer shall draw up an EU declaration of conformity for a machinery or related product model and keep it at the disposal of the national authorities for 10 years after the machinery or related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery or related product for which it has been drawn up.	<u>3.2. The manufacturer shall draw up an EU declaration of conformity for a machinery or related product model and keep it at the disposal of the national authorities for 10 years after the machinery or related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery or related product for which it has been drawn up.</u>	
Annex VIII, point (3), first paragraph		
A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.	<u>A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.</u>	
Annex VIII, point (4), introductory part		
4. Authorised representative	<u>4. Authorised representative</u>	
Annex VIII, point (4), first paragraph		
The manufacturer's obligations set out in point 3 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.	<u>The manufacturer's obligations set out in point 3 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.</u>	

**Annex IX: Modul H – Conformity based on full quality assurance**

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex IX		
ANNEX IX	ANNEX IX <del>X</del>	ANNEX X
Annex IX, first heading		
CONFORMITY BASED ON FULL QUALITY ASSURANCE	<u>CONFORMITY BASED ON FULL QUALITY ASSURANCE</u> <del>Full quality assurance</del>	Full quality assurance
Annex IX, second heading		
(Module H)	<u>(Module H)</u>	
Annex IX, point (1)		Annex X, first paragraph
1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his or her sole responsibility that the machinery or related product concerned satisfies the requirements of this Regulation that apply to it.	1. Conformity based on full quality assurance is <u>This Annex describes</u> the conformity assessment <del>of machinery referred to in Annex IV, manufactured using a full quality assurance system, and the</del> procedure whereby <u>the manufacturer fulfils</u> <del>a notified body assesses and approves</del> the obligations laid down in points 2 and 5, and ensures <u>quality system</u> and <u>declares on his or her sole responsibility that the machinery or related product concerned satisfies the requirements of this Regulation that apply to it</u> <del>monitors its application.</del>	This Annex describes the conformity assessment of machinery referred to in Annex IV, manufactured using a full quality assurance system, and the procedure whereby a notified body assesses and approves the quality system and monitors its application.
Annex IX, point (2), introductory part		
2. Manufacturing	<u>2. Manufacturing</u>	
Annex IX, point (2), first paragraph		Annex X, (1)
The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the machinery or related product concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.	<del>1.</del> The manufacturer <del>shall</del> <u>must</u> operate an approved quality system for design, manufacture <u>and</u> ; final <u>product</u> inspection and testing <u>of the machinery or related product concerned</u> ; as specified in point <del>3</del> <u>2</u> ; and shall be subject to <del>the</del>	1. The manufacturer must operate an approved quality system for design, manufacture, final inspection and testing, as specified in point 2, and shall be subject to the surveillance referred to in point 3.

DRAFT Machinery Regulation	Comparison	Machinery Directive
	surveillance <u>as specified</u> <del>referred to</del> in point <del>4</del> <u>3</u> .	
Annex IX, point (3), introductory part		Annex X, (2)
3. Quality system	<del>3</del> <u>2</u> . Quality system	2. Quality system
Annex IX, point (3)(3.1), introductory part		Annex X, (2.1), first paragraph
3.1. The manufacturer shall lodge an application for assessment of his or her quality system with the notified body of his or her choice, for the machinery or related product concerned.	<del>3</del> <u>2</u> .1. The manufacturer <del>or his authorised representative</del> shall lodge an application for assessment of his <u>or her</u> quality system <u>with the</u> <del>to a</del> notified body of his <u>or her</u> choice, <u>for the machinery or related product concerned.</u>	2.1. The manufacturer or his authorised representative shall lodge an application for assessment of his quality system to a notified body of his choice.
Annex IX, point (3)(3.1), first paragraph, introductory part		Annex X, (2.1), second paragraph
The application shall include:	The application shall <u>include</u> <del>contain</del> :	The application shall contain:
Annex IX, point (3)(3.1), first paragraph(a)		Annex X, (2.1), dash 1
(a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;	<u>(a)</u> — the name and address of the manufacturer and, <u>if the application is lodged by an</u> <del>where appropriate, his</del> authorised representative, <u>the name and address of that authorised representative;</u>	— the name and address of the manufacturer and, where appropriate, his authorised representative,
		Annex X, (2.1), dash 2
	<del>— the places of design, manufacture, inspection, testing and storage of the machinery;</del>	— the places of design, manufacture, inspection, testing and storage of the machinery,
Annex IX, point (3)(3.1), first paragraph(b), introductory part		Annex X, (2.1), dash 3
(b) the technical documentation for one model of each category of machinery or related products intended to be manufactured. The technical documentation shall, wherever applicable, contain at least:	<u>(b)</u> — the technical <u>documentation file</u> <del>described in Annex VII, Part A,</del> for one model of each category of machinery <u>or related products intended</u> <del>referred to</del> <u>be manufactured.</u> <u>The technical documentation shall, wherever</u>	— the technical file described in Annex VII, Part A, for one model of each category of machinery referred to in Annex IV which he intends to manufacture,

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>applicable, contain at least:in Annex IV which he intends to manufacture,</del>	
Annex IX, point (3)(3.1), first paragraph(b)(i)		
(i) the elements set out in points a), b), d), e), f), g) and h) of Annex IV part A; and	(i) the elements set out in points a), b), d), e), f), g) and h) of Annex IV part A; and	
Annex IX, point (3)(3.1), first paragraph(b)(vii)		Annex X, (2.1), dash 4
(vii) the documentation concerning the quality system; and	<del>(vii)— the documentation concerning</del> on the quality system; and,	— the documentation on the quality system,
Annex IX, point (3)(3.1), first paragraph(b)(viii)		Annex X, (2.1), dash 5
(viii) a written declaration that the same application has not been lodged with any other notified body.	<del>(viii)— a written declaration that the same application has not been lodged with any other</del> submitted to another notified body.	— a written declaration that the application has not been submitted to another notified body.
Annex IX, point (3)(3.2), introductory part		Annex X, (2.2), first paragraph, first sentence
3.2. The quality system shall ensure compliance of the machinery or related products with the requirements of this Regulation that apply to them.	<del>3.2.2.</del> The quality system <del>shall</del> must ensure <del>compliance</del> conformity of the machinery or related products with the <del>requirements</del> provisions of this <del>Regulation</del> Directive.	2.2. The quality system must ensure conformity of the machinery with the provisions of this Directive.
Annex IX, point (3)(3.2), first paragraph		Annex X, (2.2), first paragraph, remaining sentences
All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.	All the elements, requirements and provisions adopted by the manufacturer <del>shall</del> must be documented in a systematic and orderly manner; in the form of <del>written policies</del> measures, procedures and <del>written instructions.</del> That quality system The documentation <del>shall</del> on the quality system must permit a <del>consistent</del> uniform interpretation of the <del>procedural and</del>	All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner, in the form of measures, procedures and written instructions. The documentation on the quality system must permit a uniform interpretation of the procedural and quality measures, such as quality programmes, plans, manuals and records.

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>quality measures, such as</del> quality programmes, plans, manuals and records.	
Annex IX, point (3)(3.2), second paragraph, introductory part		Annex X, (2.2), second paragraph
It shall, in particular, contain an adequate description of:	It <del>shall</del> <u>must contain</u> , in particular, <u>contain</u> an adequate description of:	It must contain, in particular, an adequate description of:
Annex IX, point (3)(3.2), second paragraph(a)		Annex X, (2.2), dash 1
(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;	<u>(a)</u> — the quality objectives <u>and</u> , the organisational structure, <del>and the</del> responsibilities and powers of the management with regard to <del>the</del> design and <u>product</u> quality; <del>of the machinery;</del>	— the quality objectives, the organisational structure, and the responsibilities and powers of the management with regard to the design and quality of the machinery,
Annex IX, point (3)(3.2), second paragraph(b)		Annex X, (2.2), dash 2
(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or other technical specifications or common specifications adopted by the Commission in accordance with Article 17(3) will not be applied in full, the means that will be used to ensure that the essential health and safety requirements of this Regulation that apply to the machinery or related product will be met;	<u>(b)</u> — the technical design specifications, including standards, that will be applied and, where the <u>relevant harmonised standards or other technical specifications or common specifications adopted by the Commission</u> <del>referred to in accordance with Article 17(3) will</del> <u>7(2) are</u> not <u>be</u> applied in full, the means that will be used to ensure that the essential health and safety requirements of this <u>Regulation that apply to the machinery or related product will be met;</u> <del>Directive are fulfilled;</del>	— the technical design specifications, including standards that will be applied and, where the standards referred to in Article 7(2) are not applied in full, the means that will be used to ensure that the essential health and safety requirements of this Directive are fulfilled,
Annex IX, point (3)(3.2), second paragraph(c)		Annex X, (2.2), dash 3
(c) the design control and design verification techniques, processes and systematic actions that will be used when	<u>(c)</u> — the design <u>control</u> <del>inspection</del> and design verification techniques, processes and systematic actions that will be used	— the design inspection and design verification techniques, processes and systematic actions that will be used when

DRAFT Machinery Regulation	Comparison	Machinery Directive
designing the machinery or related product ;	when designing <u>the machinery or related product</u> ; <del>covered by this Directive,</del>	designing machinery covered by this Directive,
Annex IX, point (3)(3.2), second paragraph(d)		Annex X, (2.2), dash 4
(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;	<del>(d)</del> — the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used; <del>;</del>	— the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,
Annex IX, point (3)(3.2), second paragraph(e)		Annex X, (2.2), dash 5
(e) the examinations and tests that will be carried out before, during and after manufacture and the frequency with which they will be carried out;	<del>(e)</del> — the <del>examinations</del> <del>inspections</del> and tests that will be carried out before, during and after manufacture <del>;</del> and the frequency with which they will be carried out; <del>;</del>	— the inspections and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,
Annex IX, point (3)(3.2), second paragraph(f)		Annex X, (2.2), dash 6
(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;	<del>(f)</del> — the quality records, such as inspection reports and test data, calibration data, <del>qualification</del> <del>and</del> reports on the <del>qualifications of the</del> personnel concerned, <del>etc.</del> ;	— the quality records, such as inspection reports and test data, calibration data, and reports on the qualifications of the personnel concerned,
Annex IX, point (3)(3.2), second paragraph(g)		Annex X, (2.2), dash 7
(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.	<del>(g)</del> — the means of monitoring the achievement of the required design and <del>product</del> quality <del>and</del> <del>of the machinery,</del> <del>as well as</del> the effective operation of the quality system.	— the means of monitoring the achievement of the required design and quality of the machinery, as well as the effective operation of the quality system.
Annex IX, point (3)(3.3), introductory part		Annex X, (2.3), first paragraph
3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.	<del>3</del> 2.3. The notified body shall assess the quality system to determine whether it satisfies the requirements <u>referred to in</u> <del>of</del> point <del>3</del> 2.2.	2.3. The notified body shall assess the quality system to determine whether it satisfies the requirements of point 2.2.

DRAFT Machinery Regulation	Comparison	Machinery Directive
<p>Annex IX, point (3)(3.3), first paragraph</p> <p>It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.</p>	<p><u>It shall presume conformity with those requirements in respect of the</u><del>The</del> <u>elements of the quality system that comply with the corresponding specifications of</u><del>which conform to</del> the relevant harmonised standard<del>shall be presumed to conform to the corresponding requirements referred to in point 2.2.</del></p>	<p>Annex X, (2.3), second paragraph</p> <p>The elements of the quality system which conform to the relevant harmonised standard shall be presumed to conform to the corresponding requirements referred to in point 2.2.</p>
<p>Annex IX, point (3)(3.3), second paragraph</p> <p>In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant machinery or related product field and technology concerned, and with knowledge of the applicable essential health and safety requirements set out in Annex III of this Regulation. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(b), point (ii), to verify the manufacturer's ability to identify the applicable essential health and safety requirements set out in Annex III of this Regulation and to carry out the necessary examinations with a view to ensuring compliance of the machinery or related product with those requirements.</p>	<p><u>In addition to experience in quality management systems, the auditing</u> <del>The</del> <u>team shall</u><del>of auditors must</del> have at least one member <u>who is</u><del>is</del> experienced <u>as an assessor in the relevant machinery or related product field and in the</u><del>assessment of the</del> technology concerned, and with knowledge of the applicable essential health and safety requirements set out in Annex III of this Regulation. <del>The audit</del><del>machinery. The</del> <del>assessment procedure</del> shall include an <u>assessment visit to</u><del>inspection to be carried out at</del> the manufacturer's premises. <u>The auditing</u> <del>During the assessment, the</del> <del>team of auditors</del> shall <u>carry out a review of</u> the technical <u>documentation</u><del>files</del> referred to in point <u>32.1(b), point (ii), to verify the manufacturer's ability to identify the applicable essential health and safety requirements set out in Annex III of this Regulation and to carry out the necessary</u></p>	<p>Annex X, (2.3), third paragraph</p> <p>The team of auditors must have at least one member who is experienced in the assessment of the technology of the machinery. The assessment procedure shall include an inspection to be carried out at the manufacturer's premises. During the assessment, the team of auditors shall carry out a review of the technical files referred to in point 2.1, second paragraph, third indent to ensure their compliance with the relevant health and safety requirements.</p>

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<p><del>examinations with a view to ensuring;</del>  <del>second paragraph, third indent to ensure</del>                      their compliance <u>of the machinery or related product</u> with <del>those</del><del>the relevant</del>                      health and safety requirements.</p>	
Annex IX, point (3)(3.3), third paragraph		Annex X, (2.3), fourth paragraph, first sentence
The manufacturer or his or her authorised representative shall be notified of the decision.	The manufacturer or his <u>or her</u> authorised representative shall be notified of the decision.	The manufacturer or his authorised representative shall be notified of the decision.
Annex IX, point (3)(3.3), fourth paragraph		Annex X, (2.3), fourth paragraph, remaining sentences
The notification shall contain the conclusions of the audit and the reasoned assessment decision.	The notification shall contain the conclusions of the <u>audit</u> <del>examination</del> and the reasoned assessment decision. <del>An appeal procedure must be available.</del>	The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.
Annex IX, point (3)(3.4)		Annex X, (2.4), first paragraph
3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.	<p><del>3.2.4.</del> The manufacturer shall undertake to fulfil the obligations arising <u>out of</u><del>from</del> the quality system as approved and to <u>maintain it so</u><del>ensure</del> that it remains <u>adequate</u><del>appropriate</del> and <u>efficient</u><del>effective</del>.</p>	2.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to ensure that it remains appropriate and effective.
Annex IX, point (3)(3.5), introductory part		Annex X, (2.4), second paragraph
3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.	<p><del>3.5.</del> The manufacturer <del>or his authorised representative</del> shall <u>keep</u><del>inform</del> the notified body <u>that has</u><del>which</del> approved the quality system <u>informed</u> of any <u>intended</u><del>planned</del> change to <u>the quality system</u><del>it</del>.</p>	The manufacturer or his authorised representative shall inform the notified body which approved the quality system of any planned change to it.
Annex IX, point (3)(3.5), first paragraph		Annex X, (2.4), third paragraph
The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue	The notified body shall evaluate <u>any</u> <del>the</del> proposed changes and decide whether the modified quality <u>assurance</u> <del>system</del>	The notified body shall evaluate the proposed changes and decide whether the modified quality assurance system

DRAFT Machinery Regulation	Comparison	Machinery Directive
to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.	will continue to satisfy the requirements referred to in point <del>3.2.2</del> , or whether a <u>reassessment</u> <del>re-assessment</del> is necessary.	will continue to satisfy the requirements referred to in point 2.2, or whether a re-assessment is necessary.
Annex IX, point (3)(3.5), second paragraph		Annex X, (2.4), fourth paragraph
It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.	It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
Annex IX, point (4), introductory part		Annex X, (3)
4. Surveillance under the responsibility of the notified body	<del>4</del> 3. Surveillance under the responsibility of the notified body	3. Surveillance under the responsibility of the notified body
Annex IX, point (4)(4.1)		Annex X, (3.1)
4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.	<del>4</del> 3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.	3.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
Annex IX, point (4)(4.2), introductory part		Annex X, (3.2)
4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:	<del>4</del> 3.2. The manufacturer shall, for <u>assessment</u> <del>inspection</del> purposes, allow the notified body access to the <del>places of</del> design, manufacture, inspection, testing and storage <u>sites</u> , and shall provide it with all necessary information, <u>in particular</u> <del>such as</del> :	3.2. The manufacturer shall, for inspection purposes, allow the notified body access to the places of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, such as:
Annex IX, point (4)(4.2)(a)		Annex X, (3.2), dash 1
(a) the quality system documentation;	<del>(a) — the documentation concerning the quality system</del> <u>documentation</u> ;	— the documentation concerning the quality system,
Annex IX, point (4)(4.2)(b)		Annex X, (3.2), dash 2
(b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;	<del>(b) — the quality records as provided for by the design</del> <u>in that</u> part of the quality system <del>concerned with design</del> , such as	— the quality records provided for in that part of the quality system concerned with design, such as the results of analyses, calculations, tests, etc.,

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<del>the</del> results of analyses, calculations, tests, etc.; <del>;</del>	
Annex IX, point (4)(4.2)(c)		Annex X, (3.2), dash 3
(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.	<del>(c)</del> — the quality records <u>as</u> provided for <u>by the manufacturing</u> <del>in that</del> part of the quality system <del>concerned with</del> <u>manufacture</u> , such as inspection reports and test data, calibration data, <u>qualification</u> reports on the <u>qualifications</u> <del>of the</del> personnel concerned, etc.	— the quality records provided for in that part of the quality system concerned with manufacture, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.
Annex IX, point (4)(4.3)		Annex X, (3.3)
4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.	<del>4.3.3.</del> The notified body shall <u>carry out</u> <del>conduct</del> periodic audits to make sure that the manufacturer <u>maintains</u> <del>is maintaining</del> and <u>applies</u> <del>applying</del> the quality system <u>and</u> <del>;</del> it shall provide the manufacturer with an audit report. <del>The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.</del>	3.3. The notified body shall conduct periodic audits to make sure that the manufacturer is maintaining and applying the quality system; it shall provide the manufacturer with an audit report. The frequency of the periodic audits shall be such that a full reassessment is carried out every three years.
Annex IX, point (4)(4.4)		Annex X, (3.4)
4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.	<del>3.4.4.</del> In addition <del>Moreover</del> , the notified body may pay <u>unexpected visits to the manufacturer</u> . <u>During such</u> <del>unannounced</del> <u>visits</u> . <del>The need for these additional visits, and their frequency will be determined on the basis of a visit monitoring system managed by the notified body</del> <u>may, if necessary, carry out product tests, or have them carried out,</u> <del>In particular, the following factors will be taken into account</del> <u>in order to check the proper functioning of the quality system.</u> <u>It shall provide the manufacturer with a</u>	3.4. Moreover, the notified body may pay the manufacturer unannounced visits. The need for these additional visits and their frequency will be determined on the basis of a visit monitoring system managed by the notified body. In particular, the following factors will be taken into account in the visits monitoring system:

DRAFT Machinery Regulation	Comparison	Machinery Directive
	<u>visit report and, if tests have been carried out, with a test report.</u> <del>visits monitoring system:</del>	
		Annex X, (3.4), dash 1
	<del>— the results of previous surveillance visits,</del>	— the results of previous surveillance visits,
		Annex X, (3.4), dash 2
	<del>— the need to monitor remedial measures,</del>	— the need to monitor remedial measures,
		Annex X, (3.4), dash 3
	<del>— where appropriate, special conditions attaching to approval of the system,</del>	— where appropriate, special conditions attaching to approval of the system,
		Annex X, (3.4), dash 4
	<del>— significant modifications in the organisation of the manufacturing process, measures or techniques.</del>	— significant modifications in the organisation of the manufacturing process, measures or techniques.
		Annex X, (3.4), last paragraph
	<del>On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.</del>	On the occasion of such visits, the notified body may, if necessary, carry out tests or have them carried out in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if a test was carried out, with a test report.
Annex IX, point (5), introductory part		
5. CE marking and EU declaration of conformity	<u>5. CE marking and EU declaration of conformity</u>	
Annex IX, point (5)(5.1)		
5.1. The manufacturer shall affix the required CE marking set out in this Regulation, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to	<u>5.1. The manufacturer shall affix the required CE marking set out in this Regulation, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
each individual product that satisfies the applicable requirements of this Regulation.	<u>each individual product that satisfies the applicable requirements of this Regulation.</u>	
Annex IX, point (5)(5.2)		
5.2. The manufacturer shall draw up a written EU declaration of conformity for each machinery or related product model and keep it at the disposal of the national authorities for ten years after the machinery or related product has been placed on the market or put into service. The EU declaration of conformity shall identify the product model for which it has been drawn up.	<u>5.2. The manufacturer shall draw up a written EU declaration of conformity for each machinery or related product model and keep it at the disposal of the national authorities for ten years after the machinery or related product has been placed on the market or put into service. The EU declaration of conformity shall identify the product model for which it has been drawn up.</u>	
Annex IX, point (5), first paragraph		
A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.	<u>A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.</u>	
Annex IX, point (6), introductory part		Annex X, (4)
6. The manufacturer shall, for a period ending at least ten years after the machinery or related product has been placed on the market or put into service, keep at the disposal of the national authorities:	<u>6. The manufacturer <del>or his authorised representative</del> shall, for a period ending at least ten years after the machinery or related product has been placed on the market or put into service, keep at the disposal of <del>available for</del> the national authorities, <del>for a period of ten years from the last date of manufacture:</del></u>	4. The manufacturer or his authorised representative shall keep available for the national authorities, for a period of ten years from the last date of manufacture:
Annex IX, point (6)(a)		
(a) the technical documentation referred to in point 3.1;	<u>(a) the technical documentation referred to in point 3.1;</u>	
Annex IX, point (6)(b)		Annex X, (4), dash 1
(b) the documentation concerning the quality system referred to in point 3.1(b)(ii);	<u>(b) — the documentation <u>concerning the quality system</u> referred to in point <del>3.1(b)(ii);</del></u>	— the documentation referred to in point 2.1,

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex IX, point (6)(c)		
(c) the information relating to the change referred to in point 3.5, as approved;	<u>(c) the information relating to the change referred to in point 3.5, as approved;</u>	
Annex IX, point (6)(d)		Annex X, (4), dash 2
(d) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.	<u>(d)— the decisions and reports of the notified body referred to in <del>point 2.4, third and fourth subparagraphs, and in</del> points 3.5, 4.3 and <del>4</del>3.4.</u>	— the decisions and reports of the notified body referred to in point 2.4, third and fourth subparagraphs, and in points 3.3 and 3.4.
Annex IX, point (7), introductory part		
7. Each notified body shall inform its notifying authority of quality system approval decisions issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approval decisions refused, suspended or otherwise restricted.	<u>7. Each notified body shall inform its notifying authority of quality system approval decisions issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approval decisions refused, suspended or otherwise restricted.</u>	
Annex IX, point (7), first paragraph		
Each notified body shall inform the other notified bodies of quality system approval decisions, which it has refused, suspended or withdrawn, and, upon request, of quality system approval decisions, which it has issued.	<u>Each notified body shall inform the other notified bodies of quality system approval decisions, which it has refused, suspended or withdrawn, and, upon request, of quality system approval decisions, which it has issued.</u>	
Annex IX, point (8), introductory part		
8. Authorised representative	<u>8. Authorised representative</u>	
Annex IX, point (8), first paragraph		
The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.	<u>The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his or her authorised representative, on his or her behalf and under his or her responsibility, provided that they are specified in the mandate.</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex IX a (new)		
ANNEX IX a (new)	<u>ANNEX IX a (new)</u>	
Annex IX, a (new)		
CONFORMITY BASED ON UNIT VERIFICATION	<u>CONFORMITY BASED ON UNIT VERIFICATION</u>	
Annex IX, a (new) first paragraph		
(module G)	<u>(module G)</u>	
Annex IX, point (8), Annex IX, a (new) (1)		
1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his or her sole responsibility that the machinery or related product, which has been subject to the provisions of point 4, is in conformity with the essential health and safety requirements set out in Annex III.	<u>1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his or her sole responsibility that the machinery or related product, which has been subject to the provisions of point 4, is in conformity with the essential health and safety requirements set out in Annex III.</u>	
Annex IX, point (8), Annex IX, point (8), Annex IX, a (new) (2)		
2. Technical documentation	<u>2. Technical documentation</u>	
Annex IX, point (8), first paragraph		
The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the machinery or related product's conformity with the relevant essential health and safety requirements set out in Annex III, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable essential health and safety	<u>The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the machinery or related product's conformity with the relevant essential health and safety requirements set out in Annex III, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable essential health and safety</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the machinery or related product	<u>requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the machinery or related product</u>	
Annex IX, point (8), Annex IX, point (8)		
The technical documentation shall, wherever applicable, contain at least the following elements:	<u>The technical documentation shall, wherever applicable, contain at least the following elements:</u>	
Annex IX, point (8), first paragraph n		
(a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;	<u>(a) the name and address of the manufacturer and, if the application is lodged by an authorised representative, the name and address of that authorised representative;</u>	
Annex IX, point (8), first paragraph o		
(b) the technical documentation for the unit of machinery or related products intended to be manufactured. The technical documentation shall, wherever applicable, contain at least:	<u>(b) the technical documentation for the unit of machinery or related products intended to be manufactured. The technical documentation shall, wherever applicable, contain at least:</u>	
(i) the elements set out in points a), b), d), e), f), g) and h) of Annex IV part A; and	<u>(i) the elements set out in points a), b), d), e), f), g) and h) of Annex IV part A; and</u>	
(ii) the documentation concerning the quality system; and	<u>(ii) the documentation concerning the quality system; and</u>	
(iii) a written declaration that the same application has not been lodged with any other notified body.	<u>(iii) a written declaration that the same application has not been lodged with any other notified body.</u>	
Annex IX, point (8)		
The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the machinery or related product has been placed on the market.	<u>The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the machinery or related product has been placed on the market.</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex IX, point (8), Annex IX, point (8), Annex IX, point (8), Annex IX, a (new) 3		
3. Manufacturing	<u>3. Manufacturing</u>	
Annex IX, point (8)		
The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured machinery or related product with the applicable essential health and safety requirements set out in Annex III.	<u>The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured machinery or related product with the applicable essential health and safety requirements set out in Annex III.</u>	
Annex IX, point (8), Annex IX, point (8), Annex IX, point (8), Annex IX, a (new) 4		
4. Verification	<u>4. Verification</u>	
Annex IX, point (8), first paragraph r		
A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or common specifications, or equivalent tests, to check the conformity of the machinery or related product with the applicable essential health and safety requirements set out in Annex III, or have them carried out. In the absence of such a harmonised standard and/or common specification the notified body concerned shall decide on the appropriate tests to be carried out.	<u>A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or common specifications, or equivalent tests, to check the conformity of the machinery or related product with the applicable essential health and safety requirements set out in Annex III, or have them carried out. In the absence of such a harmonised standard and/or common specification the notified body concerned shall decide on the appropriate tests to be carried out.</u>	
The notified body shall issue a certificate in respect of the examinations and tests carried out and shall affix its identification number to the approved machinery or	<u>The notified body shall issue a certificate in respect of the examinations and tests carried out and shall affix its identification number to the approved machinery or</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
related product, or have it affixed under its responsibility.	<u>related product, or have it affixed under its responsibility.</u>	
The manufacturer shall keep the certificates at the disposal of the national authorities for 10 years after the machinery or related product has been placed on the market.	<u>The manufacturer shall keep the certificates at the disposal of the national authorities for 10 years after the machinery or related product has been placed on the market.</u>	
Annex IX, point (8), Annex IX, point (8), Annex IX, point (8), Annex IX, a (new) 5		
5. CE marking and EU declaration of conformity	<u>5. CE marking and EU declaration of conformity</u>	
Annex IX, point (8), Annex IX, point (8), Annex IX, point (8), Annex IX, a (new) 5.1		
5.1. The manufacturer shall affix the required CE marking set out in Article 10.2 and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each machinery or related product that satisfies the applicable essential health and safety requirements set out in Annex III.	<u>5.1. The manufacturer shall affix the required CE marking set out in Article 10.2 and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each machinery or related product that satisfies the applicable essential health and safety requirements set out in Annex III.</u>	
Annex IX, point (8), Annex IX, point (8), Annex IX, point (8), Annex IX, a (new) 5.2		
5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the machinery and related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery and related product for which it has been drawn up.	<u>5.2. The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the machinery and related product has been placed on the market or put into service. The EU declaration of conformity shall identify the machinery and related product for which it has been drawn up.</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex IX, point (8), Annex IX, point (8), Annex IX, point (8), Annex IX, a (new) 5 bis		
A copy of the declaration of conformity shall be made available to the relevant authorities upon request.	<u>A copy of the declaration of conformity shall be made available to the relevant authorities upon request.</u>	
Annex IX, point (8), Annex IX, point (8), Annex IX, point (8), Annex IX, a (new) 6		
6. Authorised representative	<u>6. Authorised representative</u>	
Annex IX, point (8), first paragraph x		
The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his or her behalf and under his responsibility, provided that they are specified in the mandate.	<u>The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his or her behalf and under his responsibility, provided that they are specified in the mandate.</u>	

## Annex X: Assembly instructions for partly completed machinery

DRAFT Machinery Regulation	Comparison	Machinery Directive
Annex X		
ANNEX X	ANNEX <del>XVI</del>	ANNEX VI
Annex X, first heading		
ASSEMBLY INSTRUCTIONS FOR PARTLY COMPLETED MACHINERY	<u>ASSEMBLY INSTRUCTIONS FOR PARTLY COMPLETED MACHINERY</u> <del>Assembly instructions for partly completed machinery</del>	Assembly instructions for partly completed machinery
Annex X, first paragraph		Annex VI, first paragraph
1. The assembly instructions for partly completed machinery shall contain a description of the conditions, which are to be met to ensure that the partly completed machinery is correctly incorporated in machinery or other partly completed machinery or equipment, and that the machinery or other partly completed machinery or equipment with the incorporated partly completed machinery does not compromise health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.	1. The assembly instructions for partly completed machinery <del>shall</del> <b>must</b> contain a description of the conditions, which <del>are to</del> <b>must</b> be met <del>to ensure that</del> <b>with a view to correct incorporation in</b> the <del>partly completed</del> <b>final</b> machinery <del>is correctly incorporated in machinery or other partly completed machinery or equipment, and that the machinery or other partly completed machinery or equipment with the incorporated partly completed machinery does,</del> <del>so as not to</del> <del>compromise safety and health</del> and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.	The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.
Annex X, second paragraph		
2. The assembly instructions shall contain relevant information to be used in the instructions of the machinery or other partly completed machinery or equipment, in which the partly completed machinery is to be assembled. Each assembly instruction shall contain, where	2. The assembly instructions shall contain <u>relevant information to be used in the instructions of the machinery or other partly completed machinery or equipment, in which the partly completed machinery is to be assembled. Each assembly instruction shall contain, where</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
applicable, at least the following information:	<u>applicable, at least the following information:</u>	
Annex X, subparagraph 2 a (new)		
a) a general description of the partly completed machinery;	<u>a) a general description of the partly completed machinery;</u>	
Annex X, second paragraph b, introductory part		
b) the drawings, diagrams, descriptions and explanations necessary for the incorporation into the final machinery , maintenance and repair of the partly completed machinery and for checking its correct functioning;	<u>b) the drawings, diagrams, descriptions and explanations necessary for the incorporation into the final machinery , maintenance and repair of the partly completed machinery and for checking its correct functioning;</u>	
Annex X, second paragraph b, point (1)		
c) warnings concerning ways in which the partly completed machinery shall not be used that experience has shown might occur;	<u>c) warnings concerning ways in which the partly completed machinery shall not be used that experience has shown might occur;</u>	
Annex X, second paragraph c, introductory part		
d) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the partly completed machinery is to be mounted;	<u>d) assembly, installation and connection instructions, including drawings, diagrams and the means of attachment and the designation of the chassis or installation on which the partly completed machinery is to be mounted;</u>	
Annex X, second paragraph c, point (1)		
e) information regarding noise or vibration which is likely to be reduced by the incorporation;	<u>e) information regarding noise or vibration which is likely to be reduced by the incorporation;</u>	
Annex X, second paragraph d, introductory part		

DRAFT Machinery Regulation	Comparison	Machinery Directive
f) information about the essential health and safety requirements set out in Annex III which are applicable to the partly completed machinery;	<u>f) information about the essential health and safety requirements set out in Annex III which are applicable to the partly completed machinery;</u>	
Annex X, second paragraph d, point (1)		
g) the essential characteristics of tools, which may be fitted to the partly completed machinery;	<u>g) the essential characteristics of tools, which may be fitted to the partly completed machinery;</u>	
Annex X, second paragraph e, introductory part		
h) the conditions in which the partly completed machinery meets the requirement of stability , transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;	<u>h) the conditions in which the partly completed machinery meets the requirement of stability , transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;</u>	
Annex X, second paragraph e, point (1)		
i) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the partly completed machinery and of its various parts where these are regularly to be transported separately;	<u>i) instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the partly completed machinery and of its various parts where these are regularly to be transported separately;</u>	
Annex X, second paragraph e, point (2)		
j) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;	<u>j) the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;</u>	
Annex X, second paragraph f, introductory part		
k) the description of the adjustment and maintenance operations that should be carried out by the user and the	<u>k) the description of the adjustment and maintenance operations that should be carried out by the user and the</u>	

DRAFT Machinery Regulation	Comparison	Machinery Directive
preventive maintenance measures that should be observed taking account of the design;	<u>preventive maintenance measures that should be observed taking account of the design;</u>	
Annex X, second paragraph f, point (1)		
l) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;	<u>l) instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;</u>	
Annex X, second paragraph g, introductory part		
m) the specifications of the spare parts to be used, when these affect the health and safety of operators;	<u>m) the specifications of the spare parts to be used, when these affect the health and safety of operators;</u>	
Annex X, second paragraph g, point (1)		
n) a clear description of which version of the assembly instructions corresponds to the partly completed machinery model;	<u>n) a clear description of which version of the assembly instructions corresponds to the partly completed machinery model;</u>	
Annex X, second paragraph g, point (2)		
If the partly completed machinery is intended to be used in machinery covered by annex III point 2 to 6, the assembly instructions must also contain relevant information to be used in the instructions for use for these machinery.	<u>If the partly completed machinery is intended to be used in machinery covered by annex III point 2 to 6, the assembly instructions must also contain relevant information to be used in the instructions for use for these machinery.</u>	
Annex X, second paragraph g, point (3)		
3. The assembly instructions for partly completed machinery shall contain the EU declaration of incorporation, or the internet address or machine readable code where the EU declaration of incorporation can be accessed.	<u>3. The assembly instructions for partly completed machinery shall contain the EU declaration of incorporation, or the internet address or machine readable code where the EU declaration of incorporation can be accessed.</u>	
Annex X, second paragraph g, point (4)		

*Annex XI: Correlation table*

<b>DRAFT Machinery Regulation</b>	<b>Comparison</b>	<b>Machinery Directive</b>
Annex XI, first heading		
CORRELATION TABLE	<u>CORRELATION TABLE</u>	

[The correlation table was dropped in this document, since it is no longer up to date.]