

# Machinery Product Regulation

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

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

## Comparison of MPR Articles 1 to 21



The European Commission has published the proposal of the Machinery Product Regulation on the 21<sup>st</sup> of April 2021.

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2021:202:FIN>

The European Parliament has published the proposal of the Machinery Product Regulation on the 8<sup>th</sup> of March 2022.

[https://www.europarl.europa.eu/doceo/document/EMPL-AD-703051\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/EMPL-AD-703051_EN.pdf)

The European Council has published the proposal of the Machinery Product Regulation on the 21<sup>st</sup> of June 2022.

<https://data.consilium.europa.eu/doc/document/ST-9801-2022-REV-1/x/pdf>

We are presenting to you the Articles 1 to 21 of the proposals for a Machinery Product Regulation together with the appropriate Articles / Annexes of the Machinery Directive 2006/42/EC and the EU Regulation on market surveillance.

Abbreviations:

MPR Machinery Product Regulation (this draft)  
MD Machinery Directive 2006/42/EC  
PCM partly completed machinery  
NLF New legislative framework

Please consider that this is only the result of a quick review, since the time to inform legal authorities is short. Thus we wanted to give our results as soon as possible.

### Major changes (excerpt)

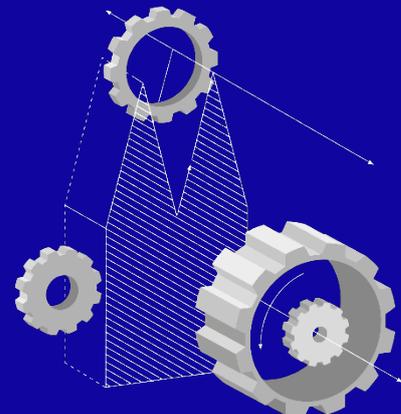
Distribution of used products is now in the scope.

Products imported for one's own use from outside Europe are no longer in the scope.

The list of products that need mandatory third-party assessment has been significantly reduced. However, after 4 years, the list must automatically be expanded again.

The national authorities may expand the MPR with own laws.

PCM must now be safe up to their interfaces.



# Introduction

References in our impact assessments are given as [number], corresponding to the appropriate chapter.

Due to the original text of the Council using a lot of highlights and stricken text, to track the changes implemented since the first published proposal by the commission, some grammatical errors remain in the proposal. In order to facilitate a better reading process, we removed these errors.

If in doubt, the text of the original document is to be consulted.

## Major changes

Out of the cases, where we found changes to the current ruling, a couple stand out as having a huge impact on certain groups. Before we show every change in detail, we would like to point out those cases in the Council's proposal that have the biggest impact.

We do not assess, if those changes might be intended or unintended.

### *Distribution of used products is now in the scope*

The MPR defines the distributor as:

*"any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product subject to this Regulation available on the market"* [50]

Making available on the market is defined as:

*"any supply of a product subject to this Regulation for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge"* [38]

The "obligations on distributors" [103] [104] also only concern themselves with *"making available on the market"*.

Recital (9) of the MPR states:

*"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."*

Thus, all texts in the MPR state that all products that at some point in time were placed new on the Union market or imported as used, are in the scope. Once such products are sold by a third party (not the manufacturer) this third party is to be considered a distributor, irrespective if the product is new or – very - old.

Such distributors only have to assess whether the product was state of the art at the time of its *"placing on the market"* [39] or *"putting into service"* [40]. It therefore will be much easier to sell used products in the scope of the MPR, once the MPR is in force.

## ***Products imported for one's own use from outside Europe is no longer in the scope***

The "catch all" paragraph from the MD's manufacturer has been removed:

*"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."* [45]

Any gaps remaining in the MPR therefore are now left open.

To handle importing from outside the Union, the "importer" has now been defined:

*"any natural or legal person established within the Union who places a product subject to this Regulation from a third country on the Union market"* [49]

Any natural or legal person is an importer if they *"place the product on the market"* [39]. But if they *"put it into service"* [40] for themselves (or their company), they do not become an *"importer"*. They are also not *"manufacturer"* [45] or *"distributor"* [21].

This legal loophole is present in all Regulations that adopted the NLF. Also, the EU-Regulation on market surveillance does not cover such persons.

Such products may now only be in the scope of the Work Safety Regulations.

## ***The list of products that need mandatory third-party assessment has been significantly reduced. However, after 4 years, the list must automatically be expanded again.***

Annex I, which in the draft from the Commission contained products needing a third-party assessment by a notified body, has been split in part A and part B.

Only such products listed in part A now need this assessment. Products in part B are treated very similarly to those of Annex IV of the MD.

However, the Commission still has the possibility and duty, to reassess the distribution between part A and B. Article 5 5. states:

*"By [OJ office: 3 years] after the date of entry into force] and every 5 years thereafter, the Commission shall carry out a review of the content of Annex I in view of the criteria set out in this article and shall submit a report to the European Parliament and to the Council."* [74]

A product shall then be moved into part A, if one of several conditions apply. The condition in Article 5 4a (i) is:

*"Lack of harmonised standards or common specifications covering the relevant essential health and safety requirements;"* [74]

However, in the current part B there are groups of products such as:

- Protective devices designed to detect the presence of persons
- Logic units to ensure safety functions

Which have a high percentage of harmonised standards. Still some products in these groups lack such a standard. Thus, such a group is forced to be moved to part A in the first assessment.

## *The national authorities may expand the MPR with own regulations.*

Article 15 from the MD was transposed in the MPR-Proposal and changed by the commission in its draft and not rectified by either parliament or presidency in theirs.

Currently it states in the MD:

*"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."*

The current proposal for Article 4a of the MPR reads:

*"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.**" [67]*

The current text of the MD forbids member states from posing additional requirements to the MD or removing requirements from the MD. The new text of MPR only forbids reducing its requirements. Therefore, member states will now be free to expand on the MPR in their national law.

## *Products may be "not substantially modified" but later considered as new at the time*

The MPR addresses the problem of substantial changes, which is important to unify in Europe.

The definition of a substantial modification is easy to understand and should be practical in its implementation.

However, the MPR distinguishes between a "*substantial modification*" (Article 15 [106]) done by the user and a "*modification*" (Article 14 [105]) done by an importer or distributor.

Since, as shown above, distributors are also those persons selling used products. Thus, if a user changes their own product and ascertain that this is no "*substantial modification*" they have to reassess this modification at a later time when they sell the used product whether it's a "*modification*" according to Article 14.

Since the bar for "*modification*" is much lower in Article 14:

*"modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected"*

the now "*distributor*" has to retroactively apply the MPR to the product.

In praxis, we will have a good ruling for "*substantial modification*", but only as long as this product is never changing hands again.

## *PCM must now be safe up to their interfaces*

In Article 10a of the MPR requirements are laid down for manufacturers of PCM.

The biggest change is regarding their safety.

Annex III 1.1.1 now describes the safety of PCM:

*"The obligations laid down by the essential health and safety requirements are applicable to partly completed machinery in as much those requirements are relevant.*

*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."*

Also, the "*Declaration of Incorporation*" has been adopted (now "*EU Declaration of Incorporation*").

PCM must now be safe up to their interfaces and the manufacturer must declare this and describe those interfaces.

This is a very important step. Currently in the MD products can be sold without the buyer knowing what the manufacturer has left open. All those regulations of MPR regarding PCM must currently in the MD be covered in private contracts.

### ***PCM are now in the scope, even if the end product is not***

The definition of PCM has been altered. [37]

One part that is different is the last requirement. In the MD it is:

*"thereby forming machinery to which this Directive applies"*

Now it shall be:

*"thereby forming a machinery"*

The last part was dropped, which now means that PCM is in the scope of the MPR, even if the MPR does not apply to the final machinery.

Since PCM are not exempted in all cases listed in Article 2 2 [5] to [27], e.g., PCM for tanks and other military products will now be in the scope. [16]

### ***The technical documentation must now be kept for as long as the product exists***

While the restriction on ten years still exists [83] [92], now a new part demands that manufacturers "*further to a reasoned request from a competent national authority*" [89] [99] must provide such data without time limit.

However, such a law is already in effect, due to the EU Regulation on market surveillance, Article 4 No. 3. (b).

### ***Instructions may now be fully electronic, when selling B2B***

The instructions, as well as the EU-Declarations, may now be provided online. The manufacturer needs to name the internet address where they are available. [87] Such addresses must be valid for at least ten years.

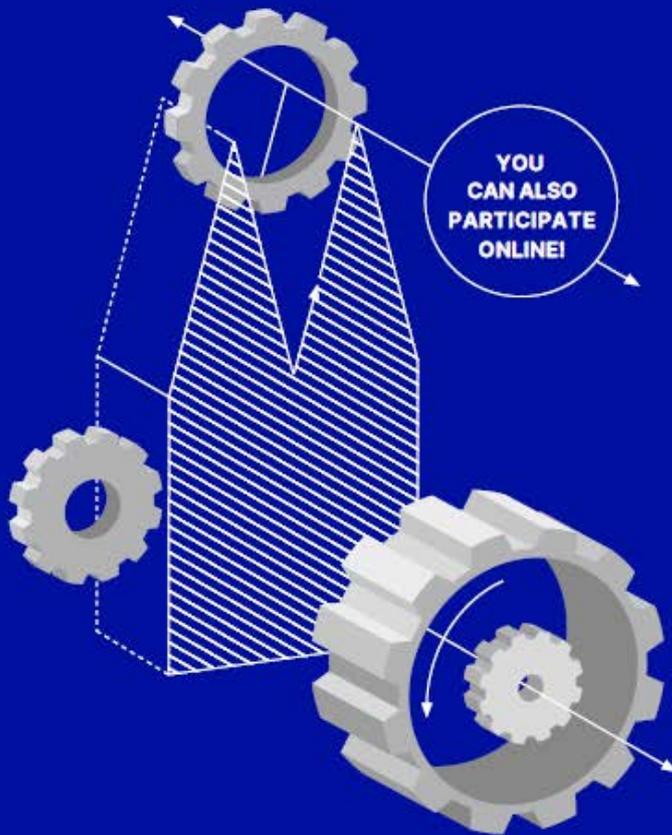
This is a requirement of industries since a long time.

However, when selling to non-professionals, the instructions still need to be provided in paper.



# 19<sup>th</sup> MASCHINERY DAYS COLOGNE

The week dedicated to the Machinery Directive:  
11<sup>th</sup> – 14<sup>th</sup> October 2022, Maritim Hotel Cologne



**GERMAN  
MACHINERY LAW DAY**  
11<sup>th</sup> October 2022

– Compressed knowledge  
about machine law

– **Lawyer Carsten Laschet**  
Sozietät Friedrich Graf von  
Westphalen & Partner

SIMULTANEOUS  
INTERPRETING  
IN ENGLISH  
AND GERMAN



**CONFERENCE  
MACHINERY DIRECTIVE**  
12<sup>th</sup> – 13<sup>th</sup> October 2022

– The conference all about  
the machinery directive

– **Dipl.-Ing. Hans-J. Ostermann**  
[www.maschinenrichtlinie.de](http://www.maschinenrichtlinie.de)

**WORKSHOPS**  
14<sup>th</sup> October 2022

– Procure CE-compliant  
machines / assemblies  
– Noise requirements on  
machinery and  
assemblies

# Content

Distribution of used products is now in the scope .....	2
Products imported for one's own use from outside Europe is no longer in the scope.....	3
The list of products that need mandatory third-party assessment has been significantly reduced. However, after 4 years, the list must automatically be expanded again. ....	3
The national authorities may expand the MPR with own regulations. ....	4
Products may be “not substantially modified” but later considered as new at the time .....	4
PCM must now be safe up to their interfaces .....	4
PCM are now in the scope, even if the end product is not.....	5
The technical documentation must now be kept for as long as the product exists.....	5
Instructions may now be fully electronical, when selling B2B .....	5
[1] Subject matter .....	16
[2] Scope .....	18
[3] Scope .....	19
[4] Scope .....	20
[5] Scope .....	21
[6] Scope .....	23
[7] Scope .....	24
[8] Scope .....	26
[9] Scope .....	27
[10] Scope .....	29

[11] Scope .....	31
[12] Scope.....	33
[13] Scope .....	35
[14] Scope .....	36
[15] Scope.....	37
[16] Scope.....	38
[17] Scope.....	39
[18] Scope.....	40
[19] Scope.....	41
[20] Scope .....	42
[21] Scope.....	44
[22] Scope .....	45
[23] Scope .....	46
[24] Scope .....	47
[25] Scope .....	48
[26] Scope .....	49
[27] Scope .....	50
[28] Definitions.....	51
[29] Definitions.....	52
[30] Definitions .....	54
[31] Definitions .....	55
[32] Definitions.....	56
[33] Definitions .....	57
[34] Definitions .....	59
[35] Definitions.....	60
[36] Definitions .....	62

[37] Definitions.....	63
[38] Definitions.....	64
[39] Definitions .....	65
[40] Definitions .....	67
[41] Definitions .....	68
[42] Definitions.....	69
[43] Definitions .....	70
[44] Definitions .....	72
[45] Definitions.....	73
[46] Definitions .....	74
[47] Definitions.....	75
[48] Definitions .....	77
[49] Definitions .....	79
[50] Definitions.....	80
[51] Definitions .....	82
[52] Definitions.....	83
[53] Definitions.....	84
[54] Definitions.....	86
[55] Definitions.....	87
[56] Definitions.....	88
[57] Definitions.....	89
[58] Definitions.....	91
[59] Definitions.....	92
[60] Definitions .....	93
[61] Definitions .....	94
[62] Definitions.....	95

[63] Definitions .....	96
[64] Definitions .....	97
[65] Definitions.....	98
[66] Definitions.....	99
[67] Definitions.....	100
[68] Free movement .....	101
[69] Free movement .....	103
[70] Protection of persons during installation or use of machinery or related products.....	105
[71] European Injury Database .....	107
[72] Machinery and related products listed in Annex I.....	109
[73] Machinery and related products listed in Annex I.....	110
[74] Machinery and related products listed in Annex I.....	112
[75] Machinery and related products listed in Annex I.....	114
[76] Machinery and related products listed in Annex I.....	118
[77] Machinery and related products listed in Annex I.....	121
[78] Machinery and related products listed in Annex I.....	124
[79] Machinery and related products listed in Annex I.....	126
[80] Safety components.....	128
[81] Safety components .....	129
[82] Essential health and safety requirements for products subject to this Regulation .....	131
[83] Specific Union harmonisation legislation .....	133
[84] Regulation (EU) .../... of the European Parliament and of the Council .....	134
[85] Obligations of manufacturers of machinery and related products.....	135

[86] Obligations of manufacturers of machinery and related products.....	136
[87] Obligations of manufacturers of machinery and related products.....	138
[88] Obligations of manufacturers of machinery and related products.....	141
[89] Obligations of manufacturers of machinery and related products.....	143
[90] Obligations of manufacturers of machinery and related products.....	145
[91] Obligations of manufacturers of machinery and related products.....	147
[92] Obligations of manufacturers of machinery and related products.....	150
[93] Obligations of manufacturers of machinery and related products.....	154
[94] Obligations of manufacturers of machinery and related products.....	157
[95] Obligations of manufacturers of partly completed machinery .....	159
[96] Obligations of manufacturers of partly completed machinery .....	161
[97] Obligations of manufacturers of partly completed machinery .....	164
[98] Obligations of manufacturers of partly completed machinery .....	166
[99] Obligations of manufacturers of partly completed machinery .....	168

[100] Obligations of manufacturers of partly completed machinery .....	170
[101] Obligations of manufacturers of partly completed machinery .....	172
[102] Obligations of manufacturers of partly completed machinery .....	175
[103] Obligations of manufacturers of partly completed machinery .....	177
[104] Obligations of manufacturers of partly completed machinery .....	180
[105] Authorised representatives .....	182
[106] Obligations of importers of machinery and related products .....	185
[107] Obligations of importers of partly completed machinery .....	194
[108] Obligations of distributors of machinery and related product .....	200
[109] Obligations of distributors of partly completed machinery .....	207
[110] Cases in which obligations of manufacturers apply to importers and distributors .....	212
[111] Other cases in which obligations of manufacturers apply .....	214
[112] Identification of economic operators .....	218
[113] Presumption of conformity of products subject to this Regulation .....	220
[114] Presumption of conformity of products subject to this Regulation .....	221
[115] Presumption of conformity of products subject to this Regulation .....	223

[116] Presumption of conformity of products subject to this Regulation .....	226
[117] Presumption of conformity of products subject to this Regulation .....	227
[118] Presumption of conformity of products subject to this Regulation .....	228
[119] Presumption of conformity of products subject to this Regulation .....	229
[120] Presumption of conformity of products subject to this Regulation .....	230
[121] Presumption of conformity of products subject to this Regulation .....	232
[122] EU declaration of conformity of machinery and related products.....	234
[123] EU declaration of incorporation of partly completed machinery .....	237
[124] General principles of the CE marking.....	240
[125] Rules for affixing the CE marking to machinery and related products.....	242
[126] Rules for affixing the CE marking to machinery and related products.....	243
[127] Rules for affixing the CE marking to machinery and related products.....	244
[128] Rules for affixing the CE marking to machinery and related products.....	246
[129] Rules for affixing the CE marking to machinery and related products.....	247
[130] Conformity assessment procedures for machinery and related products .....	249

---

[131] Conformity assessment procedures for machinery and related products .....	251
[132] Conformity assessment procedures for machinery and related products .....	253
[133] Conformity assessment procedures for machinery and related products .....	257
[134] Conformity assessment procedures for machinery products except partly completed machinery .....	258



Dipl.-Ing. Hans-J. Ostermann

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

Date: 1<sup>st</sup> September 2022

## [1] Subject matter

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Subject matter	Subject matter	Subject matter
	Article 1	Article 1	Article 1
	<p>This Regulation lays down requirements for the design and construction of machinery products to allow the making available on the market or putting into service of machinery products, and establishes rules on the free movement of machinery products in the Union.</p>	<p>This Regulation lays down <u>health and safety</u> requirements for the design and construction of machinery, <u>related</u> products <u>and partly completed machinery</u> to allow <del>their</del><u>the</u> making available on the market or putting into service <u>ensuring a high level of protection of the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment.</u> It also <del>of machinery products, and</del> establishes rules on the free movement of machinery, <u>related</u> products <u>and partly completed machinery</u> in the Union.</p>	<p>This Regulation lays down requirements for the design and construction of machinery products to allow the making available on the market or putting into service of machinery products, and establishes rules on the free movement of machinery products in the Union <u>ensuring a high level protection for all workers and other users.</u></p>

**This text has no legal impact. It is merely a preamble.**

**Thus it does not matter which version is chosen.**

## [2] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Scope	Scope	
Article 2	Article 2 1	Article 2 1	
For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f).	This Regulation applies to the following machinery products (a) [...] (g)	This Regulation applies to <u>machinery</u> and the following <u>related</u> <del>machinery</del> products <u>(b) [...]</u> <del>(f)</del> <del>...</del> <del>(g)</del>	

The term "*machinery*" being used for machinery as well as for all other products at the same time was confusing.

The Commission proposed the term "*machinery products*". The Councils changed this to "*machinery and related products*".

Theoretically it has no impact.

In praxis, in the following Council proposal in a lot of instances, only machinery is mentioned but not "*and related products*" although by logic they should be. But in the Commission text there are more instances with only machinery instead of the logical "*machinery product*".

### [3] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 1	Article 2 1	Article 2 1	
<p>1. This Directive applies to the following products:</p> <p>(a) machinery;</p> <p>(b) interchangeable equipment;</p> <p>(c) safety components;</p> <p>(d) lifting accessories;</p> <p>(e) chains, ropes and webbing;</p> <p>(f) removable mechanical transmission devices;</p>	<p>(1) This Regulation applies to the following machinery products</p> <p>(a) machinery;</p> <p>(b) interchangeable equipment;</p> <p>(c) safety components;</p> <p>(d) lifting accessories;</p> <p>(e) chains, ropes, slings and webbing;</p> <p>(f) removable mechanical transmission devices;</p>	<p>(1) This Regulation applies to <u>machinery and</u> the following <u>related</u><del>machinery</del> products</p> <p><del>(a) machinery;</del></p> <p>(b) interchangeable equipment;</p> <p>(c) safety components;</p> <p>(d) lifting accessories;</p> <p>(e) chains, ropes, <del>slings</del> and webbing;</p> <p>(f) removable mechanical transmission devices;</p>	

There is no direct impact from the different groupings.

Now, the Regulation can distinguish in its rules between machinery and other products.

## [4] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 1	Article 2 1	Article 2 1	
1. This Directive applies to the following products:  (g) partly completed machinery.	(1) This Regulation applies to the following machinery products  (g) partly completed machinery.	<del>(1)</del> -This Regulation <u>also</u> applies to <del>the following machinery products</del>  <del>(g)</del> partly completed machinery.	

Theoretically there is no impact.

Practically:

- In the Commission's proposal, if a rule does not apply to PCM, it must be clearly stated. This is often forgotten.
- In the Council's proposal, if a rule does apply to PCM, it has to be clearly stated. This is less often forgotten.

## [5] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2a	Article 2 2a	Article 2 2a	
<p>The following are excluded from the scope of this Directive:</p> <p>(a) safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;</p>	<p>This Regulation does not apply to:</p> <p>(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 product;</p>	<p>This Regulation does not apply to:</p> <p>(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, <u>related product or partly completed machinery</u>;</p>	

The difference of the Commission's and Council's proposal is due to the description of the scope in [2] Scope.

The MD's exclusion of safety components as spare parts from the original machine manufacturer will now be extended.

Currently under MD only such safety components supplied by the manufacturer of the final machinery are exempted.

In both proposals this exemption is now extended to the manufacturer of all products in the scope of the MPR, if they are supplied by their original manufacturer.

- Safety components as replacements for the same safety components, delivered by the manufacturer of those safety components, are now exempted. Thus, manufacturers of safety components can now sell old components whose standards are no longer harmonised and whose type examination has expired as spare parts.
- Safety components for PCM, delivered by the PCM's manufacturer, are now exempted.

## [6] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2b	Article 2 2b	Article 2 2b	
2. The following are excluded from the scope of this Directive:  (b) specific equipment for use in fairgrounds and/or amusement parks;	(2) This Regulation does not apply to:  (b) specific equipment for use in fairgrounds or amusement parks;	(2) This Regulation does not apply to:  (b) specific equipment for use in fairgrounds or amusement parks;	

In its proposal from 24 February 2022, the Parliament wanted this exception to be dropped. This is not part of its final proposal.

Thus, "*specific equipment for use in fairgrounds or amusement parks*" will remain to be part of the Low Voltage Directive 2014/35/EC.

Also, it will not be clarified if "*fairground*" means mobile amusement parks only or the outside grounds of fairs as well. (see also [69])

## [7] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2c	Article 2 2c	Article 2 2c	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;</p>	<p>(2) This Regulation does not apply to:</p> <p>(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;</p>	<p>(2) This Regulation does not apply to:</p> <p>(c) machinery <u>and related products</u> specially designed <del>or put into service</del> for <u>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>;</p>	

The Commission's and Council's proposal fundamentally differ in their scope.

The Commission did not change the current exemption of the MD.

The Council's exception now no longer applies to any product in the scope of the MPR.

"*whose conformity with this Regulation may undermine the nuclear safety*" will never be possible since the Council's proposal for Annex III B. 2. states that the EHSR only apply if the hazard exists and 3. states that not all EHSR may be met due to the state of the art.

Conforming with the EHSR shall thus never undermine the safety of nuclear installations.

It is also not an argument to state that some functions have to be completed, no matter the safety of singular persons. Same as with fire doors, sometimes "closing no matter what" is the "safer" option.

**[8] Scope**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2d	Article 2 2d	Article 2 2d	
2. The following are excluded from the scope of this Directive:  (d) weapons, including firearms;	(2) This Regulation does not apply to:  (d) weapons, including firearms;	(2) This Regulation does not apply to:  (d) weapons, including firearms;	

No change.

## [9] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2e -5	Article 2 2e	Article 2 2e	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(e) the following means of transport:</p> <p>— means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport</p>	<p>(2) This Regulation does not apply to:</p> <p>(e) vehicles which have as their only objective the transport of goods or persons by road, air, water or rail except for machinery mounted on those vehicles</p>	<p>(2) This Regulation does not apply to:</p> <p>(e) <u>means of</u> <del>vehicles which have as their only objective the transport of goods or persons</del> by <del>road</del>, air, <u>on water and on</u> <del>or</del> rail <u>networks with the exclusion of</u> <del>except for</del> machinery mounted on <u>these means of transport</u> <del>these vehicles</del></p>	

The Commission's proposal fundamentally changes the exemption of the MD:

- Vehicles on roads are excluded.
- Vehicles on all rails, not just rail networks are excluded.

This would famously exclude E-Bikes, to which then local law would apply, increasing the difficulty of putting such on the market.

But it would also exclude the cart-units of industrial cranes, moving under the workshop's ceiling on rails, with the same consequence. The lifting part would still be in the scope of MPR.

The Council's proposal does not change the MD's text, but due to the reduced meaning of "*machinery*" still increases the scope of the exemption.

Other exemptions by Commission and Council ([11] Scope, [12] Scope and [14] Scope) also include an exemption for "*systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*". This is not stated here.

## [10] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Scope</u>	
		<u>Article 2 2ea</u>	
		<u>(2) This Regulation does not apply to:</u>  <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>	

This exemption by the Council has minimal legal impact.

Like any others exemption based on other Regulations and Directives that cover the relevant health and safety requirements, this is already covered by Article 8 [83] (former Article 3) and thus this exemption is unnecessary.

The added benefit this exemption gives, is that one no longer has to decide whether the MPR is more specific or the Regulation (EU) 2018/1139.

The downside is that for all EHSR covered by the Regulation (EU) 2018/1139, harmonised standards of MPR no longer apply.

## [11] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2e -3	Article 2 2f	Article 2 2f	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(e) the following means of transport:</p> <p>— 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>	<p>(2) This Regulation does not apply to:</p> <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;</p>	<p>(2) This Regulation does not apply to:</p> <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, <u>except for machinery mounted on those vehicles</u>;</p>	

The Commission's proposal added "*as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*" to the exemption but removed "*with the exclusion of machinery mounted on these vehicles*".

Thus, according to the Commission's proposal all machinery mounted on a truck are exempted.

The Council's proposal remedies this problem.

The "*systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*" are not mentioned in the current MD. But they are also considered to be exempted by most interpretations of the MD. Thus, this is not new, but a clarification.

However, by clarifying this only in [11], [12] and [14] but no other places (e.g. [9], [13], [15], [16], [17], ...), a new discussion will arise.

## [12] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope		<u>Scope</u>	
Article 1 2e -2		<u>Article 2 2fa</u>	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(e) the following means of transport:</p> <p>— 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,</p>		<p><u>(2) This Regulation does not apply to:</u></p> <p><u>(fa) motor vehicles and their trailers, as well as systems, components and separate technical units, parts and equipment designed and constructed for such vehicles, that fall within the scope of application of Regulation (EU) 2018/858, except for machinery mounted on those vehicles</u></p>	

In the Commission's proposal this was covered by [9].

Since the Council's proposal changed [9], they had to bring back the MD's exemption.

For “*systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*” see [11].

### [13] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope		<u>Scope</u>	
Article 1 2e -4		<u>Article 2 2fb</u>	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(e) the following means of transport:</p> <p>— motor vehicles exclusively intended for competition</p>		<p><u>(2) This Regulation does not apply to:</u></p> <p><u>(fb) vehicles exclusively intended for competition</u></p>	

In the Commission's proposal this was covered by [9].

Since the Council's proposal changed [9], they had to bring back the MD's exemption.

However, the Council extended the original exemption to cover all vehicles, not just motor vehicles. Thus, now also competition vehicles using wind are excluded.

For the missing new "*systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*" see [9].

## [14] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2e -1	Article 2 2g	Article 2 2g	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(e) the following means of transport:</p> <p>— agricultural and forestry tractors, with the exclusion of machinery mounted on those vehicles</p>	<p>(2) This Regulation does not apply to:</p> <p>(g) agricultural and forestry vehicles, as well as systems, components, separate technical units, parts <b>and equipment designed and constructed for such vehicles</b>, that fall within the scope of application of Regulation (EU) No 167/2013</p>	<p>(2) This Regulation does not apply to:</p> <p>(g) agricultural and forestry <u>tractors</u><del>vehicles</del>, as well as systems, components, separate technical units, parts and equipment designed and constructed for such <u>tractors</u><del>vehicles</del>, that fall within the scope of application of Regulation (EU) No 167/2013, <u>except for machinery mounted on those vehicles</u></p>	

Same as [11]. But here it clashes with the definition of "*interchangeable equipment*". [32] In both proposals, "*interchangeable equipment*" no longer applies to equipment for tractors.

## [15] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2f	Article 2 2h	Article 2 2h	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;</p>	<p>(2) This Regulation does not apply to:</p> <p>(h) seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;</p>	<p>(2) This Regulation does not apply to:</p> <p>(h) seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;</p>	

No change in text.

But in the MPR proposals machinery in both cases no longer includes "*machinery products*" or "*related products*". Thus "*safety components*" and "*lifting accessories*" installed on board are no longer excluded.

For the missing new "*systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*" see [9].

## [16] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2g	Article 2 2i	Article 2 2i	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(g) machinery specially designed and constructed for military or police purposes;</p>	<p>(2) This Regulation does not apply to:</p> <p>(i) machinery specially designed and constructed for military or police purposes;</p>	<p>(2) This Regulation does not apply to:</p> <p>(i) machinery <u>or related products</u> specially designed and constructed for military or police purposes;</p>	

No change from MD to the Council's proposal.

The Commission's proposal only excludes "*machinery*" but no other "*machinery products*".

Still, both proposals do not exclude PCM. This is an old "*error*" of the MD that was not rectified here.

For the missing new "*systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*" see [9].

## [17] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2h	Article 2 2j	Article 2 2j	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;</p>	<p>(2) This Regulation does not apply to:</p> <p>(j) machinery specially designed and constructed for research purposes for temporary use in laboratories;</p>	<p>(2) This Regulation does not apply to:</p> <p>(j) machinery <u>or related products</u> specially designed and constructed for research purposes for temporary use in laboratories;</p>	

No change from MD to the Council's proposal.

The Commission's proposal only excludes "*machinery*" but no other "*machinery products*".

Still, both proposals do not exclude PCM. This is an old "*error*" of the MD that was not rectified here.

For the missing new "*systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*" see [9].

## [18] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2i	Article 2 2k	Article 2 2k	
2. The following are excluded from the scope of this Directive:  (i) mine winding gear;	(2) This Regulation does not apply to:  (k) mine winding gear;	(2) This Regulation does not apply to:  (k) mine winding gear;	

No change from MD to the MPR's proposal.

Since the term "*machinery*" was never used here, it is unclear if "*gear*" includes related products and PCM.

For the missing new "*systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*" see [9].

## [19] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2j	Article 2 2l	Article 2 2l	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(j) machinery intended to move performers during artistic performances;</p>	<p>(2) This Regulation does not apply to:</p> <p>(l) machinery intended to move performers during artistic performances;</p>	<p>(2) This Regulation does not apply to:</p> <p>(l) machinery <u>or related products</u> intended to move performers during artistic performances;</p>	

No change from MD to the Council's proposal.

The Commission's proposal only excludes "*machinery*" but no other "*machinery products*".

Still, both proposals do not exclude PCM. This is an old "*error*" of the MD that was not rectified here.

For the missing new "*systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*" see [9].

**[20] Scope**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2k	Article 2 2m	Article 2 2m	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(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</p>	<p>(2) This Regulation does not apply to:</p> <p>(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</p>	<p>(2) This Regulation does not apply to:</p> <p>(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</p>	

The exception of the Low Voltage Directive will be increased to the Radio Equipment Directive.

This has become necessary since the RED excludes the LVD. Thus, “LDV products” including a radio equipment currently are in the scope of the MD, which was not intended.

The new "*systems, components, separate technical units, parts and equipment designed and constructed for such vehicles*" is missing in all products under Article 2 2m. See [9].

**[21] Scope**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2k -1	Article 2 2m i	Article 2 2m i	
- household appliances intended for domestic use	(i) household appliances intended for domestic use which are not electrically operated furniture	(i) household appliances intended for domestic use which are not electrically operated furniture	

This change in the MPR's proposal is only a clarification.

(Electrically operated) furniture has always been considered not to be household appliance.

## [22] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2k -2	Article 2 2m ii	Article 2 2m ii	
- audio and video equipment	(ii) audio and video equipment;	(ii) audio and video equipment;	

No change.

**[23] Scope**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2k -3	Article 2 2m iii	Article 2 2m iii	
- information technology equipment	(iii) information technology equipment;	(iii) information technology equipment;	

No change.

## [24] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2k -4	Article 2 2m iv	Article 2 2m iv	
- ordinary office machinery	(iv) office machinery	(iv) <u>ordinary</u> office machinery, <u>except additive printing machinery for producing three-dimensional products</u>	

Both MPR proposals "*machinery*" no longer includes "*machinery products*" or "*related products*".

The Commission's proposal dropped the "*ordinary*" and thus excluded all "*machinery*" in an office.

The Council's proposal goes the other direction. Small 3d-printers can be "*office machinery*". With more and more cheap offers, they can even be considered "*ordinary*" soon. Thus the Council's proposal excludes "*additive printing machinery*" from the exemption, in order to keep them in the MPR.

Since 3d-printers were not considered "ordinary" before, the Council's proposal is no change in application towards the MD.

**[25] Scope**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2k -5	Article 2 2m v	Article 2 2m v	
- low-voltage switchgear and control gear	(v) low-voltage switchgear and control gear;	(v) low-voltage switchgear and control gear;	

No change.

## [26] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2k -6	Article 2 2m vi	Article 2 2m vi	
- electric motors	(vi) electric motors;	(vi) electric motors;	

In the current MD, only those electric motors are excluded, which are in the scope of the LVD. Thus only those motors between 50V and 1500V. Motors in the scope of ATEX Directive are also not excluded from MD, since they are excluded from LVD.

In the proposals, also motors in the scope of RED will be excluded.

The RED does not have any limits on the Voltage. It also does not exclude ATEX devices. Thus all motors that contain radio equipment are now excluded from MPR.

However, according to the Guide to MD § 69:

*"An electric motor is a device for converting electrical energy into mechanical energy. The exclusion applies to the motor itself without a specific application and without additional mechanical elements of a drive system."*

According to this interpretation, is a motor containing a radio equipment still "*only a motor*"? If not, no motor in the scope of RED is excluded from MPR.

## [27] Scope

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Scope	Scope	
Article 1 2l	Article 2 2n	Article 2 2n	
<p>2. The following are excluded from the scope of this Directive:</p> <p>(l) the following types of high-voltage electrical equipment:</p> <ul style="list-style-type: none"> <li>— switch gear and control gear,</li> <li>— transformers.</li> </ul>	<p>(2) This Regulation does not apply to:</p> <p>(n) the following high-voltage electrical products:</p> <ul style="list-style-type: none"> <li>(i) switch gear and control gear;</li> <li>(ii) transformers.</li> </ul>	<p>(2) This Regulation does not apply to:</p> <p>(n) the following high-voltage electrical products:</p> <ul style="list-style-type: none"> <li>(i) switch gear and control gear;</li> <li>(ii) transformers.</li> </ul>	

The MD's "*equipment*" was changed in the proposals to "*products*".

In praxis this will not lead to any change, but in theory "*products*" is a wider definition.

## [28] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 0	Article 3 0	Article 3 0	
For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f).  The following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:	

Before the term "*machinery*" meant all products except partially completed machinery.

This has been moved in the proposals to Article 2 1. [2] as "*machinery products*" or the additional group "*related products*".

"*Machinery*" in the MPR proposals is now limited to machinery as defined in Article 3 1 [29][30].

**[29] Definitions**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 a	Article 3 1 a-e	Article 3 1 a-e	
<p>(a) 'machinery' means:</p> <p>— 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,</p> <p>— an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,</p> <p>— an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if</p>	<p>(1)'machinery' means:</p> <p>(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;</p> <p>(b)an assembly referred to in point (a), missing only the components to connect it on site or to sources of energy and motion;</p> <p>(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</p>	<p>(1)'machinery' means:</p> <p>(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;</p> <p>(b)an assembly referred to in point (a), missing only the components to connect it on site or to sources of energy and motion;</p> <p>(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</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>mounted on a means of transport, or installed in a building or a structure,</p> <p>— 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,</p> <p>— an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;</p>	<p>means of transport, or installed in a building or a structure;</p> <p>(d)assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point (7) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;</p> <p>(e)an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;</p>	<p>means of transport, or installed in a building or a structure;</p> <p>(d)assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point (10<del>7</del>) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;</p> <p>(e)an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;</p>	

No change, except the Commission's proposal referenced the wrong article for PCM.

## [30] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 1 f	Article 3 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 its specific application	(f) an assembly as referred to in points (a), (b), (c), (d) and (e) missing only the upload of a software intended for its specific application.	

Additionally to Article 3 1 (b) and (c) [29], machinery in the MPR proposals may also lack software that is required “*for its specific application*”. According to this text any software, also such that is “*safety component*” according to Article 3 3 [33] is allowed to be missing.

This definition should not refer to the necessary safety software, but this is not excluded by this text.

The term “*specific application*” is used in the Council’s Recital 17, 18, Article 3 1 (a), (f) and Article 3 10, but it is never defined. Already in the context of MD’s PCM, the question of what the “*specific application*” entails has always been a widely discussed topic.

Since there is no definition for “*specific application*”, it could be interpreted that the complete operating system of a PLC may be missing, since the machine needs this for its specific application.

On the other hand, it could also be discussed that only the parametrisation is the software part allowed to be missing.

## [31] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
			<a href="#">Definitions</a>
			<a href="#">Article 3 1a</a>
			<a href="#">When machinery contains embedded software, preinstalled or installed subsequently, the latter shall be considered as an integrated part of the machinery;</a>

The Parliament's proposal is clearly aimed at the new definition in Article 3 1 f [30].

This is a clarification, that embedded software, e.g. the firmware, is an integrated part of the machinery. However, this has no impact on Article 3 1 f since that does not contain the term "*integrated part*". Thus the intention of the Parliament is unclear and it has no effect on the MPR.

If anything at all, the Parliament here confirms our interpretation given in [30] that safety relevant software is allowed to be missing.

### [32] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 b	Article 3 2	Article 3 2	
(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	(2) 'interchangeable equipment' means a device which, after the putting into service of a machinery product, is assembled with that machinery product by the operator himself in order to change its function or attribute to it a new function, in so far as that equipment is not a tool	(2) 'interchangeable equipment' means a device which, after the putting into service of a machinery <u>or an agricultural or forestry tractor</u> <del>product</del> , is assembled with that machinery <u>or agricultural or forestry tractor</u> <del>product</del> by the operator <del>himself</del> in order to change its function or attribute to it a new function, in so far as that equipment is not a tool;	

While it can be argued that a tractor is still a "*machinery product*" even though it is excluded from the MD and MPR, the Commission's omission of them would surely spark discussions in the department of "*interchangeable equipment*".

However, the Commission's and Council's proposal excludes such "*equipment*" in their exception in article 2 2g [14]: "*agricultural and forestry tractors, as well as [...] equipment designed and constructed for such tractors*"

Thus, in both proposals, "*interchangeable equipment*" no longer applies to equipment for tractors.

### [33] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 c	Article 3 3	Article 3 3	
<p>(c) 'safety component' means a component</p> <p>— which serves to fulfil a safety function,</p> <p>— which is independently placed on the market,</p> <p>— the failure and/or malfunction of which endangers the safety of persons, and</p> <p>— which is not necessary in order for the machinery to</p>	<p>(3) 'safety component' means a physical or digital component, including software, of machinery</p> <p>which serves to fulfil a safety function</p> <p>and</p> <p>which is independently placed on the market,</p> <p>the failure or malfunction of which endangers the safety of persons</p> <p>but</p> <p>which is not necessary in order for the machinery to function</p>	<p>(3) 'safety component' means a <u>component of physical, <del>or</del> digital or mixed nature</u><del>component</del>, including software, of <u>products subject to this Regulation</u> <del>machinery</del></p> <p>which serves to fulfil a safety function</p> <p>and</p> <p>which is independently placed on the market,</p> <p>the failure or malfunction of which endangers the safety of persons</p> <p>but</p> <p>which is not necessary in order for the <u>products subject to this</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
function, or for which normal components may be substituted in order for the machinery to function.	or may be substituted by normal components in order for the machinery to function;	<u>Regulation</u> <del>machinery</del> to function or may be substituted by normal components in order for the <u>products subject to this Regulation</u> <del>machinery</del> to function;	

Both proposals now include “*software*”, the Commission’s only for “*machinery*” the Council’s for all “*products subject to this Regulation*”.

The Commission’s proposal only acknowledges safety components for machinery, while the Council’s does so for all “*products subject to this Regulation*”.

### [34] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Definitions</u>	
		<u>Article 3 3a</u>	
		<u>(3a) 'safety function' means a function that serves to fulfil a protective measure to eliminate hazards or, if not possible, to reduce risks and where its failure can result in an increase of the risks</u>	

The Council's definition of "*safety function*" should be broad enough as to not cause any changes in the application of safety components.

## [35] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 d	Article 3 4	Article 3 4	
(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;	(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;	(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;	

Both proposals' last part "*including slings and their components*" differs from the text of the MD. This change of a previously clear definition is unnecessary and will lead to wrong conclusions.

In theory, all might mean the same, but in praxis, the new text will lead to different interpretations. (e.g. "Slings are only covered as far as they are part of lifting accessory, but not when they can be used as such independently by themselves.")

It would be far more important to define "*lifting machinery*" since there is a court ruling in Austria that only machinery lifting from above (e.g. crane) is "*lifting machinery*" but not from below (e.g. forklift).

**[36] Definitions**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 e	Article 3 5, 6, 8	Article 3 5, 6, 8	
(e) 'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;	(5) 'chains' means chains designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;  (6) 'ropes' means ropes designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;  (8) 'webbing' means webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;	(5) 'chains' means chains designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;  (6) 'ropes' means ropes designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;  (8) 'webbing' means webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;	

No change.

### [37] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	<u>Definitions</u>	
	Article 3 7	<del>Article 3 7</del>	
	(7) 'slings' means slings designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;	<del>(7) 'slings' means slings designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;</del>	

In the Commission's proposal, slings that, when used as intended, become part of a lifting machine, should fall under the scope of the MPR.

In the MD there is no such definition. The Council's proposes, to cancel this new definition. Thus only those slings that are "*lifting accessory*" are in the scope of the MD/MPR. [35]

## [38] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 f	Article 3 9	Article 3 9	
(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;	(9) '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;	(9) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another <del>machine</del> <u>machinery</u> by joining them at the first fixed bearing. <u>When it is placed on the market with the guard it shall be regarded as one item;</u>	

The Commission's proposal omitted the clarification, that a guard belonging to the "*removable mechanical transmission device*" is considered part of the product.

In theory, this should not make any difference.

In praxis, the omission will give reason to interpretation and might be seen as a negation.

**[39] Definitions**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 g	Article 3 10	Article 3 10	
<p>(g) 'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application.</p> <p>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>(10) 'partly completed machinery' means an assembly which is machinery but for the fact that it cannot in itself function so as to perform a specific application</p> <p>and which</p> <p>is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming a machinery product;</p>	<p>(10) 'partly completed machinery' means an assembly which is <u>not yet</u> machinery <u>as</u> <del>but for the fact that</del> it cannot in itself function so as to perform a specific application</p> <p>and which</p> <p>is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming a machinery <del>product</del>;</p>	

Both proposals change the term "*almost machinery*". In both cases the new term is much wider and it will no longer be necessary to discuss when "*almost*" is reached.

The only defining point remaining here is that the product "*cannot in itself function so as to perform a specific application*". This clarifies that a PCM might "*perform*" in the meaning of "move" already but cannot "*function ...*" safely according to the MPR.

The "Drive system" example has been deleted. This does not mean that drive systems will no longer be PCM in the future. It is only unusual to list examples in legal texts, so that the deletion is consistent.

The end "to which this Directive applies" has been deleted.

Not all machinery are in the scope of the MPR. Thus PCM can also exist for machinery that are not in the scope by themselves.

E.g. a switchgear of military tanks will be in the scope of the MPR, while the whole tank is excluded by Article 2 i [16]. This particular example is in conflict with the Treaty on the Functioning of the European Union (TFEU) Article 346 1 b.

## [40] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 11	Article 3 11	
	(11) 'making available on the market' means any supply of a machinery product for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge	(11) 'making available on the market' means any supply of a <del>machinery</del> product <u>subject to this Regulation</u> for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	

Here, as in other places, the proposals for the MPR follow the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products".

This definition also covers the entire retail chain with the economic actors concerned. In the future also "*making available*" of used products on the market will be in the scope of the MPR. According to Recital 9 all "*new products made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country*" will be covered. This condition is fulfilled by any product existing in Europe and will not end, when it is used.

The term "*commercial activity*" makes it clear that the Machinery Product Regulation is not aimed at private individuals in C-to-C supply. This is already regulated in the Treaty on the Functioning of the European Union (TFEU) and therefore has no factual effects. That has always been the case, but it was not specified in the Machinery Directive itself. However, "*putting into service*" has no such exception for consumers. See [42].

## [41] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 h	Article 3 12	Article 3 12	
(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	(12) 'placing on the market' means the first making available of  a machinery product on the Union market	(12) 'placing on the market' means the first making available of  a <del>machinery</del> product <u>subject to this Regulation</u> on the Union market;	

no change

The terms "*distribution or use*" and "*whether for reward or free of charge*" is now part of "*making available on the market*". see Article 3 11 [40]

It would be better to use only one term: either "*making available on the market*" or "*making available on the Union market*"  
But "*making available on the market*" in Article 3 No 11 [41] is limited to the Union market.

## [42] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 k	Article 3 13	Article 3 13	
(k) 'putting into service' means the first use, for its intended purpose, in the Community, of machinery covered by this Directive;	(13) 'putting into service' means the first use, for its intended purpose, in the Union, of a machinery product;	(13) 'putting into service' means the first use, for its intended purpose, in the Union, of a machinery <u>or related products</u> <del>product</del> ;	

The proposals do not change the text, but for legal clarity it would have been nice to add "*in the course of a commercial activity*" here as well. See Article 3 No 11 [40]

**[43] Definitions**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions		<u>Definitions</u>	
Article 2 m		<u>Article 3 13a</u>	
<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>The essential health and safety requirements are set out in Annex I.</p>		<p><u>(13a) 'essential health and safety requirements' means mandatory provisions relating to the design and construction of the products subject to 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,</u></p> <p><u>as set out in Annex III;</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
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.			

The Council's proposal does not change the meaning of the MD's text.

The MD's text "*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.*" has been moved to Annex III B 4.

The Commission's proposal omitted this definition.

## [44] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Definitions</u>	
		<u>Article 3 13b</u>	
		<u>(13b) 'presenting a risk' means that products subject to this Regulation pose a risk against the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment;</u>	

The Council proposes a new definition.

In theory this has no impact, since the MD only poses requirements on safety.

However, due to the additional requirements on "*security*" in Annex III, this definition now clearly states that only such "*security*" is concerned that influences "*safety*".

**[45] Definitions**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 14	Article 3 14	
	(14) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;	(14) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;	

The definition serves to clarify what is meant by this term used in the MPR. It does not affect the practice.

## [46] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	<u>Definitions</u>	
	Article 3 15	<del>Article 3 15</del>	
	(15) 'artificial intelligence system' means an artificial intelligence system as defined in Article 3(1) of Regulation (EU) .../... of the European Parliament and of the Council 28 +	<del>(15) 'artificial intelligence system' means an artificial intelligence system as defined in Article 3(1) of Regulation (EU) .../... of the European Parliament and of the Council 28 +</del>	

This definition was deleted in the Council's proposal.

The Regulation on AI will not be ready at the same time as the MPR. At the time of the Commission's proposal both were scheduled to be published at the same time.

## [47] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 16	Article 3 16	
	<p>(16) 'substantial modification' means a modification of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen by the manufacturer and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements may be affected;</p>	<p>(16) 'substantial modification' means a modification of a machinery <u>or related</u> product, by physical or digital means after that machinery <u>or related</u> product has been placed on the market or put into service, which is not foreseen <u>nor planned</u> by the manufacturer, and <u>affects its safety by creating as a new hazard or by increasing an existing risk</u> <del>result of</del> which <u>requires:</u></p> <p><u>(i) additional guards or protective devices, whose processing modifies the existing safety control system,</u> <u>or</u> <u>(ii) additional protective measures to ensure the</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>stability or mechanical strength</u> <del>compliance</del> of the machinery <u>or related</u> product <del>with the relevant essential health and safety requirements may be affected;</del>	

So far, the topic of "*substantial modification*" has only been part of different European and national interpretations. Thus, any unified definition is better than none.

The Commission's proposal follows the explanation in the EU internal market guide "Blue Guide" in chapter 2.1.

The Council's proposal limits the substantial modification to such cases, where additional guards or protective measures for stability and mechanical strength are required.

In case of (i) it could be clarified that "*processing*" means the "processing of signals from the guards or protective devices".

The "*substantial modification*" of PCM is not covered by the Council's proposal. Thus a "*substantial modification*" of a PCM which is part of a machinery or of an assembly of machinery will lead to the "*substantial modification*" of the whole (assembly of) machinery. See Article 15. [...]

## [48] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 i	Article 3 17	Article 3 17	
<p>(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 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.</p> <p>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</p>	<p>(17) 'manufacturer' means any natural or legal person who manufactures machinery products or who has machinery products designed or manufactured, and markets those machinery products under his or her name or trademark or who designs and constructs machinery products for his or her own use;</p>	<p>(17) 'manufacturer' means any natural or legal person who manufactures <u>a product subject to this Regulation</u> <del>, machinery products</del> or who has <u>a product subject to this Regulation</u> <del>machinery products</del> designed or manufactured, and markets <u>such a product</u> <del>those machinery products</del> under his or her name or trademark, <u>or manufactures a product subject to this Regulation</u> <del>who designs and puts it into service</del> <del>constructs machinery products</del> for his or her own use;</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
machinery covered by this Directive shall be considered a manufacturer			

In both proposals, "*manufacturer*" is no longer the person who designs the machinery product, but only the person who manufactures it. In the MD, the manufacturer can also be the person who designs a product.

"*Manufacturer*" is still the person who labels the machinery product with their brand.

A manufacturer "*for his or her own use*" differs in the proposals:

- In the Commission's proposal, only such persons that "*design and construct*" the product is a "*manufacturer*".
- In the Council's proposal, the product only has to be "*manufactured*" by the person in order to be a "*manufacturer*".

"*non professional users*" can become manufacturers. If they manufacture / design and construct a product for their own use and put it into service, Article 3 13 [42] does not exclude them. Thus they would be "*manufacturers for own use*".

However, if they would place the product on the market they are not a manufacturer, since the product is not "made available" according to Article 3 11 [38], since this is not "in the course of a commercial activity".

The MD's part "*In the absence of a manufacturer as defined above [...]*" has been dropped in both proposals.

This was a "catch all" so that there always was a manufacturer. In the MPR, many economic actors who make machinery products available on the market are included. However, there are a few gaps left to put machinery in use without applying the MPR. (see Article 3 No 20 [52])

## [49] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Definitions</u>	
		<u>Article 3 17a</u>	
		<u>definition of "user" was added and later deleted</u>	

Although the definition of “*user*” has been added and subsequently deleted in the Council’s proposal, a lot of requirements on users remain in the text of the MPR proposal.

An indirect definition can be found in Article 28 No 4. where persons are listed:

*“A conformity assessment body [...] shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of machinery or related products”*

Thus, a “*user*” should be another person than those listed. E.g. a “*user*” is not an “*installer*” or “*maintainer*”.

All mentions of “*user*” should be replaced by “*operator*”. See Anex III A (e).

## [50] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 18	Article 3 18	
	(18) 'instructions for use' means the information provided by the manufacturer when the machinery product is placed on the market or put into service to inform the user of the machinery product of the intended purpose and the proper use of that machinery product as well as information on any precautions to be taken when using or installing the machinery product, including information on the safety aspects;	(18) 'instructions <del>for use</del> ' means the information provided by the manufacturer when the machinery <u>or related</u> product is placed on the market or put into service to inform the user of the machinery <u>or related</u> product of the intended <del>purpose</del> and <del>the</del> proper use of that machinery <u>or related</u> product as well as information on any precautions to be taken when using or installing the machinery <u>or related</u> product, including information on the safety aspects;	

Theoretically, this has no impact.

But due to Article 28 4, the “*user*” is different from the “*installer*”. If the “*instructions for use*” were only for “*users*”, there would be no need to explain “*installing*”.

## [51] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 j	Article 3 19	Article 3 19	
(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;	(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;	(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;	

An authorised representative is no longer allowed to take over all obligations of the manufacturer, but only tasks defined in Article 11 [105].

The change of "Community" to "Union" has no impact.

## [52] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 20	Article 3 20	
	(20) 'importer' means any natural or legal person established within the Union who places machinery products from a third country on the Union market;	(20) 'importer' means any natural or legal person established within the Union who places <u>a product subject to this Regulation</u> <del>machinery products</del> from a third country on the Union market;	

Here, as in other places, the proposals for MPR follow the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products". This also covers the entire retail chain with the economic actors concerned. This adjustment was made in 2014 for many other product directives.

The problem arising here, is that the NLF does not cover the "manufacturer for own use" and also not the "importer for own use".

An "importer for own use" does not manufacture the product (Art. 3 17 [45]), he does not place it on the market (Art. 3 20 [49]) and he does not make it available on the market (Art. 3 21 [50]). Thus the MPR will not apply to him.

See also the deleted part in the old manufacturer definition "*In the absence of a manufacturer as defined above [...]*" in Article 3 17 [45]

### [53] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 21	Article 3 21	
	(21) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes machinery products available on the market;	(21) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes <u>a product subject to this Regulation</u> <del>machinery products</del> available on the market;	

Here, as in other places, the MPR follows the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products". This adjustment was made in 2014 for many other product directives.

This definition has a huge impact due to its wording. It is not restricted to only "new products". Thus any product subject to MPR that is sold (or gifted) after MPR takes effect leads to the seller being a "distributor", since he "*makes the product available on the market*". See Article 3 11 [40]: "*any supply of a product for distribution or use on the Union market*". The products under MPR are currently also not limited to "new" products.

This also applies to inner conglomerate shifting of products, if a product is shifted across a virtual border. (e.g. from Machinery AG to Machinery & Co. KG)

This (probably unintended) outcome leads to used machinery products finally being handled in European law. Currently the sale of used machinery products is handled in national law (or, also unintended, in other Regulations following NLF e.g. the Low Voltage Directive).

It mainly affects Article 13 and 13a, stating that the product has to be safe according to the state of the art when it was first placed on the market. It also affects "*substantial modification*" where a distributor is handled in Article 14, while any other user is handled in Article 15.

The Blue Guide (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C:2022:247:TOC>) states in chapter 2.1

*"Furthermore, Union harmonisation legislation applies when the product is placed on the market (or put into service) and to any subsequent making available until the product reaches the end-user."*

However, it is not clear according to the definition if the "*end-user*" is the last user in a user chain or if every user is meant. The definition in Regulation (EU) 2019/1020 and the BlueGuide only describe that an "*end-user*" is the "*end-user*". It is although not described in the BlueGuide, what happens when a user becomes a "*distributor*" again, ceasing to be the "*user*".

Chapter 2.3 of the blue guide is in line with the current proposals of the MPR. It states:

*"When made available on the Union market, products must be in compliance with the Union harmonisation legislation applicable at the time of placing on the market. Accordingly, new products manufactured in the Union and all products imported from third countries – whether new or used – must meet the provisions of the applicable Union harmonisation legislation when placed on the market i.e. when made available for the first time on the Union market. Compliant products once they have been placed on the market may subsequently be made available along the delivery chain without additional considerations, even in case of revisions to the applicable legislation or the relevant harmonised standards, unless otherwise specified in the legislation."*

Since there is no other specification, the product must be only safe according to the state of the art when first placed on the European market.

## [54] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 22	Article 3 22	
	(22) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;	(22) 'economic <u>operator</u> ' <del>operators'</del> means the manufacturer, the authorised representative, the importer, <del>and</del> the distributor, <u>and the fulfilment service provider as defined in Regulation (EU) 2019/1020</u> ;	

Here, as in other places, the MPR proposals follows the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products". This also covers the entire retail chain with the economic actors concerned. This adjustment was made in 2014 for many other product directives.

The Council's proposal additionally includes the fulfilment service provider as defined in Regulation (EU) 2019/1020.

## [55] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 23	Article 3 23	
	(23) 'technical specification' means a document that prescribes technical requirements to be fulfilled by machinery products;	(23) 'technical specification' means a document that prescribes technical requirements to be fulfilled by machinery <u>or related</u> products;	

The Council adopted the Commission's definition. But instead of using "a product subject to this regulation" as in [52] and [53], they used "machinery or related products". Thus, according to the Council's definition, no technical specifications for partly completed machinery exists.

Common specifications [56] and harmonised standards are more than "other" technical specifications. (e.g. see Annex IV A. g)

## [56] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Definitions</u>	
		<u>Article 3 23a</u>	
		<u>(23a) 'common specification' means a technical specification as defined in point 4 of Article 2 of Regulation (EU) No 1025/2012 that provides a means to comply with the essential requirements for machinery and related products;</u>	

According to the Council's definition, no "*common specifications*" for partly completed machinery may exist, since no "*technical specification*" for partly complete machinery exists (see [55]).

"*common specifications*" are the "*harmonised standards*" equivalents of the Commission. But there are harmonised standards for a lot of partly completed machinery.

**[57] Definitions**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Definitions	Definitions	
Article 2 I	Article 3 24	Article 3 24	
(l) '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	(24) 'harmonised standard' means a harmonised standard as defined in Article 2(1), point (c) of Regulation (EU) No 1025/2012;  Article 2(1), point (c) of Regulation (EU) No 1025/2012:  (c) 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation;	(24) 'harmonised standard' means a harmonised standard as defined in Article 2(1), point (c) of Regulation (EU) No 1025/2012;  Article 2(1), point (c) of Regulation (EU) No 1025/2012:  (c) 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation;	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
regulations and of rules on Information Society services ( 4 );			

For this definition, reference is made to the stipulations in the corresponding EU regulation. Due to the restriction to letter (c), however, the part "*a non-binding technical specification*", which is contained in the MD in Article 2 (1) first sentence, is omitted.

**[58] Definitions**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 25	Article 3 25	
	(25) 'CE marking' means a marking by which the manufacturer indicates that a machinery product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;	(25) 'CE marking' means a marking by which the manufacturer indicates that a machinery <u>or related</u> product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;	

No effect, see also Article 20 [125] ff.

**[59] Definitions**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 26	Article 3 26	
	(26) 'accreditation' means accreditation as defined in Article 2, point (10) of Regulation (EC) No 765/2008;	(26) 'accreditation' means accreditation as defined in Article 2, point (10) of Regulation (EC) No 765/2008;	

This serves to adapt to the EC-R No 765/2008 "Accreditation and Market Surveillance"

No consequences.

## [60] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 27	Article 3 27	
	(27) 'national accreditation body' means a national accreditation body as defined in Article 2(11) of Regulation (EC) No 765/2008;	(27) 'national accreditation body' means a national accreditation body as defined in Article 2 <u>point</u> (11) of Regulation (EC) No 765/2008;	

This serves to adapt to the EC-R No 765/2008 "Accreditation and Market Surveillance"

No consequences.

## [61] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 28	Article 3 28	
	(28) 'conformity assessment' means the process demonstrating whether the essential health and safety requirements of this Regulation relating to machinery products have been fulfilled;	(28) 'conformity assessment' means the process demonstrating whether the <u>applicable</u> essential health and safety requirements of this Regulation relating to machinery <u>or related</u> products have been fulfilled;	

This serves to adapt to the EC-R No 765/2008 "Accreditation and Market Surveillance"

No consequences

But in the Council's proposal, there is no "*conformity assessment*" for partly completed machinery.

In the Commission's proposal, the "*conformity assessment*" is for all products, but cannot be fulfilled by partly completed machinery. (see [130] ff.)

**[62] Definitions**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 29	Article 3 29	
	(29) 'conformity assessment body' means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;	(29) 'conformity assessment body' means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;	

This serves to adapt to the EC-R No 765/2008 "Accreditation and Market Surveillance"

No consequences

**[63] Definitions**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 30	Article 3 30	
	(30) 'notified body' means a conformity assessment body notified in accordance with Article 26 of this Regulation;	(30) 'notified body' means a conformity assessment body notified in accordance with Article <del>28</del> <sup>26</sup> of this Regulation;	

This serves to adapt to the EC-R No 765/2008 "Accreditation and Market Surveillance"

No consequences

## [64] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 31	Article 3 31	
	(31) 'market surveillance authority' means a market surveillance authority as defined in Article 3, point (4) of Regulation (EU) 2019/1020;	(31) 'market surveillance authority' means a market surveillance authority as defined in Article 3, point (4) of Regulation (EU) 2019/1020;	

Remark:

Article 3, point (4) of Regulation (EU) 2019/1020:

'market surveillance authority' means an authority designated by a Member State under Article 10 as responsible for carrying out market surveillance in the territory of that Member State;

This serves to adapt to the EC-R No 765/2008 "Accreditation and Market Surveillance"

No consequences

## [65] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 32	Article 3 32	
	(32) 'recall' means any measure aimed at achieving the return of a machinery product that has already been made available to the end-user;	(32) 'recall' means any measure aimed at achieving the return of a <del>machinery</del> product <u>subject to this Regulation</u> that has already been made available to the <del>end</del> -user;	

Remark:

Article 3, point (22) of Regulation (EU) 2019/1020:

'recall' means any measure aimed at achieving the return of a product that has already been made available to the end user;

This serves to adapt to the EC-R No 765/2008 "Accreditation and Market Surveillance"

No consequences

The word "end" is dropped in the Council's proposal. This is necessary, since partly completed machinery need not be supplied to the end-user but can also be supplied to another manufacturer.

## [66] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Definitions	Definitions	
	Article 3 33	Article 3 33	
	(33) 'withdrawal' means any measure aimed at preventing a machinery product in the supply chain from being made available on the market.	(33) 'withdrawal' means any measure aimed at preventing a <del>machinery</del> product <u>subject to this Regulation</u> in the supply chain from being made available on the market.	

Remark:

Article 3, point (4) of Regulation (EU) 2019/1020:

'withdrawal' means any measure aimed at preventing a product in the supply chain from being made available on the market;

This serves to adapt to the EC-R No 765/2008 "Accreditation and Market Surveillance"

No consequences

## [67] Definitions

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Definitions</u>	
		<u>Article 3 33a</u>	
		<u>(33a) `Source code` means the currently installed version of the software of a product covered by this Regulation, written in a programming language so that it is unambiguous, understandable to humans;</u>	

Per this definition the AI's code is not "*source code*". An AI's code is not understandable to humans.

As per Annex IV A.(n) / B.(l) only the "*source code*" is part of the technical documentation. Thus the code of the AI needs not to be supplied to market surveillance authorities according to the MPR.

**[68] Free movement**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Freedom of movement	Free movement	Free movement	
Article 6 1+2	Article 4 1	Article 4 1	
<p>1. Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of machinery which complies with this Directive.</p> <p>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.</p>	<p>1. Member States shall not impede, for reasons relating to the aspects covered by this Regulation, the making available on the market or the putting into service of machinery products which comply with this Regulation.</p>	<p>1. Member States shall not impede, for reasons relating to the aspects covered by this Regulation, the making available on the market <u>of products subject to this Regulation</u> or the putting into service of machinery <u>or related</u> products which comply with this Regulation.</p>	

The text of the proposals is differently written, but the content is the same.

The Commission's proposal has a technical error, because PCM as part of "machinery products" cannot be put into service.

In the Council's proposal, PCM are now covered by the first "products subject to this Regulation", and the second part covers only putting into service of "machinery or related products".

Thus, there is no longer any need for a separate regulation, so that No. 2 of the old text can be omitted.

**[69] Free movement**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Freedom of movement	Free movement	Free movement	
Article 6 3	Article 4 2	Article 4 2	
<p>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.</p> <p>Furthermore, during demonstrations of such non-conforming machinery or partly completed machinery, adequate safety measures shall</p>	<p>2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the display of a machinery product 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.</p> <p>During demonstrations, adequate measures shall be taken to ensure the protection of persons.</p>	<p>2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the display of a <del>machinery</del> product <u>subject to this Regulation</u> 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.</p> <p>During demonstrations, adequate measures shall be taken to ensure the protection of persons.</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
be taken to ensure the protection of persons.			

no change

Still, only persons need to be protected in such cases, but not other products or animals.

There could be a misunderstanding with "*fair grounds*". Products on "*fair grounds*" are exempted from the MPR in general. See [6]

*[70] Protection of persons during installation or use of machinery or related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Installation and use of machinery	Protection of persons during installation and use of machinery products	Protection of persons during installation <del>or</del> and use of machinery <u>or related</u> products	
Article 15	Article 23	Article <del>4a</del> <sup>23</sup>	
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.	Member States may lay down requirements to ensure that persons, including workers, are protected when installing and using machinery products, provided that such rules do not allow for modification of a machinery product in a way that is not compatible with this Regulation.	Member States may lay down requirements to ensure that persons, including workers, are protected when installing <del>or</del> and using machinery <u>or related</u> products, provided that such rules do not allow for modification of a machinery <u>or related</u> product in a way that is not compatible with this Regulation.	

This proposed article is not part of the NLF. It is also not conform with the Treaty on the Functioning of the European Union (TFEU), especially its Article 26 and Article 114.

Additionally, since this article only concerns the member states, it could be omitted. The member states have to act according to the TFEU.

The proposal is similar in terms of content but partially deviating from Article 15 of the MD. The part "*in due observance of Community law*" has been omitted. Also "*provided that this does not mean that such machinery is modified in a way not specified in this Directive.*" has been changed to "*provided that such rules do not allow for modification of a machinery product in a way that is not compatible with this Regulation*".

This can lead to a huge impact. Currently in the MD, additional national rules could not demand more or less than the MD. Now, such additional rules can not demand less than the Regulation, but can demand more.

The Council's proposal limits such additional rules to "*machinery or related products*", omitting PCM.

*[71] European Injury Database*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
			<a href="#">European Injury Database</a>
			<a href="#">Article 4a</a>
			<p><a href="#">1. The Commission shall upgrade and extend the European Injury Database (IDB), to collect information on all type of injuries linked to machinery products covered by this regulation.</a></p> <p><a href="#">2. The competent national authorities of Member States shall provide the Commission with the relevant data, in compliance with Union and national rules on data protection.</a></p> <p><a href="#">3. The Commission shall establish a common methodology for the collection of the data.</a></p>

The Parliament's proposal contains the "European Injury Database".

This database is then proposed to be used in Article 5 4 [76] as an additional source for "*statistics on accidents caused by the machinery product for the preceding four years based*".

However, since its organisation EuroSafe is not a governmental service, the law would require the Commission to regularly pay money to one specific organisation:

"*Since we do not receive any funding for our central services, we have to charge a cost-covering fee (EUR 750/working day) for a data analysis report.*" [https://www.eurosafe.eu.com/uploads/inline-files/EU-IDB%20flyer\\_OCT%202020.pdf](https://www.eurosafe.eu.com/uploads/inline-files/EU-IDB%20flyer_OCT%202020.pdf)

This organisation will also update and increase their value by mandatory provision of data.

**[72] Machinery and related products listed in Annex I**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	High-risk machinery products	<u>Machinery and related</u> <del>High-risk</del> <del>machinery</del> products <u>listed in Annex I</u>	
	Article 5 1	Article 5 1	
	1. High-risk machinery products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Article 21(2).	<u>1. Machinery and related</u> <del>High-risk</del> <del>machinery</del> products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Article 21(2) <u>and 21(2a)</u> .	

The Council's proposal does not contain PCM. Thus, even if PCM would be listed in Annex I, it would have no effect.

Only when PCM are include in the complete machinery or related product will they be part of the specific conformity assessment procedures.

*[73] Machinery and related products listed in Annex I*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	High-risk machinery products	<u>Machinery and related</u> <del>High-risk</del> <u>machinery</u> products <u>listed in Annex I</u>	
	Article 5 2	Article 5 2	
	<p>2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I</p> <p>in view of technical progress and knowledge or new scientific evidence by including in the list of high-risk machinery products a new machinery product or withdrawing an existing machinery product from that</p>	<p>2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I, <u>after consultation with experts of Member states and relevant stakeholders representing all concerned sectors and interests</u></p> <p>in view of technical progress and knowledge or new scientific evidence by including in the list of <del>high-risk</del> <u>machinery and related</u> products <u>in Annex I</u> a new <u>category of machinery or related</u> product or withdrawing an existing <u>category of</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	list, pursuant to the criteria laid down in paragraphs 3 and 4.	machinery <u>or related</u> product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.	

The list of machinery products in Annex I can later be changed by the EU Commission by means of a delegated legal act. It is not intended that a committee according to Article 46 of the MPR is involved, as stipulated e.g. in the context of the EU Market Surveillance Ordinance.

The Council's proposal requires a consultation of experts. However, the Commission is not bound by their opinion.

Also, the Council again (see [72]) excludes PCM from appearing in Annex I.

*[74] Machinery and related products listed in Annex I*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	High-risk machinery products	<u>Machinery and related machinery</u> <del>High-risk</del> products <u>listed in Annex I</u>	
	Article 5 5	Article 5 <u>2a</u>	
	<p>5. A Member State which has concerns about a machinery product</p> <p>being listed or not listed in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof.</p>	<p><u>2.a.</u> A Member State which has concerns about a <u>category of</u> machinery or related product</p> <p>being listed or not listed in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof.</p> <p><u>The Commission shall thoroughly assess the risks as referred to in paragraph 3 immediately after having being informed by a Member State.</u></p> <p><u>After that assessment the Commission may initiate the</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>procedure laid down in paragraph 2.</u>	

In the Council's proposal, there are consequences given, if a member state informs on Annex I products. This shall trigger an immediate update.

This is in addition to the regular update, proposed in Article 5 5 [78].

Also, the Council again (see [72]) excludes PCM from appearing in Annex I.

*[75] Machinery and related products listed in Annex I*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	High-risk machinery products	<u>Machinery and related machinery</u> products <del>High-risk</del> <u>listed in Annex I</u>	
	Article 5 3	Article 5 3	
	<p>3.</p> <p>A machinery product shall be included in the list of high-risk machinery products in Annex I if it poses a risk to human health taking into account its design and intended purpose. A machinery product shall be withdrawn from the list of high-risk machinery products in Annex I if it no longer poses such risk. The risk posed by a certain machinery product shall be established based on the</p>	<p>3. <u>The inclusion or removal of a machinery or related product to Annex I shall rely on the assessment of the seriousness of the inherent potential risk. That assessment</u> <del>A machinery product shall be included in the list of high-risk machinery products in Annex I if it poses a risk to human health taking into account its design and intended purpose. A machinery product shall be withdrawn from the list of high-risk machinery products in Annex I if it no longer poses such risk. The risk posed by a certain machinery product shall be</del> established based on the</p>	<p>3. A machinery product shall be included in the list of high-risk machinery products in Annex I if it poses a risk to human health taking into account its design and intended purpose <u>and foreseeable use</u>. A machinery product shall be withdrawn from the list of high-risk machinery products in Annex I if it no longer poses such risk. The risk posed by a certain machinery product shall be established based on the probability of occurrence of harm and the severity of that harm.</p>

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>combination of the probability of occurrence of harm and the severity of that harm.</p> <p>In determining the probability and severity of harm, the following shall be taken into account:</p> <p>(a) the degree to which each affected person would be impacted by the harm;</p> <p>(b) the number of persons potentially affected;</p> <p>(c) the degree to which potentially affected parties are</p>	<p>combination of the probability of occurrence of harm and the severity of that harm.</p> <p>In determining the probability and severity of harm, the following <u>criteria</u> shall be taken into account, <u>where relevant</u>:</p> <p>(a') <del>a)</del> <u>the nature of the hazard inherent <del>degree</del> to the function of the machinery or related product category, taking into account the intended use and reasonably foreseeable misuse;</u></p> <p>(a) <u>the severity of harm <del>h</del> by which <u>a</u> <del>each-affected</del> person would be <u>affected, including the degree of reversibility of such <del>impacted by the</del> harm;</u></u></p> <p>(b) the number of persons potentially affected <u>by the harm;</u></p> <p><del>(c) the degree to which potentially affected parties are</del></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>dependent on the outcome produced by the machinery product;</p> <p>(d) the degree to which potentially affected parties are in a vulnerable position vis-à-vis the user of the machinery product;</p> <p>(e) the degree of reversibility of the harm produced by the machinery product;</p>	<p><del>dependent on the outcome produced by the machinery product;</del></p> <p><u>(c) 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></p> <p><del>(d) the degree to which potentially affected parties are in a vulnerable position vis-à-vis the user of the machinery product;</del></p> <p><u>(d) possibilities of avoiding or limiting harm;</u></p> <p><del>(e) the degree of reversibility of the harm produced by the machinery product;</del></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>(f) the degree to which the machinery product has been used for a specific purpose;</p> <p>(g) indications of harm that have been caused in the past by machinery products which have been used for a specific purpose.</p>	<p><del>(f) the degree to which the machinery product has been used for a specific purpose;</del></p> <p><del>(g) indications of harm that have been caused in the past by machinery products which have been used for a specific purpose.</del></p> <p><u>(h) in case of safety components, the likelihood of serious consequences for the safety of the persons exposed in the event of failure.</u></p>	

While the proposals are similar up to point (b), the last points differ.

The Council's proposal follows the traditional proven assessment of risks.

In both proposals, the rules of assessing products are "soft". It is not required to assess all products equally, but only according to given criteria.

Also, the Council again (see [72]) excludes PCM from appearing in Annex I.

*[76] Machinery and related products listed in Annex I*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	High-risk machinery products	<u>Machinery and related</u> <del>High-risk</del> <u>machinery</u> products <u>listed in Annex I</u>	High-risk machinery products
	Article 5 4	Article 5 4	Article 5 4
	<p>4. The Commission shall thoroughly assess the criteria laid down in paragraph 3 on the basis of available information. In particular the following information shall be communicated to the Commission by the Member States when it becomes available to them in connection with market surveillance or as a result of the concerns referred to in the fifth paragraph:</p> <p>(a) an assessment of the risks as referred to in paragraph 3;</p>	<p>4. <u>When applying</u> <del>The Commission shall thoroughly assess</del> the criteria laid down in paragraph 3 <del>on the</del> <u>Commission may consider any</u> <del>basis of available information. In particular</del> the following <u>elements that</u> <del>information</del> shall be <u>provided</u> <del>communicated to the Commission</del> by the Member States <del>when it becomes available to them</del> in connection with market surveillance or as a result of the concerns referred to in the <del>fifth</del> <u>paragraph 2.</u></p> <p><del>(a) an assessment of the risks as referred to in paragraph 3;</del></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>(b) a cost-effectiveness analysis;</p> <p>(c) a machinery accident analysis;</p> <p>(d) statistics on accidents caused by the</p>	<p><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 any reasonably foreseeable misuse</u> ;</p> <p><u>(ba) information about safety defects detected in the course of market surveillance, and possible available material in the information systems administered by the Commission;</u></p> <p><del>(b) a cost-effectiveness analysis;</del></p> <p><del>(c) a machinery accident analysis;</del></p> <p><u>(ca) known-accidents and serious close calls, including characteristics of these accidents or close call;</u></p> <p><u>(d) <del>statistics</del> data on accidents or damage to the health caused</u></p>	<p>(d) statistics on accidents caused by the machinery</p>

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	machinery product for the preceding four years based, in particular information obtained from the Information and Communication System for Market Surveillance (ICSMS) information, safeguard clauses, Rapid Alert System (RAPEX) and the Machinery Administrative Cooperation Group reporting.	by the machinery <u>or related</u> product <u>at least</u> for the preceding four years <del>based, in particular information obtained from the Information and Communication System for Market Surveillance (ICSMS) information, safeguard clauses, Rapid Alert System (RAPEX) and the Machinery Administrative Cooperation Group reporting.</del>	product for the preceding four years based, in particular information obtained from the Information and Communication System for Market Surveillance (ICSMS) information, safeguard clauses, Rapid Alert System (RAPEX), the Machinery Administrative Cooperation Group reporting <u>and the European Injury Database.</u>

The Commission’s proposal of risk assessment in (a) was moved to Article 5 3 [75] by the Council.

The Council omitted the sources in point (d). This is opposite to the Parliament, who added an additional source. (see also [71] on the new source)

Naming those sources in the legal text would restrict the work of the Commission. They would need to assess all those information and only from those sources.

Also, the Council again (see [72]) excludes PCM from appearing in Annex I.

*[77] Machinery and related products listed in Annex I*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Machinery and related products listed in Annex I</u>	
		<u>Article 5 4a</u>	
		<p><u>4a. A category of machinery or related product which seriousness of its inherent potential risk is established according to §3 and taking into account data required in §4, shall be included in Annex I, Part A if at least one the following criteria is fulfilled:</u></p> <p><u>(i) Lack of harmonised standards or common specifications covering the relevant essential health and safety requirements;</u></p> <p><u>(ii) Existence of residual risks including those which could be reduced by particular training or personal protective</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>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></p> <p><u>(iii) data and information set out in §4 which demonstrate a recurring wrongful application of the relevant harmonised standards or common specifications and conducted market surveillance activities have not lead to major improvements of the market situation, in a reasonable period of time;</u></p> <p><u>(iv) The degree of uncertainty of the existig risk assessment methods related to new categories of machinery or technologies.</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Any other machinery or related product which seriousness of its inherent potential risk is established according to §3 and taking into account data required in §4, shall be included in Annex I, Part B.</u>	

While (i) sounds good at first glance, it is unnecessary at best.

- If there is no harmonised standard for the product, the options for conformity assessment are the same for products in A. and B. Thus there is no need to move such products to A.

- If the product is in Annex I A. and a harmonised standard is published, still this product will be treated as if the harmonised standard doesn't exist until the re-evaluation period.

- If the product would be in Annex I B., the publication of a harmonised standard would have an immediate automatic effect.

Additionally how to assess larger groups of products (E.g. "Protective devices designed to detect the presence of persons.") where most of these products have a harmonized standard, but others don't?

(ii) "Training" and "PPA" is solely in the hand of the user, not the manufacturer. Using a notified body for type examination will not affect this problem.

(iii) is a good and reasonable criteria.

(iv) is aimed solely on AI "*with fully or partially self-evolving behaviour*". By the time such systems are possible, the risk assessment will be thoroughly investigated.

Also, the Council again (see [72]) excludes PCM from appearing in Annex I.

*[78] Machinery and related products listed in Annex I*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>Machinery and related <del>High-risk</del> machinery products listed in Annex I</u></p>	
		<p>Article 5 5</p>	
		<p><u>5. By [2 years after the date of the entry into force of the Regulation], and every 5 years thereafter, Member States shall provide, if available, the information referred to in paragraph 4 for any category of machinery or related products which ought to be included in or excluded from the annex.</u></p> <p><u>By [OJ office: 3 years] after the date of entry into force] and every 5 years thereafter, the Commission, shall carry out a review of the content of Annex I in view of the criteria set out in this article and shall submit a</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>report to the European Parliament and to the Council.</u>	

Once a product is in Annex I A/B it will remain there for at least 5 years, unless a member state triggers a re-evaluation (see [74]).

Drafting a new harmonized standard generally takes slightly longer, thus the product will remain in Part A for at least 10 years.

Also, any product now in Part B where no harmonized standard exists for all sub-products will move to Part A after 3 years after the date of entry into force of the MPR.

A lot of broader categories like "*21. Logic units to ensure safety functions*" will have to be moved to part A.

Also, the Council again (see [72]) excludes PCM from appearing in Annex I.

*[79] Machinery and related products listed in Annex I*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Machinery and related products listed in Annex I</u>	
		<u>Article 5 6</u>	
		<p><u>6. The Commission is empowered to adopted implementing acts establishing and updating, in view of technological and market development, a template to collect the data and information set out in this Article.</u></p> <p><u>These implementing shall be adopted in accordance with the examination procedure referred to in Article 46(3).</u></p> <p><u>The first implementing act shall be adopted not later than twelve months after the entry into force of this Regulation.</u></p>	

According to the Council's proposal, the Commission will tell the member states which data needs to be provided in which format.

The member states will have to implement a rapport system in their industry, if none exists.

This is similar to the mandatory report to the European Injury Database, proposed by the Parliament in [71], but independent from a specific third party. The Commission might still decide to use the European Injury Database, but is not forced to, because it is not fixed in the legal text.

Also, the Council again (see [72]) excludes PCM from appearing in Annex I.

**[80] Safety components**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Safety components	Safety components	
Article 2 c	Article 6 1	Article 6 1	
An indicative list of safety components is set out in Annex V;	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 II.	

no change, other than the new number of the Annex.

**[81] Safety components**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Specific measures	Safety components	Safety components	
Article 8 1+2	Article 6 2-4	Article 6 2-4	
<p>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.</p> <p>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).</p>	<p>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.</p> <p>3. The Commission shall thoroughly assess the risks that require the inclusion of a new safety component in the list of safety components in Annex II or a withdrawal of a safety component from that list.</p>	<p>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.</p> <p><del>3. The Commission shall thoroughly assess the risks that require the inclusion of a new safety component in the list of safety components in Annex II or a withdrawal of a safety component from that list.</del></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	4. A Member State which has concerns about a safety component being listed or not listed in Annex II shall immediately inform the Commission of its concerns and provide reasons in support thereof.	4. A Member State which has concerns about a safety component being listed or not listed in Annex II shall immediately inform the Commission of its concerns and provide reasons in support thereof.	

No change in content.

Also: Since this list only contains examples, it is sometimes a helpful clarification but there is no impact on such products.

Since a safety component in this list is only based on its definition and independent from the risk mitigated by that component, the Council's proposal to delete No 3 makes sense.

*[82] Essential health and safety requirements for products subject to this Regulation*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Market surveillance	Requirements for machinery products	<u>Essential health and safety requirements</u> <del>Requirements</del> for <del>machinery</del> products <u>subject to this Regulation</u>	
Article 4 1+2	Article 7	Article 7	
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 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.	Machinery products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended purpose or under conditions which can reasonably be foreseen, they meet the essential health and safety requirements set out in Annex III.	Machinery <u>or related</u> products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended <del>use</del> <del>purpose</del> or under conditions which can reasonably be foreseen, they meet the 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>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<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>			

In the MD this was a general obligation only of the Member States. In the proposals, it is also addressed towards the economic operators.

In the proposal by the Commission this Article requires that also PCM must fully fulfil Annex III. That is new. It is in the nature, that PCM cannot fulfil all the requirements of Annex III.

The Council remedies this problem. In its proposal there are new requirements on PCM to fulfil, including the requirement on fulfilling as much of Annex III as possible.

The contents of this general Article are repeated at other places more specifically and with a clear address.

### [83] Specific Union harmonisation legislation

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Specific Directives	Specific Union harmonisation legislation	Specific Union harmonisation legislation	
Article 3	Article 8	Article 8	
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 from the date of implementation of those other Directives.	Where, for a certain machinery product, 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 to that machinery product to the extent that that specific Union legislation covers such risks.	Where, for a certain <b>machinery</b> product <u>subject to this Regulation</u> , 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 to that <b>machinery</b> product <u>subject to this Regulation</u> to the extent that that specific Union legislation covers such risks.	

Due to the broader term "*machinery product*" | "*product subject to this Regulation*", this now also applies to PCM. This closes a formal gap in the MD.

*[84] Regulation (EU) .../... of the European Parliament and of the Council*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Regulation (EU) .../... of the European Parliament and of the Council	<del>Regulation (EU) .../... of the European Parliament and of the Council</del>	
	Article 9	<del>Article 9</del>	
	Where machinery products contain an artificial intelligence system, to which the essential health and safety requirements of Regulation (EU) .../... apply, this Regulation shall, in relation to that artificial intelligence system, only apply with regard to its safe integration into the overall machinery, so as not to compromise the safety of the machinery product as a whole.	<del>Where machinery products contain an artificial intelligence system, to which the essential health and safety requirements of Regulation (EU) .../... apply, this Regulation shall, in relation to that artificial intelligence system, only apply with regard to its safe integration into the overall machinery, so as not to compromise the safety of the machinery product as a whole.</del>	

The Commission's proposal for Article 9 is a more restricted copy of its own Article 8. Thus, it is surplus and has no effect.

It was deleted in the Council's proposal, also because the referenced Regulation will not exist at the time of publication of the MPR.

*[85] Obligations of manufacturers of machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Placing on the market and putting into service	Obligations of manufacturers	Obligations of manufacturers <u>of machinery and related products</u>	
Article 5 1a	Article 10 1	Article 10 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;	1. When placing a machinery product on the market, 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. When placing a machinery <u>or a related</u> product on the market <u>or putting it into service</u> , manufacturers shall ensure that it has been designed and constructed in accordance with the essential health and safety requirements set out in Annex III.	

The difference of “Before” and “When” is important. Now it is clear, that a product must fulfil Annex III at the time it is placed on the market. This will end some discussions.

The Council's proposal corrects the problem that the Commission forgot about “machinery for one's own use”.

*[86] Obligations of manufacturers of machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Placing on the market and putting into service	Obligations of manufacturers	Obligations of manufacturers <u>of machinery and related products</u>	
Article 5 1b+1d	Article 10 2 -(1)	Article 10 2 -(1)	
<p>1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:</p> <p>(b) ensure that the technical file referred to in Annex VII, part A is available;</p> <p>(d) carry out the appropriate procedures for assessing conformity in accordance with Article 12;</p>	<p>2. Before placing a machinery product on the market, manufacturers shall draw up the technical documentation referred to in Annex IV ('technical documentation') and carry out the relevant conformity assessment procedures referred to in Article 21 or Article 22 or have them carried out.</p> <p>[...]</p>	<p>2. Before placing a machinery <u>or related</u> product on the market <u>or putting it into service</u>, manufacturers shall draw up the technical documentation <u>set out</u> <del>referred to</del> in <u>part A of Annex IV</u> <del>('technical documentation')</del> and carry out the relevant conformity assessment <u>procedure</u> <del>procedures</del> referred to in Article 21 or <del>Article 22 or</del> have <u>it</u> <del>them</del> carried out.</p> <p>[...]</p>	

Generally no change between MD and the Council's proposal. But now the TD only needs to be drawn up. In the MD it needed to be available.

In the Commission's proposal the "manufacturer for own use" was forgotten. This was rectified by the Council.

Also, the Commission did not distinguish between PCM and other products in the scope of the Regulation.

**[87] Obligations of manufacturers of machinery and related products**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Placing on the market and putting into service	Obligations of manufacturers	Obligations of manufacturers <u>of machinery and related products</u>	
Article 5 1 e+f	Article 10 2, 8	Article 10 2, 8	
<p>1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:</p> <p>(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>(f) affix the CE marking in accordance with Article 16.</p>	<p>2. [...]</p> <p>Where compliance of the machinery 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, except for partially completed machinery.</p> <p>[...]</p>	<p>2. [...]</p> <p>Where compliance of <del>a</del><u>the</u> machinery <u>or related</u> 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, <del>except for partially completed machinery.</del></p> <p>[...]</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>8. Manufacturers shall either provide the EU declaration of conformity with the machinery product or include in the instructions and information set out in section 1.7 of Annex III the internet address at which the EU declaration of conformity can be accessed.</p>	<p>8. Manufacturers shall <u>ensure that the machinery or related products is accompanied by the</u> <del>either provide the</del> EU declaration of conformity <u>set out in Part A of Annex V or shall provide the internet address at which it can be accessed</u> <del>with the machinery product or include</del> in the instructions and information set out in section 1.7 of Annex III.</p> <p><u>Digital</u> <del>the internet address at which the</del> EU <u>declarations</u> <del>declaration</del> of conformity <u>shall be made accessible online for at least 10 years after placing on the market or putting into service of the machinery or related product</u> <del>can be accessed</del>.</p>	

In the proposals, the EU declaration of conformity no longer has to be attached. Instead, its URL can be included in the instructions.

Annex III 1.7.4.2. c) has also been adapted to this requirement in the Council's proposal.

The requirement on affixing a CE mark is also covered by Article 20 2 [126]. Thus this requirement is handled at two different places!

The main difference in the proposals is that the Council added a minimum timeframe of availability for the EU declaration. Since not everything online is available 100% of the time, court rulings will have to show, if availabilities of 99%, 99.9% or higher are sufficient.

**[88] Obligations of manufacturers of machinery and related products**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Placing on the market and putting into service	Obligations of manufacturers	Obligations of manufacturers <u>of machinery and related products</u>	
Article VII 1 b Annex 5 A 2.	Article 10 3	Article 10 3	
<p>1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:</p> <p>(b) ensure that the technical file referred to in Annex VII, part A is available;</p> <p>Annex VII A</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</p>	<p>3. Manufacturers shall keep the technical documentation and the EU declaration of conformity, where relevant, at the disposal of the market surveillance authorities for ten years after the machinery product has been placed on the market. Where relevant, the source code or programmed 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</p>	<p>3. Manufacturers shall keep the technical documentation and the EU declaration of conformity, <del>where relevant,</del> at the disposal of the market surveillance authorities for ten years after the machinery <u>or the related</u> product has been placed on the market <u>or put into service</u>. <del>Where relevant,</del> <del>the source code or programmed 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</del></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>manufacture of the machinery or, in the case of series manufacture, of the last unit produced.</p> <p>[...]</p>	<p>be able to check compliance with the essential health and safety requirements set out in Annex III.</p>	<p><del>order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.</del></p>	

The proposals present no huge change in content.

The omitted text from the Council's proposal has no effect. Since the source code is part of the "technical documentation", it still must be made available.

The Council's proposal also fixes another instance, where the Commission forgot "machinery for own use".

The start time "*following the date of manufacture of [...] the last unit produced*" from the MD was dropped. This should have no consequence, since all products of a series are treated as a separate single unit.

In praxis the technical documentation of a 10 year old product can be declared by the manufacturer as "no longer available" for that unit, even though the same product is still being produced.

A legal trick in the current MD is that the time starts after "*the date of manufacture*". Thus if the product is not sold, but kept in storage, the 10 years countdown is still ticking. In the new MPR this changes to "*has been placed on the market*". Thus, putting the product in the manufacturers storage will extend this timeframe.

Currently in the MD the EU declaration of conformity must be made available to market authorities as part of the technical documentation. In the MPR the EU declaration is no longer part of the technical documentation (see Annex IV). However, due to this paragraph, it must still be made available to the market authorities.

*[89] Obligations of manufacturers of machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Technical file for machinery	Obligations of manufacturers	Obligations of manufacturers <u>of machinery and related products</u>	
Annex VII A1.b	Article 10 4 -(1)	Article 10 4 -(1)	
<p>(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.</p> <p>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 safely. The relevant reports and results shall be included in the technical file.</p>	<p>4. Manufacturers shall ensure that procedures are in place for machinery products 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 machinery product and changes in the harmonised standards or the technical specifications referred to in Article 17 by reference to which the conformity of the machinery product is declared or by application of which its conformity is verified shall be adequately taken into account.</p>	<p>4. Manufacturers shall ensure that procedures are in place for machinery <u>or related</u> products 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 machinery <u>or related</u> product and changes in the harmonised standards or the <u>common</u><del>technical</del> specifications referred to in Article 17 <u>or other technical specifications</u> by reference to which the conformity of the machinery <u>or related</u> product is declared <del>or by application of</del></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	[...]	<del>which its conformity is verified</del> shall be adequately taken into account.  [...]	

1. Here, as in other places, the MPR proposals follow the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products". (Article R2 4. with adaptations)
2. no change in content
3. Documentation of these measures is still part of Technical Documentation (Annex IV m)

*[90] Obligations of manufacturers of machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Obligations of manufacturers	Obligations of manufacturers <u>of machinery and related products</u>	
	Article 10 4 -(2)	Article 10 4 -(2)	
	When deemed appropriate with regard to the risks presented by machinery products, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of machinery products made available on the market or put into service, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery products and machinery product recalls, and shall keep distributors informed of any such monitoring.	When deemed appropriate with regard to the risks presented by machinery <u>or related</u> products, manufacturers shall, <u>in order</u> to protect the health and safety of <del>end</del> -users, carry out sample testing of machinery <u>or related</u> products made available on the market <u>and, or put into service,</u> investigate. <u>If, and, if</u> necessary, <u>manufacturers shall</u> keep a register of complaints, of non-conforming machinery <u>or related</u> products and machinery <u>or related products</u> <del>product</del> recalls, and	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		shall keep distributors informed of any such monitoring.	

Here, as in other places, the MPR proposals follow the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products". (Article R2 4.)

NLF's "consumer" is replaced by "user". (see missing definition of user [49])

The test in the field is not required in the MD, except for machines in accordance with Annex IX or X. (by notified bodies)

The "*register of complaints*" must be kept, but there is no obligation to show or use it at any time. It is not part of the technical documentation.

*[91] Obligations of manufacturers of machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Essential health and safety requirements ...	Obligations of manufacturers	Obligations of manufacturers <u>of machinery and related products</u>	
Annex I 1.7.3	Article 10 5, 6	Article 10 5, 6	
<p>1.7.3. Marking of machinery</p> <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> </ul>	<p>5. Manufacturers shall ensure that the machinery products which they place on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the machinery product does not allow it, that the required information is provided on the packaging or in a document accompanying the machinery product.</p>	<p>5. Manufacturers shall ensure that the machinery <u>or related product</u> <del>products</del> which they place on the market <u>or put into service</u> bears <u>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</u> <del>or other element</del> allowing its identification, or, where the size or nature of the machinery <u>or related</u> product does not allow it, that the required information is provided on the packaging or in a document</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>— the year of construction, that is the year in which the manufacturing process is completed.</p> <p>It is prohibited to pre-date or post-date the machinery when affixing the CE marking.</p> <p>Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.</p> <p>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.</p> <p>Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.</p>	<p>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and the email address at which they can be contacted on the machinery product or, where that is not possible, on its packaging or in a document accompanying the machinery product. 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 end-users and market surveillance authorities.</p>	<p>accompanying the machinery <u>or related</u> product.</p> <p>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and, <u>if available, a digital contact</u> <del>the email address</del> at which they can be contacted on the machinery <u>or related</u> product or, where that is not possible, on its packaging or in a document accompanying the machinery <u>or related</u> <del>products</del>. <del>product</del>. 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 <del>end</del>-users and market surveillance authorities.</p>	

1. In the Commission's proposal an E-Mail address and in the Council's proposal a more technology neutral "*digital contact*" needs to be provided, "*if available*". That is an addition to the information required by the MD.

The Council also moved the "*year of construction*" from Annex III 1.7.3 to this article and Article 10a 5 for partly completed machinery, eliminating having different requirements at different locations in the MPR.

2. The language of the contact detail in Annex 10 6. only needs to be "*easily understood*". Annex III 1.7.1. expands this as "*easily understood by users, as determined by the Member State concerned.*"

Thus the similar restrictions on language options as in the current MD remain.

3. The language only needs to be "a" language, as in one of all given options.

It no longer needs to be every official language.

The new wording allows Member States to have their own list of allowed languages, which would make it harder for foreign manufacturers to find those lists in each Member State.

E.g. in Germany, the permitted languages also include Sorbian, Low German, Frisian as well as Danish and French.

(see German laws: LVwG,SH; SächsSorbG; SWG; SVwVfG)

4. The MD's sentence "*It is prohibited to pre-date or post-date the machinery when affixing the CE marking.*" has been struck from Annex III 1.7.3 and not included here. This is an important point in the discussion on how to remedy machinery with missing CE marks that have been illegally put on the market after 1995.

5. The information may be on the packaging and need not be on the machinery product, where this is not possible.

*[92] Obligations of manufacturers of machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Placing on the market and putting into service	Obligations of manufacturers	Obligations of manufacturers <u>of machinery and related products</u>	
Article I 1c Annex 5 1.7.1.	Article 10 7	Article 10 7	
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;  Annex I 1.7.1.  Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. Any	7. Manufacturers shall ensure that the machinery products are accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and information shall be clear, understandable, intelligible and legible.	7. Manufacturers shall ensure that the machinery <u>or related</u> products are accompanied by the instructions and information set out in <del>section 1.7 of</del> Annex III.  <u>When the instructions are provided in digital format, the manufacturer shall:</u>  <u>(a) mark on the machinery or related product and in an accompanying document how to access the digital instructions;</u>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>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>		<p><u>(b) present them in a format that makes it possible for the user to download the 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 the machinery or related product. This requirement also applies where the instructions are embedded in the software of the machinery or related product.</u></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><u>However, upon request of the user at the time of the purchase or up to 6 months after that purchase, the manufacturer shall provide the</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>instructions in paper format free of charge.</u></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><u>The instructions and information shall be</u> -in a language which can be easily understood by <del>end</del>-users, as determined by the Member State concerned. <del>Such instructions and information</del> shall be clear, understandable, intelligible and legible.</p>	

1. Currently in the MD, instructions (Annex I 1.7.4) are given as an example for “*necessary information*” to be provided. In the MPR proposals all “*information*” listed in Annex III (Annex III 1.7) is mandatory.

In the MD nearly all contents of Annex I 1.7 have to be provided as well. But according to the MPR proposals, also the “*Sales literature*” defined in Annex III 1.7.4.3. has to be provided, since it is part of the “*instructions*” of Annex III 1.7.

The Council dropped the reference to Annex III 1.7, but only because there are instructions listed in later chapters of Annex III as well. This does not remedy the problem of “*Sales literature*” defined in Annex III 1.7.4.3.

2. Instructions can in both proposals be provided digital. In the Commission’s proposal, this was part of Annex III 1.7.4. The Council again sets a timeframe with “*not less than 10 years*”. (see [87]) Here it is unclear if a direct web address is required or a simple “somewhere on our website, good luck searching” is sufficient.

3. on “language” see Article 10 5. + 6. [91]

4. In case of non-professional users, the Council proposes that the instructions have to be provided in paper format.

There is no recognizable difference between “*instructions*” and “*the safety information that are essential for putting the machinery or related product into service and for using it in a safe way*”. “*instructions*” are defined in Annex III 1.7.4 and the only thing that could be omitted is 1.7.4.2. (c) “*the EU declaration of conformity*”.

*[93] Obligations of manufacturers of machinery and related products*

Regulation on market surveillance, Article 4 3	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Tasks of economic operators regarding products subject to certain Union harmonisation legislation	Obligations of manufacturers	Obligations of manufacturers <u>of machinery and related products</u>	
Article 4 3	Article 10 9	Article 10 9	
<p>3. Without prejudice to any obligations of economic operators under the applicable Union harmonisation legislation, the economic operator referred to in paragraph 1 shall perform the following tasks:</p> <p>(c) when having reason to believe that a product in question presents a risk, informing the market surveillance authorities thereof;</p> <p>(d) cooperating with the market surveillance authorities,</p>	<p>9. Manufacturers who consider or have reason to believe that a machinery product, which they have placed on the market or put into service is not in conformity with the essential health and safety requirements set out in Annex III shall immediately take the corrective measures necessary to bring that machinery product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the machinery product presents a risk, manufacturers shall</p>	<p>9. Manufacturers who consider or have reason to believe that a machinery <u>or related</u> product, which they have placed on the market or put into service is not in conformity with <u>this Regulation</u><del>the essential health and safety requirements set out in Annex III</del> shall immediately take the corrective <u>actions</u><del>measures</del> necessary to bring that machinery <u>or related products</u><del>product</del> into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the machinery <u>or related</u> product</p>	

Regulation on market surveillance, Article 4 3	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>including following a reasoned request making sure that the immediate, necessary, corrective action is taken to remedy any case of non-compliance with the requirements set out in Union harmonisation legislation applicable to the product in question, or, if that is not possible, to mitigate the risks presented by that product, when required to do so by the market surveillance authorities or on its own initiative, where the economic operator referred to in paragraph 1 considers or has reason to believe that the product in question presents a risk.</p>	<p>immediately inform the competent national authorities of the Member States in which they made the machinery product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.</p>	<p>presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the machinery <u>or related</u> product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective <u>actions</u><del>measures</del> taken.</p>	

1. Here, as in other places, the MPR follows the NLF, i.e. the EC Decision No 768/2008/EC “common framework for the marketing of products”. (Article R2 8. with adaptations)

2. It is no longer necessary for the market surveillance authority to make a reasoned request. Now Manufacturers need to act on their own accord, when a nonconformity of a product is to be assumed.

This also extends the tasks of economic operators as defined in the Market Surveillance Regulation (EU) 2019/1020 in Article 4 (3) c and d.

3. Germany's highest court has made a ruling in 2008 (VI ZR 170/07) that it is sufficient, if the manufacturer warns the customers not to use the defective product.

It will be interesting to see if this is considered as “take the corrective actions necessary”.

*[94] Obligations of manufacturers of machinery and related products*

Regulation on market surveillance, Article 4 3	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Tasks of economic operators regarding products subject to certain Union harmonisation legislation	Obligations of manufacturers	Obligations of manufacturers <u>of machinery and related products</u>	
Article 4 3	Article 10 10	Article 10 10	
<p>3. Without prejudice to any obligations of economic operators under the applicable Union harmonisation legislation, the economic operator referred to in paragraph 1 shall perform the following tasks:</p> <p>(a) [...]</p> <p>(b) further to a reasoned request from a market surveillance authority, providing that authority with all information and documentation necessary to demonstrate the conformity of</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 product with the essential health and safety requirements set out in Annex III, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks</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 <u>or related products with this Regulation</u> <del>product with the essential health and safety requirements set out in Annex III</del>, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its</p>	

Regulation on market surveillance, Article 4 3	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
the product in a language which can be easily understood by that authority;	posed by the machinery product, which they have placed on the market or put into service.	request, on any <del>actions</del> <del>measures</del> taken to eliminate the risks <del>presented</del> <del>posed</del> by the machinery <u>or related</u> <del>products</del> <del>product</del> , which they have placed on the market or put into service.	

1. Here, as in other places, the MPR follows the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products". (Article R2 9. with adaptations)
2. This replaces the EU-Regulation on market surveillance, Article 4, which is currently in effect alongside the MD.
3. This is an addition to Article 10 3. [83] It theoretically "only" concerns the information on risk assessment (Annex III) of the MPR, but here no time limit is given.
4. Paper or electronic form is now acceptable.
5. on "language" see Article 10 5. + 6.

So far, this information, along with the rest of the technical documentation, only has to be kept for ten years according to MD. But due to the EU-Regulation on market surveillance, for any product sold after 16. July 2021 a similar law has already been in effect.

A corresponding regulation can be found in Article 10 3 [83]. However, since no time limit is specified here and no reference is made to Article 10 3, this – similar – information has to be kept for at least as long as the product exists.

*[95] Obligations of manufacturers of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Relevant technical documentation for partly completed machinery	Conformity assessment procedures for partly completed machinery	<u>Obligations of manufacturers of</u> <del>Conformity assessment procedures for</del> partly completed machinery	
Annex VII B (a) 3.- (i)	Article 22 1	Article <del>10a</del> <u>22</u> 1	
<p>It shall comprise the following:</p> <p>(a) a construction file including:</p> <ul style="list-style-type: none"> <li>- the risk assessment documentation showing the procedure followed, including:</li> <li>(i) a list of the essential health and safety requirements applied and fulfilled,</li> </ul>	<p>1. The manufacturer of partly completed machinery or the manufacturer's authorised representative shall, before placing partly completed machinery on the market, ensure that the following documents are drawn up:</p> <p>(a) the relevant technical documentation that satisfies the requirements laid down in Annex IV, part B;</p>	<p>1. <u>When placing a</u> <del>The manufacturer of</del> partly completed machinery <del>or the manufacturer's authorised representative shall, before placing partly completed machinery</del> on the market, <u>manufacturers shall</u> ensure that <u>it has been designed and constructed in accordance with</u> <del>the following documents are drawn up:</del></p> <p><del>(a) the relevant</del> <u>essential health and safety</u> <del>technical documentation that satisfies the requirements laid down in Annex IV, part B;</del></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	(b) assembly instructions that satisfy the requirements laid down in Annex X;  (c) the EU declaration of incorporation that has the model structure set out in Annex V.	<del>(b) assembly instructions that satisfy the requirements laid down in Annex X;</del>  <del>(c) the EU declaration of incorporation that has the model structure set out in Annex <u>III</u>.</del>	

The Commission's proposal sometimes treats PCM the same way as machinery, meaning that it should be completely safe. Here the Commission proposes additional rules only for PCM.

*"The relevant ESHR"* in the Council's proposal are much more than *"a list of the EHSR applied and fulfilled"*. Now the manufacturer is according to Annex III 1.1.1 obligated to make the PCM safe. Relevant is to be understood as *"up to certain interfaces"*.

Before manufacturers of PCM could decide which EHRS to follow. Now, also according to the Council's Annex III 1.1.1, manufacturers of PCM need to apply all *"possible"* EHRS up to the *"incorporation-interface"*:

*"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."*

*[96] Obligations of manufacturers of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Procedure for partly completed machinery	Conformity assessment procedures for partly completed machinery	<u>Obligations of manufacturers of</u> <del>Conformity assessment procedures for</del> partly completed machinery	
Article 13 1. (a) + (c)	Article 22 2	Article <del>10a</del> 22 2	
<p>1. The manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that:</p> <p>(a) the relevant technical documentation described in Annex VII, part B is prepared;</p> <p>(c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up.</p>	<p>2. Where relevant, the manufacturer of partly completed machinery or the manufacturer's authorised representative shall make available to the competent national authority upon its request the source code or programmed logic included in the technical documentation referred to in paragraph 1, point (a), provided that it is needed in order for that authority to be able to check compliance with the essential health and safety requirements set out in Annex III. The assembly instructions referred to in paragraphs 1,</p>	<p>2. <u>Before placing a</u> <del>Where relevant, the manufacturer of</del> partly completed machinery <u>on the market, manufacturers</u> <del>or the manufacturer's authorised representative</del> shall <u>draw up the</u> <del>make available to the competent national authority upon its request the source code or programmed logic included in the</del> technical documentation <u>set out in part B of Annex IV.</u></p> <p><u>Where</u> <del>referred to in paragraph 1, point (a), provided that it is needed in order for that</del> authority to be able to check</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>point (b), and the declaration of incorporation referred to in paragraph 1, point (c), shall accompany the partly completed machinery until it is incorporated into the final machinery product and shall afterwards form part of the technical file for that machinery product.</p>	<p>compliance <u>of a partly completed machinery</u> with the <u>relevant</u> essential health and safety requirements <u>laid down</u><del>set out</del> in Annex III <u>has been demonstrated in the technical documentation set out in Part B of Annex IV,</u> <u>manufacturers shall draw up the EU.</u><del>The assembly instructions referred to in paragraphs 1, point (b), and the declaration of incorporation in accordance with Article 18a referred to in paragraph 1, point (c), shall accompany the partly completed machinery until it is incorporated into the final machinery product and shall afterwards form part of the technical file for that machinery product.</del></p>	

At first glance the Council's proposal reverted to the former requirements of the MD. But the requirements have changed.

Now the manufacturer must demonstrate in the technical documentation that the PCM is in compliance with the relevant essential health and safety requirements, that means up to certain interfaces. Thus, it is no longer up to the decision of the manufacturer which essential health and safety requirements to apply.

*[97] Obligations of manufacturers of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Declarations		<u>Obligations of manufacturers of partly completed machinery</u>	
Annex II 2. Annex VII B		<u>Article 10a 3</u>	
<p>2. CUSTODY</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> <p>Relevant technical documentation for partly completed machinery</p> <p>The relevant technical documentation must be available for at least 10 years following the date of</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></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>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>			

Same problems as Article 10 3. [88]

*[98] Obligations of manufacturers of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Relevant technical documentation for partly completed machinery		<u>Obligations of manufacturers of partly completed machinery</u>	
Annex VII B (b)		<u>Article 10a 4</u>	
<p>It shall comprise the following:</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>		<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 the common specifications referred to in Article 17 or in other technical specifications by reference to which the conformity of the partly completed machinery is declared or by application of which its conformity is verified</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>shall be adequately taken into account.</u>	

Same problems as Article 10 4. [89]

*[99] Obligations of manufacturers of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Obligations of manufacturers of partly completed machinery</u>	
		<u>Article 10a 5</u>	
		<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</u>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>accompanying the partly completed machinery.</u>	

Although regularly done in praxis, there is no formal requirement in the MD to outfit a PCM with a marking following MD's Annex I 1.7.3.

*[100] Obligations of manufacturers of partly completed machinery*

Regulation on market surveillance	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Tasks of economic operators regarding products subject to certain Union harmonisation legislation		<u>Obligations of manufacturers of partly completed machinery</u>	
Article 4 4		<u>Article 10a 6</u>	
4. Without prejudice to the respective obligations of economic operators under the applicable Union harmonisation legislation, the name, registered trade name or registered trade mark, and contact details, including the postal address, of the economic operator referred to in paragraph 1 shall be indicated on the product or on its packaging, the parcel or an accompanying document.		<u>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and, if available, a 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</u>	

Regulation on market surveillance	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>incorporates the partly completed machinery into a machinery and market surveillance authorities.</u>	

Currently in the Market Surveillance Regulation (EU) 2019/1020 in Article 4 similar provisions exist for PCM. These will be replaced by the more specific regulations of MPR.

See Article 10 6. [91] for more.

*[101] Obligations of manufacturers of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Procedure for partly completed machinery		<u>Obligations of manufacturers of partly completed machinery</u>	
Article Annex 13 VI 2.		<u>Article 10a 7</u>	
<p>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.</p> <p>Assembly instructions for partly completed machinery</p> <p>The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the</p>		<p><u>7. Manufacturers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Annex X</u></p> <p><u>When the assembly instructions are provided in digital format, the manufacturer shall:</u></p> <p><u>(a) mark on the partly completed machinery and in an accompanying document how to access the digital assembly instructions;</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>partly completed machinery will be assembled, or to his authorised representative.</p>		<p><u>(b) present them in a format that makes it is possible for the person who incorporates the partly completed machinery to 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 the partly completed machinery. This requirement also applies to a partly completed machinery where the assembly instructions are embedded in the software of the partly completed machinery.</u></p> <p><u>(c) make them accessible online not less than 10 years after the placing on the market of the partly completed machinery.</u></p> <p><u>However, upon request of the person who incorporates the partly completed machinery, at the time of the purchase or up</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>to 6 months after that purchase, assembly instructions shall be provided in paper format free of charge.</u></p> <p><u>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. Such assembly instructions shall be clear, understandable, intelligible and legible.</u></p>	

The content of the assembly instructions was heavily expanded upon in the Council's proposal (compare new Annex X and old Annex VI).

1. It is possible to supply assembly instructions in a digital format.
2. The language is now restricted. This restriction is difficult, since it concerns the persons incorporating it as well as the state in which the PCM is placed on the market.

If an Italian person installs a German PCM in Belgium, which language does the assembly instructions have to be in?

Before the answer was simply Italian. Now the Belgium state has to decide.

*[102] Obligations of manufacturers of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Procedure for partly completed machinery		<u>Obligations of manufacturers of partly completed machinery</u>	
Article 13 2.		<u>Article 10a 8</u>	
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.		<u>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 or shall provide the internet address at which it can be accessed in the assembly instructions set out in Annex X.</u>  <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>	

1. The "declaration of incorporation" has become an "EU declaration of incorporation"

**2. It can now be provided in a digital format.**

*[103] Obligations of manufacturers of partly completed machinery*

Regulation on market surveillance	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Tasks of economic operators regarding products subject to certain Union harmonisation legislation		<u>Obligations of manufacturers of partly completed machinery</u>	
Article 4 3		<u>Article 10a 9</u>	
<p>3. Without prejudice to any obligations of economic operators under the applicable Union harmonisation legislation, the economic operator referred to in paragraph 1 shall perform the following tasks:</p> <p>(c) when having reason to believe that a product in question presents a risk, informing the market surveillance authorities thereof;</p> <p>(d) cooperating with the market surveillance</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</u></p>	

Regulation on market surveillance	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>authorities, including following a reasoned request making sure that the immediate, necessary, corrective action is taken to remedy any case of non-compliance with the requirements set out in Union harmonisation legislation applicable to the product in question, or, if that is not possible, to mitigate the risks presented by that product, when required to do so by the market surveillance authorities or on its own initiative, where the economic operator referred to in paragraph 1 considers or has reason to believe that the product in question presents a risk.</p>		<p><u>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>	

No longer the manufacturer needs to react only to the action of the market surveillance authority. Now Manufacturers need to remedy the problem on their own accord.

Germany's highest court has made a ruling in 2008 (VI ZR 170/07) that it is sufficient, if the manufacturer warns the customers not to use the defective product. It will be interesting to see if this is considered as "take the corrective actions necessary".

*[104] Obligations of manufacturers of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Obligations of manufacturers of partly completed machinery</u>	
		<u>Article 10a 10</u>	
		<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 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</u>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>they have placed on the market.</u>	

Similar to Article 10 10. [94].

Clashing with Article 10a 3. [97] on time limit of storage of Technical Documents.

*[105] Authorised representatives*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Scope	Authorised representatives	Authorised representatives	
Article Article 2 5 j (1)	Article 11	Article 11	
<p>2 (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:</p> <p>5 (1) Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:</p>	<p>1. A manufacturer may, by a written mandate, appoint an authorised representative.</p> <p>The obligations laid down in Article 10(1) and the obligation to draw up the technical documentation shall not form part of the authorised representative's mandate.</p> <p>2. An authorised representative shall perform the tasks specified in the mandate received from the</p>	<p>1. A manufacturer <u>of a product subject to this Regulation</u> may, by a written mandate, appoint an authorised representative.</p> <p>The obligations laid down in Article 10(1) and <u>Article 10a(1) and</u> the obligation to draw up the technical documentation <u>set out in Annex IV</u> shall not form part of the authorised representative's mandate.</p> <p>2. An authorised representative shall perform the tasks specified in the mandate received from the</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
[...]	<p>manufacturer. The mandate shall allow the authorised representative to do at least the following:</p> <p>(a) keep the EU declaration of conformity and the technical documentation at the disposal of the national market surveillance authorities for ten years after the machinery product has been placed on the market;</p> <p>(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 machinery</p>	<p>manufacturer. The mandate shall allow the authorised representative to do at least the following:</p> <p>(a) keep the <u>technical documentation and the EU declaration of conformity of machinery and related products or the EU declaration of incorporation of partly completed machinery</u> <del>and the technical documentation</del> at the disposal of the national market surveillance authorities for ten years after the <del>machinery</del> product has been placed on the market;</p> <p>(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 <del>machinery</del></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>product;</p> <p>(c) cooperate with the competent national authorities, at their request, on any measures taken to eliminate the risks posed by a machinery product covered by the authorised representative's mandate.</p>	<p>product <u>subject to this Regulation</u>;</p> <p>(c) cooperate with the competent national authorities, at their request, on any <del>actions</del><u>measures</u> taken to eliminate the risks <del>presented</del><u>posed</u> by a <del>machinery</del> product <u>subject to this Regulation</u> covered by the authorised representative's mandate.</p>	

1. Here, as in other places, the MPR proposals follow the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products".

2. The tasks that can be assigned to the authorized representative are very limited compared to the MD.

The authorized representative must have the EU declaration of conformity and the technical documents and, if necessary, further information ready for the authorities.

This is limited in 2. (a) to ten years, but in (b) no time limit is given. Thus the same situation arises as with the manufacturer (see Article 10 10. [94] and Article 10a 10. [104])

The authorized representative has to work with the authority.

*[106] Obligations of importers of machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Obligations of importers	Obligations of importers <u>of machinery and related products</u>	
Article 2 i	Article 12	Article 12	
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>1. Importers shall only place on the market machinery products that comply with the essential health and safety requirements set out in Annex III.</p> <p>2. Before placing a machinery product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 21 or Article 22 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that</p>	<p>1. Importers shall <del>only</del> place <u>only compliant on the market</u> machinery <u>or related</u> products <u>on the market</u> <del>that comply with the essential health and safety requirements set out in Annex III.</del></p> <p>2. Before placing a machinery <u>or related</u> product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 21 <del>or Article 22</del> have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation <u>set</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>the machinery 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).</p> <p>Where an importer considers or has reason to believe that a machinery product is not in conformity with the essential health and safety requirements set out in Annex III, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the machinery product poses 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</p>	<p><u>out in Part A of Annex IV</u>, that the machinery <u>or related</u> 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).</p> <p>Where an importer considers or has reason to believe that a machinery <u>or related</u> product is not in conformity with the <u>applicable</u> essential health and safety requirements set out in Annex III, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the machinery <u>or related product presents a risk</u><del>product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment,</del> the importer shall inform the</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>surveillance authorities to that effect.</p> <p>3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and the email address at which they can be contacted on the machinery product or, where that is not possible, on its packaging or in a document accompanying the machinery product. The contact details shall be in a language easily understood by end-users and market surveillance authorities.</p> <p>4. Importers shall ensure that the machinery product is accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users, as</p>	<p>manufacturer and the market surveillance authorities to that effect.</p> <p>3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and, <u>if available, a digital contact</u> <del>the email address</del> at which they can be contacted on the machinery <u>or related</u> product or, where that is not possible, on its packaging or in a document accompanying the machinery <u>or related</u> product. The contact details shall be in a language easily understood by <del>end</del>-users and market surveillance authorities.</p> <p>4. Importers shall ensure that the machinery <u>or related</u> product is accompanied by the instructions and information set out in <del>section 1.7 of</del> Annex III. <u>The importer shall ensure that the instructions in paper format</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	determined by the Member State concerned.	<p><u>can be provided to the user in accordance with article 10.7.</u></p> <p><u>In the case of a machinery or related product intended for use by non-professional operators users or which can, under reasonably foreseeable conditions, be used by non-professional operators users even if not intended for them, the importer shall ensure that such product is accompanied by the safety information in paper format that are essential for putting the machinery or related product into service and for using it in a safe way.</u></p> <p><u>The instructions set out in Annex III shall be in a language which can be easily understood by <del>end</del>-users, as determined by the Member State concerned and shall be clear, understandable, intelligible and legible.</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>5. Importers shall ensure that, while the machinery product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements set out in Annex III.</p> <p>6. When deemed appropriate with regard to 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 product, importers shall carry out sample testing of machinery products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery products and machinery products recalls, and shall keep distributors informed of any such monitoring.</p>	<p>5. Importers shall ensure that, while the machinery <u>or related</u> product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements set out in Annex III.</p> <p>6. When deemed appropriate with regard to the risks <u>presented by a machinery or related product, importers shall, in order to protect</u> <del>to the</del> health and safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment, <del>presented by a machinery product, importers shall</del> carry out sample testing of machinery <u>or related</u> products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery <u>or related</u> products</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>7. Importers who consider or have reason to believe that a machinery product, which they have placed on the market, is not in conformity with the essential health and safety requirements set out in Annex III shall immediately take the corrective measures necessary to bring that machinery product into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the machinery product poses 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</p>	<p>and machinery <u>or related</u> products recalls, and shall keep distributors informed of any such monitoring.</p> <p>7. Importers who consider or have reason to believe that a machinery <u>or related</u> product, which they have placed on the market, is not in conformity with <u>this Regulation</u><del>the essential health and safety requirements set out in Annex III</del> shall immediately take the corrective <u>actions</u><del>measures</del> necessary to bring that machinery <u>or related</u> product into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the machinery <u>or related product presents a risk</u><del>product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment,</del> importers shall immediately</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>machinery product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.</p> <p>8. Importers shall, for ten years after the machinery 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 can be made available to those authorities. Where relevant, the source code or programmed logic included in the technical documentation shall be made available upon a reasoned request from competent national authorities provided</p>	<p>inform the competent national authorities of the Member States in which they made the machinery <u>or related</u> product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective <u>actions</u><del>measures</del> taken.</p> <p>8. Importers shall, for ten years after the machinery <u>or related</u> 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 <u>set out in Part A of Annex IV can be made available to those authorities upon request.</u> <del>can be made available to those authorities. Where relevant, the source code or programmed logic included in the technical documentation shall be made</del></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>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>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 product with the essential health and safety requirements set out in Annex III in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks to the health and safety of</p>	<p><del>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.</del></p> <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 <u>or related products with this Regulation</u><del>product with the essential health and safety requirements set out in Annex III</del> in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	persons and, where appropriate, domestic animals and property and, where applicable, the environment posed by a machinery product, which they have placed on the market.	<del>actions</del> <del>measures</del> taken to eliminate the risks <u>presented to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment posed by a machinery or related products</u> <del>product</del> , which they have placed on the market.	

1. Here, as in other places, the MPR proposals follow the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products".

2. Currently in the MD, importers are treated as manufacturers, if the manufacturer "did not exist" (e.g. if the market surveillance could not get a hold of them).

In the MPR there are concrete requirements on all importers.

3. Persons who import for their own use are not "Importers".

Such persons are also not manufacturers or distributors. Thus importing for own use is not covered by the MPR.

4. For "instructions for non-professional users" see Article 10 7.

5. For problems of Article 12 8. vs. Article 12 9. (ten years and forever) see Article 10 3. [87] / 10a 3. [97] vs. Article 10 10. [94] / 10a 10. [104]

*[107] Obligations of importers of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions		<u>Obligations of importers of partly completed machinery</u>	
Article 2 i		<u>Article 12a</u>	
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><u>1. Importers shall place only compliant partly completed machinery on the market.</u></p> <p><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></p> <p><u>Where an importer considers or has reason to believe that a partly completed machinery is</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>not in conformity the relevant essential health and safety requirements set out in Annex III, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the partly completed machinery presents a risk as regards the e relevant essential health and safety requirements , the importer shall inform the manufacturer and the market surveillance authorities to that effect.</u></p> <p><u>3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and, if available, a 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</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>the person who incorporates the partly completed machinery and market surveillance authorities.</u></p> <p><u>4. Importers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Annex X. The importer shall ensure that the assembly instructions in paper format can be provided to the person who incorporates the partly completed machinery in accordance with article 10a.7</u></p> <p><u>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.</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>5. Importers shall ensure that partly completed machinery, while it is under their responsibility, storage or transport conditions do not jeopardise its conformity with the relevant essential health and safety requirements set out in Annex III.</u></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, importers shall immediately inform the competent national authorities of the Member States in which they made the partly</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>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><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.</u></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 partly completed machinery</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>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>	

See comments on Article 12 [106]

*[108] Obligations of distributors of machinery and related product*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Obligations of distributors	Obligations of distributors <u>of machinery and related product</u>	
	Article 13	Article 13	
	<p>1. When making a machinery product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.</p> <p>2. Before making a machinery product available on the market, distributors shall verify that:</p> <p>(a) the machinery product bears the CE marking;</p> <p>(b) the machinery product is accompanied by the required documents and by the instructions and information set out in section 1.7 of Annex III in a language which can be easily</p>	<p>1. When making a machinery <u>or related</u> product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.</p> <p>2. Before making a machinery <u>or related</u> product available on the market, distributors shall verify that:</p> <p>(a) the machinery <u>or related</u> product bears the CE marking;</p> <p>(b) the machinery <u>or related</u> product is accompanied by the <u>EU declaration of conformity set out in Part A of Annex V</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>understood by end-users in the Member State in which the machinery product is to be made available on the market;</p>	<p><u>(ba) The machinery or related product is accompanied <del>required documents and</del> by the instructions and information set out in <del>section 1.7 of</del> Annex III, and that they are in a language which can be easily understood by <del>end-users</del> as determined <del>by</del> the Member State in which the machinery or related product is to be made available on the market. <u>The distributor shall ensure that the instructions in paper format can be provided to the user in accordance with article 10.7.</u></u></p> <p><u>In the case of a machinery or related product intended for use by non- professional operators users or which can, under reasonably foreseeable conditions, be used by non-professional operators users even if not intended for them, the distributor shall ensure that such product is accompanied by the safety information in</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>(c) the manufacturer and the importer have complied with the requirements set out in Article 10(5) and (6) and Article 12(3) respectively.</p> <p>3. Where a distributor considers or has reason to believe that a machinery product is not in conformity with the essential health and safety requirements set out in Annex III, the distributor shall not make the machinery product available on the market until it has been brought into conformity. Furthermore, where the machinery product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment,</p>	<p><u>paper format that are essential for putting the machinery or related product into service and for using it in a safe way.</u></p> <p>(c) the manufacturer and the importer have complied with the requirements set out in Article 10(5) and (6) and Article 12(3) respectively.</p> <p>3. Where a distributor considers or has reason to believe that a machinery <u>or related</u> product is not in conformity with the essential health and safety requirements set out in Annex III, the distributor shall not make the machinery <u>or related</u> product available on the market until it has been brought into conformity. Furthermore, where the machinery <u>or related</u> product <u>presents</u><del>poses</del> a risk <del>to the health and safety of persons and, where appropriate, domestic animals</del></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>the distributor shall inform the manufacturer and the market surveillance authorities to that effect.</p> <p>4. Distributors shall ensure that, while a machinery product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements set out in Annex III.</p> <p>5. Distributors who consider or have reason to believe that a machinery product, which they have made available on the market, is not in conformity with the essential health and safety requirements set out in Annex III shall make sure that the corrective measures necessary to bring that</p>	<p><del>and property and, where applicable, the environment,</del> the distributor shall inform the manufacturer <u>or the importer to that effect as well as</u> <del>and</del> the market surveillance authorities <del>to that effect.</del></p> <p>4. Distributors shall ensure that, while a machinery <u>or related</u> product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements set out in Annex III.</p> <p>5. Distributors who consider or have reason to believe that a machinery <u>or related</u> product, which they have made available on the market, is not in conformity with <u>this Regulation</u> <del>the essential health and safety requirements set out in Annex III</del> shall make sure that the corrective</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>machinery product into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the machinery product poses 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 product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.</p> <p>6. Distributors shall, further to a reasoned request from a competent national authority,</p>	<p><u>actions</u><del>measures</del> necessary to bring that machinery <u>or related</u> product into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the machinery <u>or related product presents a risk</u><del>product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment,</del> distributors shall immediately inform the competent national authorities of the Member States in which they have made the machinery <u>or related</u> product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective <u>actions</u><del>measures</del> taken.</p> <p>6. Distributors shall, further to a reasoned request from a competent national authority,</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery product with the essential health and safety requirements set out in Annex III in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, posed by a machinery product, which they have made available on the market.</p>	<p>provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery <u>or related</u> product. <del>with the essential health and safety requirements set out in Annex III in a language that can be easily understood by that authority.</del> They shall cooperate with that authority, at its request, on any <u>actions</u><del>measures</del> taken to eliminate the risks <u>presented</u><del>to</del> <del>the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment,</del> <del>posed</del> by a machinery <u>or related</u> product, which they have made available on the market.</p>	

1. Here, as in other places, the MPR follows the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products" and also covers this economic operator. This defines requirements for machinery products for the entire retail chain.

2. The distributors were previously not covered by the MD.

The Regulation on market surveillance defines the "distributor" but excludes him from any obligations in regards to its Article 4.

3. For "instructions for non-professional users" see Article 10 7.

4. In Article 13 6. the "problem" exists, that also distributors must keep the Technical Documentation of the product forever. (see Article 10 10. [94] and other)

*[109] Obligations of distributors of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Obligations of distributors of partly completed machinery</u>	
		<u>Article 13a</u>	
		<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> <p><u>2. Before making a partly completed machinery available on the market, distributors shall verify that:</u></p> <p><u>(a) the partly completed machinery is accompanied by the EU declaration of incorporation set out in part B of Annex V</u></p> <p><u>(aa) the partly completed machinery is accompanied by the assembly instructions set</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>out in Annex X, and that they are in a language which can be easily understood by the person who incorporates the partly completed machinery as determined by the Member State in which the machinery or related product is to be made available on the market. The distributor shall ensure that the assembly instructions in paper format can be provided to the person who incorporates the partly completed machinery in accordance with article 10a.7</u></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> <p><u>3. Where a distributor considers or has reason to believe that a partly completed machinery is not in conformity with the e relevant essential health and safety requirements</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>set out in Annex III, 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> <p><u>4. Distributors shall ensure that, while a partly completed machinery is under their responsibility, storage or transport conditions do not jeopardise its conformity with the relevant essential health and safety requirements set out in Annex III.</u></p> <p><u>5. Distributors who consider or have reason to believe that a partly completed</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>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><u>6. Distributors shall, further to a reasoned request from a competent national authority,</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the partly completed machinery. 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 made available on the market.</u></p>	

See Article 13 [108]

*[110] Cases in which obligations of manufacturers apply to importers and distributors*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Cases in which obligations of manufacturers apply to importers and distributors	Cases in which obligations of manufacturers apply to importers and distributors	
Article 2 i	Article 14	Article 14	
(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 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	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 where that importer or distributor places a machinery product on the market under his or her name or trademark or carries out a substantial modification of a machinery product that has already been placed on the market or put into service.	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 <u>and 10a</u> where that importer or distributor places a <del>machinery</del> -product <u>subject to this Regulation</u> on the market under his or her name or trademark or <del>modifies</del> <u>carries out</u> a <del>substantial modification of a machinery</del> -product <del>that has</del> -already <del>been</del> -placed on the market <u>in such a way that compliance with the</u>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Directive shall be considered a manufacturer;		<u>applicable requirements may be affected</u> <del>or put into service.</del>	

Here, as in other places, the MPR follows the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products", see here Article R 10:

- It has always been the case that the person who puts their trademark / name on a product becomes the manufacturer.
- This corresponds to the definition in Article 3 (17) [48].

The Commission's and the Council's proposal are fundamentally different.

- The Commission makes no difference between importer, distributor and other persons (see Article 15 [111]). All are subject to the "*substantial modification*" defined in Article 3 16 [47]
- The Council puts a much higher burden on importers and distributors. While its definition of "substantial modification" is easier to avoid (and much more practical), it no longer applies to importers and distributors. They need to regard the product as new, if it is modified "*in such a way that compliance with the applicable requirements may be affected*".

The Council's proposal is much stricter than any other requirement given in current national papers or the Blue Guide before. Already the chance that the EHSR "*may be affected*" leads to a new product which has to follow all corresponding requirements, i.g. a new EU declaration.

This also becomes a problem, if a product was modified, but not "*substantially modified*" in regard to Article 15, and is later sold. The distributor would then need to consider Article 14 instead and re-certify the product.

*[111] Other cases in which obligations of manufacturers apply*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Other cases in which obligations of manufacturers apply	Other cases in which obligations of manufacturers apply	
	Article 15	Article 15	
	A natural or legal person, other than the manufacturer, the importer or the distributor, that carries out a substantial modification of the machinery 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 the part of the machinery product that is affected by the modification or, if the substantial modification has an impact on the safety of the machinery product as a whole, for the entire machinery product.	A natural or legal person, <del>other than the manufacturer, the importer or the distributor,</del> that carries out a substantial modification of <del>a</del> <u>the</u> machinery <u>or related</u> 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 <u>that</u> <del>the part of the machinery</del> <u>or related</u> product <del>that is affected by the modification</del> or, if the substantial modification has <u>only</u> an impact on the safety of <u>a part of an assembly of the machinery</u> <del>product as a whole,</del> for the <u>affected</u> <del>entire</del>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>machinery of this assembly as demonstrated in the risk assessment.</u></p> <p><u>The person who carries out the substantial modification shall in particular and without prejudice of the 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></p> <p><u>A natural person 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</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>obligations of the manufacturer set out in Article 10.</u>	

1. The question of "*substantial modification*" has so far only been interpreted in the Blue Guide and is part of national specifications. Therefore, covering this in the European law is important.

2. Article 15 covers any person other than an importer or distributor.

Since importer and distributor cover any person possible that make a product subject to MPR available on the market, this article only covers persons that do not give this product away.

If at any future point in time the product is made available on the market, Article 14 applies.

3. Due to 1. this only affects "modifiers" of machinery or related product for own use.

4. The Commission's and the Council's proposal, while at the first glance sounding similar, have huge differences.

- In the Commission's proposal, the "*substantial modification*" can be reduced to a small part of the product that was changed. "*Machinery product*" also contains PCM and thus, any "*substantial modification*" could be contained to a PCM.
- In the Council's proposal, the reduction of a "*substantial modification*" to only certain PCM is not possible. Also it can not be reduced, to a modified "*safety device*" or other "*related products*" which have already been integrated into an assembly. Always the whole machinery needs to be reassessed.
- The reduction of a "*substantial modification*" in an assembly of machinery to only one machinery as part of the assembly is theory. In praxis most assemblies of machinery includes only PCM and no machinery.

5. Non professional users (consumers) as "natural persons" are not in the scope of the Commission's proposed Art. 14 and 15:

- If non professional supply the product for distribution or use, they do not do this as part of a "commercial activity". Thus they do not make this product available, as defined in Article 3 (11) [38].
- If they only use the product themselves, they do put it into service according to Article 3 (13) [40], but the last paragraph of Article 15 states that it does not apply to them.

6. According to the Commission's proposal, any person can modify any product subject to MPR without regard, as long as it is their property and they are the only ones using it. Never the less, other people may still be subjected to the risks of said product.

- A lot of excavator controllers are single person companies (at least in Germany, due to tax and insurance) who are hired on construction sites along with their personal excavator. If such an excavator is then substantially modified (under the guide of said controller) the MPR is not to be considered. The only laws to apply in this case are the work safety regulations, where the other companies on site need to consider the risks from this excavator.
- It will be interesting to discuss the last paragraph, if a person only plans out the change and then has other persons helping them carry it out. Or if even the planning is outsourced...

7. If natural persons which are professionals make a modified product available on the market, they do this as part of a "commercial activity" and therefore are distributor. Thus for them Article 14 [105] applies.

*[112] Identification of economic operators*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Identification of economic operators	Identification of economic operators	
	Article 16	Article 16	
	<p>1. Economic operators shall, on request, identify the following to the market surveillance authorities:</p> <p>(a) any economic operator who has supplied them with a machinery product;</p> <p>(b) any economic operator to whom they have supplied a machinery product.</p> <p>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 machinery product and for ten years after</p>	<p>1. Economic operators shall, on request, identify the following to the market surveillance authorities:</p> <p>(a) any economic operator who has supplied them with a <del>machinery</del> product <u>subject to this Regulation</u>;</p> <p>(b) any economic operator to whom they have supplied a <del>machinery</del> product <u>subject to this Regulation</u>.</p> <p>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 <del>machinery</del> product <u>subject to this</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	they have supplied the machinery product.	<u>Regulation</u> and for ten years after they have supplied the <del>machinery</del> product <u>subject to this Regulation</u> .	

1. Here, as in other places, the MPR proposals follow the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products", see here Article R 7.

2. The suppliers of all products must be identifiable for ten years.

3. All customers who are economic operators must be identifiable for ten years.

While the point 2 should already be established in most businesses, point 3 will create problems.

How to do this in a cash business (e.g. hardware store) when some customers are economic operators? An electrician, buying a drive system for a garage door in a hardware store is per definition a "distributor". If he pays in cash, how will the store track him?

Will we get "not for resale" stickers on products similar to ice cream packages from the supermarket?

*[113] Presumption of conformity of products subject to this Regulation*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Presumption of conformity and harmonised standards	Presumption of conformity of machinery products	Presumption of conformity of <del>machinery</del> products <u>subject to this Regulation</u>	
Article 7 2	Article 17 1	Article 17 1	
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.	1. A machinery product 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.	1. A <del>machinery</del> product <u>subject to this Regulation</u> 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.	

1. Now, also a PCM which is in conformity with harmonised standards shall be presumed to be in conformity with the covered essential health and safety requirements. The focus of the MD to this point is only machinery.

2. New is a clarification that also partly followed standards can give presumption of conformity for the applied parts. This has already been handled as such in praxis.

**[114] Presumption of conformity of products subject to this Regulation**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Definitions	Presumption of conformity of machinery products	Presumption of conformity of <del>machinery</del> products <u>subject to this Regulation</u>	
Article 2 I	Article 17 2	Article 17 2	
(l) '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	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.	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.	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
provision of information in the field of technical standards and regulations and of rules on Information Society services			

no impact but superfluous

Article 10(1) of Regulation (EU) No 1025/2012 is applicable on its own accord.

*[115] Presumption of conformity of products subject to this Regulation*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Presumption of conformity of machinery products	Presumption of conformity of <del>machinery</del> products <u>subject to this Regulation</u>	Presumption of conformity of machinery products
	Article 17 3	Article 17 3	Article 17 3 subparagraph 2
	<p>3. The Commission is empowered to adopt implementing acts establishing technical specifications for the essential health and safety requirements set out in Annex III where the following conditions have been fulfilled:</p> <p>(a) no reference to harmonised standards covering the relevant essential health and safety requirements is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;</p>	<p>3. The Commission is empowered to adopt implementing acts establishing <u>common technical</u> specifications <u>to cover</u> <del>for</del> the essential health and safety requirements set out in Annex III where the following conditions have been fulfilled:</p> <p>(a) no reference to harmonised standards covering the relevant essential health and safety requirements <u>set out in Annex III</u> is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements and there are undue delays in the standardisation procedure or the request has not been accepted by any of the European standardisation organisations.</p>	<p>(b) the Commission has requested, <u>pursuant to Article 10(1) of Regulation 1025/2012,</u> one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements <u>set out in Annex III</u> <del>and there are undue delays in the standardisation procedure or the request has not been accepted by any of the European standardisation organisations.</del></p> <p>(c) <u>the request referred to in point (b) has not been accepted by any of the European standardisation organisations or the European standards 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</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).	<p><u>deliverables does not comply with the request.</u></p> <p>Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).</p>	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3). <u>The Commission shall also consult relevant stakeholders, including social partners in this context.</u>

If the standardization organizations do not carry out a standardization order in good time or the EU-Commission is not satisfied with a result from a standardization organizations, the EU Commission can issue appropriate common specifications itself. The Member States must be involved in this. This shall give the EU leverage against the standardization organizations.

The Council bases its point (c) on an existing Regulation and deletes the vague "*and there are undue delays in the standardisation procedure or the request has not been accepted by any of the European standardisation organisations*".

The Parliament proposes an addition to consult third parties. In praxis this will be necessary regardless, since the Commission is no expert on writing standards. Putting it in the law will increase the burocratic burden of proving and archiving the process. Also "*consult*" means only to ask and not to regard.

Such "*common specifications*" are not listed in the "*list of harmonized standards*" in the official journal, but for each there exists an "*implementing act*" which will be listed in the official journal by itself.

*[116] Presumption of conformity of products subject to this Regulation*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Presumption of conformity of products subject to this Regulation</u>	
		<u>Article 17 3a</u>	
		<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>	

This is not a provision to obtain the opinion of the committee. It only needs to be informed.

*[117] Presumption of conformity of products subject to this Regulation*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Presumption of conformity of products subject to this Regulation</u>	
		<u>Article 17 3b</u>	
		<u>3b. In the early preparation of the draft implementing act establishing <del>the</del> the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectorial Union law. Based on that consultation, the Commission shall prepare the draft implementing act.</u>	

Regularly, the same experts who draft a standard will have to be consulted to draft this "common specification". But the Commission is free to ask and possibly pay other experts, which at the time are not involved in the standardisation process.

**[118] Presumption of conformity of products subject to this Regulation**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Presumption of conformity of machinery products	Presumption of conformity of <del>machinery</del> products <u>subject to this Regulation</u>	
	Article 17 4	Article 17 4	
	4. A machinery product which is in conformity with the technical specifications 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 technical specifications or parts thereof.	4. A <del>machinery</del> product <u>subject to this Regulation</u> which is in conformity with the <del>common technical</del> specifications <u>established by one or more implementing acts referred to in paragraph 3</u> 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 <del>common technical</del> specifications or parts thereof.	

Like harmonized standards, the common specifications of the EU Commission trigger the presumption of conformity. The difference in wording is due to the Council's proposed definition of "*common specifications*".

**[119] Presumption of conformity of products subject to this Regulation**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Presumption of conformity of products subject to this Regulation</u>	
		<u>Article 17 4a</u>	
		<u>4a. When references of a harmonised standard are published in the Official Journal of the European Union, implementing acts referred to in paragraph 3, or parts thereof which cover the same essential health and safety requirements set out in Annex III shall be repealed.</u>	

This process is not automatic. The common specification is still in effect until repealed from the EU-Commission. It has to be repealed through another "*implementing act*" (see [115]).

*[120] Presumption of conformity of products subject to this Regulation*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<u>Presumption of conformity of products subject to this Regulation</u>	
		<u>Article 17 4b</u>	
		<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 inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate, amend the implementing at establishing the common specification in question.</u>	

This process is not analogue to the process concerning standards that do not satisfy the EHSR.

Common specifications cannot be revoked. They can only be amended.

Any amendment happens "*at establishing the common specification in question*". It is not really understandable what is meant here. Does this mean "At the time the common specification was first published"?

*[121] Presumption of conformity of products subject to this Regulation*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Presumption of conformity of machinery products	Presumption of conformity of <del>machinery</del> products <u>subject to this Regulation</u>	
	Article 17 5	Article 17 5	
	5. Machinery 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) 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	5. Machinery <u>and related</u> 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) 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	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	the cybersecurity certificate or statement of conformity or parts thereof.	requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.	

This content is superfluous. It is already covered by Article 8 [83] and is only a clarification here which is not necessary.

*[122] EU declaration of conformity of machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Declarations	EU declaration of conformity	EU declaration of conformity <u>of machinery and related products</u>	
Annex II 1. A.	Article 18	Article 18	
<p>The EC declaration of conformity must contain the following particulars:</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>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>2. The EU declaration of conformity shall have the model structure set out in Annex V, shall contain the elements specified in the relevant modules set out in Annexes VI, VII, VIII and IX and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the machinery product is</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>2. The EU declaration of conformity shall have the model structure set out in <u>part A of Annex V, and</u> shall contain the elements specified in the relevant modules set out in Annexes VI, <del>VII, VIII, and IX</del>, <u>IXa</u> and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the machinery <u>or</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	<p>placed on the market or is made available on the market.</p> <p>3. Where a machinery 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.</p> <p>4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the machinery product with the requirements laid down in this Regulation.</p>	<p><u>related</u> product is placed on the market, <del>or</del> is made available on the market <u>or put into service</u>.</p> <p>3. Where a machinery <u>or related</u> 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.</p> <p>4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the machinery <u>or related</u> product with the requirements laid down in this Regulation.</p>	

Here, as in other places, the MPR follows the NLF, i.e. the EC Decision No 768/2008/EC "*common framework for the marketing of products*", see Article 5 and R 10 here.

For the declaration of conformity, the main requirements are formulated in the "model structure" of Annex V of the MPR. But in the legal text of Article 18 additional elements are required which thus become content of the DOC:

1. The first point of the proposed Article 18 is currently not a separate part of the required content of the EC Declaration of Conformity in Annex II 1 A of the MD. The statement that the product fulfills Annex III is superfluous, since Annex V No 6 of the MPR requires a confirmation that the machinery fully complies with the MPR and thus also with Annex III.
2. The first point would be better positioned as part of the proposed Annex V.
3. The second point requires additional elements to be included in respect to Annexes VI, VII, VIII and IX independently of there is a Notified Body involved or not. No such additional elements are described in these annexes.

The second point also requires the EU Declaration of Conformity to be continuously updated. However, an EU Declaration of Conformity only applies to the condition of the product at the time it was placed on the market. If at a later date, the state of the art changes, this does not concern products already placed on the market. So no update is legally possible.

An update is only possible for series manufacturers. But in such cases, the old series ends and a new series with a new DOC begins.

*[123] EU declaration of incorporation of partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Declarations		<u>EU declaration of incorporation of partly completed machinery</u>	
Annex II B		<u>Article 18a</u>	
<p>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.</p> <p>The declaration of incorporation must contain the following particulars:</p> <p>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</p>		<p><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></p> <p><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 completed machinery is placed on the market or is made available on the market.</u></p> <p><u>3. Where a partly completed machinery is subject to more than one Union act</u></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the Official Journal of the European Union;</p>		<p><u>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></p> <p><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></p>	

The "*declaration of incorporation*" has become an "EU Declaration of Incorporation"

On "*language*" see Article 10 5. and 6.

The manufacturer "*shall state that the fulfilment of the applicable essential health and safety requirements [...] has been demonstrated*". In Article 10 a [95] "*applicable*" was changed to "*relevant*". There should be the same wording in the MPR for the same facts.

Even as the manufacturer has to apply the "*relevant essential health and safety requirements*", that means up to certain interfaces, he - according to Annex V B - still has to "*declare which essential requirements [...] are applied and fulfilled.*"

**[124] General principles of the CE marking**

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
CE marking	General principles of the CE marking	General principles of the CE marking	
Article 16	Article 19	Article 19	
<p>1. The CE conformity marking shall consist of the initials 'CE' as shown in Annex III.</p> <p>2. The CE marking shall be affixed to the machinery visibly, legibly and indelibly in accordance with Annex III.</p> <p>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 prohibited. Any other marking may be affixed to the machinery provided that the visibility, legibility and meaning</p>	<p>The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.</p>	<p>The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.</p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
of the CE marking is not thereby impaired.			

Here, as in other places, the MPR follows the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products", see Article R 11 here.

Requirements on the CE marking are now outsourced to the appropriate Regulation.

*[125] Rules for affixing the CE marking to machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
CE marking	Rules for affixing the CE marking	Rules for affixing the CE marking <u>to machinery and related products</u>	
Article 16 2	Article 20 1	Article 20 1	
2. The CE marking shall be affixed to the machinery visibly, legibly and indelibly in accordance with Annex III.	1. The CE marking shall be affixed visibly, legibly and indelibly to the machinery product. Where that is not possible or not warranted on account of the nature of the machinery product, it shall be affixed to the packaging and to the documents accompanying the machinery product.	1. The CE marking shall be affixed visibly, legibly and indelibly to the machinery <u>or related</u> product. Where that is not possible or not warranted on account of the nature of the machinery <u>or related</u> product, it shall be affixed to the packaging and to the documents accompanying the machinery <u>or related</u> product.	

Here, as in other places, the MPR follows the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products", see Article R 12 here.

It is now allowed to have CE-marking on the package only, if that is "not possible" on the product.

*[126] Rules for affixing the CE marking to machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Placing on the market and putting into service	Rules for affixing the CE marking	Rules for affixing the CE marking <u>to machinery and related products</u>	
Article 5 1f	Article 20 2	Article 20 2	
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.	2. The CE marking shall be affixed before the machinery product is placed on the market.	2. The CE marking shall be affixed before the machinery <u>or related</u> product is placed on the market <u>or put into service</u> .	

no change

This Requirement is already covered by the requirement of Article 10 2 [87].

The Commission's proposal forgot the "machinery for own use". The Council remedied this.

*[127] Rules for affixing the CE marking to machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
CE marking	Rules for affixing the CE marking	Rules for affixing the CE marking <u>to machinery and related products</u>	
Annex III	Article 20 3	Article 20 3	
Where the full quality assurance procedure referred to in Article 12(3)(c) and 12(4)(b) has been applied, the CE marking must be followed by the identification number of the notified body.	3. For a machinery product in the conformity assessment of which a notified body participates in accordance with Annex IX, the CE marking shall be followed by the identification number of that notified body.  The identification number of the notified body shall be affixed by the body itself or,	3. <u>Where</u> <del>For a machinery product in</del> the conformity <del>assessment</del> <u>of machinery or related products is assessed</u> <del>which a notified body participates</del> in accordance with <u>the conformity procedure † referred to in Article 21 (2) points a) and b) and c) and in article 21 (2a) points b) and c) and d)</u> <del>Annex IX</del> , the CE marking shall be followed by the identification number of <u>the</u> <del>that</del> notified body <u>involved in that procedure</u> .  The identification number of the notified body shall be affixed by the body itself or,	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	under its instructions, by the manufacturer or the manufacturer's authorised representative.	under its instructions, by the manufacturer or the manufacturer's authorised representative.	

The manufacturer is no longer allowed to affix the number of the notified body on their own.

*[128] Rules for affixing the CE marking to machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
CE marking	Rules for affixing the CE marking	Rules for affixing the CE marking <u>to machinery and related products</u>	
Annex III	Article 20 4	Article 20 4	
[...] Where the full quality assurance procedure referred to in Article 12(3)(c) and 12(4)(b) has been applied, the CE marking must be followed by the identification number of the notified body.	4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or other marking indicating a special risk or use.	4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or <u>any</u> other marking indicating a special risk or use.	

Here, as in other places, the MPR follows the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products", see Article R 12 here.

For machinery and related products a new label is required, which indicates a special risk or a special use. This should be located next to the CE marking.

This can be useful in other EU-Regulations but not in the MPR. No such special risk is defined here. Thus this part should be omitted from the MPR, since it will lead to confusions.

***[129] Rules for affixing the CE marking to machinery and related products***

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Non-conformity of marking	Rules for affixing the CE marking	Rules for affixing the CE marking <u>to machinery and related products</u>	
Article 17	Article 20 5	Article 20 5	
<p>1. Member States shall consider the following marking not to conform:</p> <p>(a) the affixing of the CE marking pursuant to this Directive on products not covered by this Directive;</p> <p>(b) the absence of the CE marking and/or the absence of the EC declaration of conformity for machinery;</p> <p>(c) the affixing on machinery of a marking, other than the CE marking, which is prohibited under Article 16(3).</p>	<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>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>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>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.</p> <p>3. Where non-conformity persists, the Member State shall take all appropriate measures to restrict or prohibit the 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>			

Here, as in other places, the MPR follows the NLF, i.e. the EC Decision No 768/2008/EC "common framework for the marketing of products", see Article R 12 here.

The old specific demands are given here as a more general demand on member states.

*[130] Conformity assessment procedures for machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Procedures for assessing the conformity of machinery	Conformity assessment procedures for machinery products except partly completed machinery	Conformity assessment procedures for machinery <u>and related</u> products <del>except partly completed machinery</del>	
Article 12 1	Article 21 1	Article 21 1	
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.	1. In order to certify the conformity of a machinery product with this Regulation, the manufacturer or its authorised representative and the person who has carried out a substantial modification to the machinery product, shall apply one of the procedures for assessment of conformity referred to in paragraphs 2 and 3.	1. <del>The</del> <u>In order to certify the conformity of a machinery product with this Regulation,</u> <del>the</del> manufacturer <u>of machinery</u> or <u>a related product</u> <del>its authorised representative and the person who has carried out a substantial modification to the machinery product,</del> shall apply one of the procedures for assessment of conformity referred to in paragraphs 2, <u>2a</u> and 3.	

The Council's proposal is closer to the original text. While having the same effect as the Commission's proposal, it omits unnecessary text.

Since "*the person who has carried out a substantial modification to the machinery product*" is regarded as its manufacturer, it can be omitted without any effect.

*[131] Conformity assessment procedures for machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Procedures for assessing the conformity of machinery	Conformity assessment procedures for machinery products except partly completed machinery	Conformity assessment procedures for machinery <u>and related</u> products <del>except partly completed machinery</del>	
Article 12 4	Article 21 2	Article 21 2	
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:	2. Where the machinery product is a high-risk machinery product listed in Annex I, the manufacturer or the manufacturer's authorised representative and the person who has carried out a substantial modification to the machinery product shall apply one of the following procedures:  (a) EU type-examination procedure (module B) provided for in Annex VII, followed by conformity to type based on internal production control	2. Where the machinery <u>or related</u> product is <del>a high-risk machinery product</del> listed in Annex I <u>part A</u> , the manufacturer <del>or the manufacturer's authorised representative and the person who has carried out a substantial modification to the machinery product</del> shall apply one of the following procedures:  (a) EU type-examination procedure (module B) <u>set out</u> <del>provided for</del> in Annex VII, followed by conformity to type based on internal production	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>(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;</p> <p>(b) the full quality assurance procedure provided for in Annex X.</p>	<p>(module C) set out in Annex VIII;</p> <p>(b) Conformity based on full quality assurance (module H) set out in Annex IX.</p>	<p>control (module C) set out in Annex VIII;</p> <p>(b) Conformity based on full quality assurance (module H) set out in Annex IX;</p> <p><u>(c) Conformity based on unit verification (module G) set out in Annex IXa.</u></p>	

The Council's proposal again omits unnecessary text (see article 21 1 [130]). Additionally, the Council restricts the mandatory involvement of notified bodies to Annex I Part A products. And it extends the options for such products to Annex IXa.

*[132] Conformity assessment procedures for machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Procedures for assessing the conformity of machinery		<u>Conformity assessment procedures for machinery and related products</u>	
Article 12 3		<u>Article 21 2a</u>	
<p>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:</p> <p>(a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII;</p>		<p><u>2a. Where the machinery or related product is listed in Annex I part B the manufacturer shall apply one of the following procedures:</u></p> <p><u>(a) Conformity with the internal production control procedure (module A) set out in Annex VI;</u></p> <p><u>(b) 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></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
<p>(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;</p> <p>(c) the full quality assurance procedure provided for in Annex X.</p>		<p><u>(c) Conformity based on full quality assurance (module H) set out in Annex IX;</u></p> <p><u>(d) Conformity based on unit verification (module G) set out in Annex IXa.</u></p> <p><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></p>	

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
		<p><u>Where the machinery or related product is listed in Annex I part B</u></p> <p><u>and has not been manufactured in accordance with the harmonized standards or common specifications specific for that category of machinery or related product</u></p> <p><u>and provided that those standards covering all the relevant essential health and safety requirements,</u></p> <p><u>the manufacturer shall apply one of the procedures referred to in paragraph 2.a(b),(c) or(d)</u></p>	

Most products in Annex I are currently residing in Part B of the MPR. Those products are technically treated the same way as Annex IV machinery of the MD.

However, the way the Council has proposed this Article is unnecessarily confusing and (thus) not in line with the former ruling of the MD:

If the product is part of Annex I B (MD's Annex IV) according to the MD, the manufacturer can use the "*internal production control procedure (module A)*", if the product is "*manufactured in accordance with the harmonised standards [...], and provided that those standards cover all of the relevant essential health and safety requirements*" (EHSR).

According to the Council's proposal, module A can not be used if no harmonised standard is used AND provided those standards cover all EHSR. While sounding similar, it is different. The following truth table shows, that a manufacturer is now also allowed to use module A, if not all EHSR are covered by the harmonised standards.

Product in MD Annex IV / MPR Annex I B	manufactured in accordance with the harmonised standards	standards cover all of the EHSR	MD Module A allowed	MPR Module A not allowed	MPR Module A allowed
1	0	0	0	0	1
1	0	1	0	1	0
1	1	0	0	1	0
1	1	1	1	0	1

This case is somewhat covered by Article 5 5. which states that all such products need to be moved to Part A. Theoretically this move from B to A should happen, right when the Regulation takes effect.

*[133] Conformity assessment procedures for machinery and related products*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
Procedures for assessing the conformity of machinery	Conformity assessment procedures for machinery products except partly completed machinery	Conformity assessment procedures for machinery <u>and related</u> products <del>except partly completed machinery</del>	
Article 12 2	Article 21 3	Article 21 3	
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.	3. Where the machinery product is not a high-risk machinery product listed in Annex I, the manufacturer or the manufacturer's authorised representative and the person who has made a substantial modification to the machinery product shall apply the internal production control procedure (module A) set out in Annex VI.	3. Where the machinery <u>or related</u> product is not <del>a high-risk machinery product</del> listed in Annex I, the manufacturer <del>or the manufacturer's authorised representative and the person who has made a substantial modification to the machinery product</del> shall apply the internal production control procedure (module A) set out in Annex VI.	

no change

### *[134] Conformity assessment procedures for machinery products except partly completed machinery*

MD 2006 42 EC	MPR proposal Commission	MPR proposal Council	MPR proposal Parliament
	Conformity assessment procedures for machinery products except partly completed machinery	<del>Conformity assessment procedures for machinery products except partly completed machinery</del>	
	Article 21 4	<del>Article 21 4</del>	
	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 and reduce those fees proportionately to their specific interests and needs.	<del>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 and reduce those fees proportionately to their specific interests and needs.</del>	

This Article was proposed by the Commission and removed in the Council's proposal.

The content still remains in recital (24).

*"Small and medium enterprises"* (SME) are not defined in the law and in statistics different definitions exist.

The Commission's proposal is severely problematic:

As a binding law, notified bodies shall work more cost-effectively for SME. Which would mean that they currently overcharge everyone.

Or big businesses will now have to compensate the costs for SME.

Also there is no fixed rate at which the conformity assessment must be cheaper for smaller businesses.

From a business point of view, if a notified body is fully booked, they should stop working on SME clients and only concentrate on big business clients.

All in all, this law would be at best difficult to enact and at worst counterproductive to its idea of promoting SME.