Machinery Regulation (EU) 2023/1230

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Comparison to the EC Machinery Directive

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Analysis of the Machinery Regulation (EU) 2023/1230 of 06/29/2023

On June 29, 2023, the EU Machinery Regulation (MR) was published in the European Official Journal. A correction was already published on July 4, 2023, which changes the various dates of application of the MRR:

www.2023-1230.eu

Economic operators must apply the regulation from January 20, 2027.

We have summarized some of the major changes to the Machinery Directive 2006/42/EG (MD) in this paper. We present some changes that we believe are important for the industry. This is not an exhaustive list of all changes.

Furthermore, we have compared the text of the MR and MD in the appendix. This allows you to follow the changes directly in the legal text.

Abbreviations:

- MR: Machinery Regulation (EU) 2023/1230
- MD: Machinery Directive 2006/42/EC
- PCM: partly complete machinery
- NLF: New Legislative Framework
- EU-DoC: European Declaration of Conformity

Changes

About 2/3 of all provisions of the new EU Machinery Regulation show changes to the current EC Machinery Directive. Among other things, it is important to expand the target group to include all economic operators, such as distributors.

However, some changes seem more "accidental" and not necessarily intended.

There are no fundamental changes to the safety of machinery, but there are various "clarifications and specifications". A machinery that is safe today according to the Machinery Directive is also safe under the new EU Machinery Regulation.

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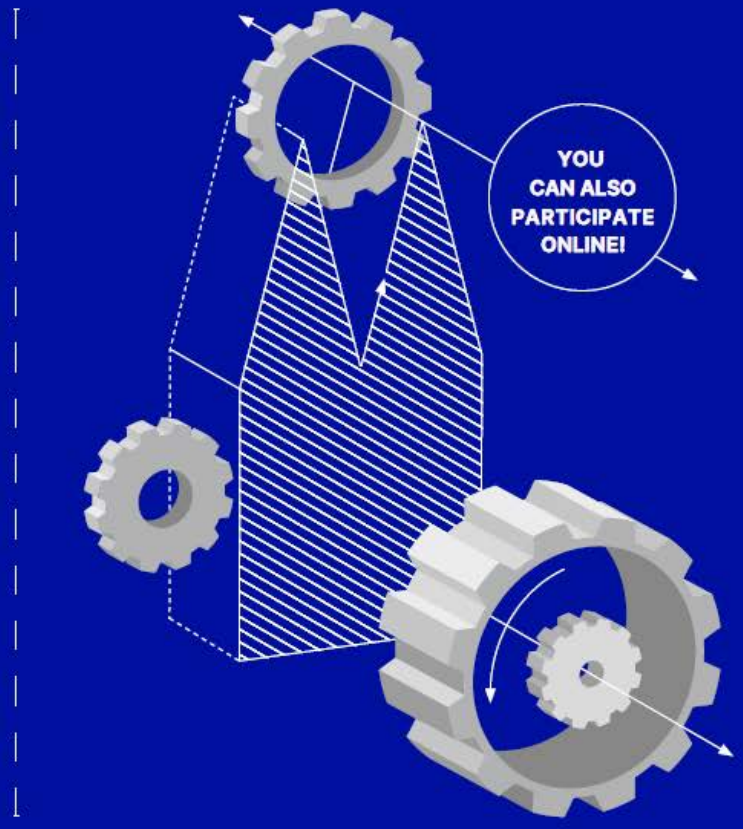
MACHINERY DAYS COLOGNE

The week dedicated to the Machinery Directive:
October, Maritim Hotel Cologne



GERMAN
MACHINERY LAW DAY
Tuesday
–
Compressed knowledge about machine law
–
Lawyer Carsten Laschet
Sozietät Friedrich Graf von Westphalen & Partner

SIMULTANEOUS INTERPRETING IN ENGLISH AND GERMAN

CONFERENCE
MACHINENRY DIRECTIVE
Wednesday, Thursday
–
The conference all about the Machinery Regulation
–
Dipl.-Ing. Hans-J. Ostermann
www.maschinenrichtlinie.de

WORKSHOPS
Friday
– 2 workshops on current topics in the field of Machinery Regulation

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Time of application

Entry into force and application

The MR will enter into force on the twentieth day after its publication in the Official Journal of the European Union, i.e., on July 19, 2023.

However, it cannot yet be applied.

Article 54 of the MR lists the times when which parts of the MR must/may be applied.

Annotation:
According to information from the EU Commission to the authors of this article, the following should apply:
If a date is specified in an article or in a paragraph of an article, this article or the specific paragraph of this article shall apply, notwithstanding what is stipulated in Article 54, from that date. Example of this: Article 6 paragraph 9 is to apply from July 20, 2025.

Examples:

- According to Article 54 c, Article 6 (7) applies from July 19, 2023, i.e., when the Regulation comes into force.
- Articles 6 (2) to (6), (8) and (11) apply according to Article 54 d from July 20, 2024.
- Article 6 (10) contains the date “20. July 2024" and will apply from then onwards according to the EU Commission.
- Article 6 (9) contains the date “20. July 2025” and will apply from then onwards according to the EU Commission.
- The unmentioned Article 6 (1) applies from January 20, 2027.

What applies directly?

From the day it came into effect, July 19, 2023, the following parts of the MR apply directly:

- Article 6 paragraph 7
  Classification of dangerous machinery and related products in Annex I A and B
- Articles 43 to 46
  Union Market Surveillance and Union Safeguard Procedures
- Article 47 paragraph 2
  Power of the Commission to adopt delegated acts
- Article 48
  Assistance to the Commission by a committee
- Article 52
  Transitional provisions for safeguard clause procedures and EC type examination certificates

Manufacturers, importers, distributors

For manufacturers and other economic operators, the MR applies in principle from January 20, 2027. (Article 54, corrected in the European Official Journal L 169/35)

Notified bodies

Articles 26 to 42 applicable to notified bodies must be applied from January 20, 2024. (Article 54 a, corrected in L 169/35)

Since new requirements for the notified bodies are formulated at this point, they must be re-accredited by then to be able to continue testing "Annex IV Products" according to the MD after this date.

Annex I List

From January 20, 2027, products listed in Annex I of the MR may also have to be tested by notified bodies to be allowed to be placed on the market under the MR. For this purpose, the notified bodies must also obtain accreditation for Annex I products according to the MR in good time.

This accreditation can be obtained before this date. It must be noted that the Annex I list of MR can be amended by the Commission in accordance with Article 6 and Article 47 from July 20, 2024 onwards. (Article 54d, corrected in L 169/35)

A delegated act amending the Annex I list of the MR could appear on 20 July 2026, when

the Commission must report on the accident figures of specific machines. (Article 53(3), corrected in L 169/35)

Future changes to the MR

The Commission must publish a report by July 20, 2028 and every four years thereafter, in which the essential health and safety requirements and the conformity assessment procedures for Annex I products are examined.

At this point, the Commission can submit proposals to amend the MR.

Position of the contents of the MR

Article

The items of the MR have been rearranged compared to the MD. Meaningful chapters have been formed so that the articles of a subject area are now coherently arranged.

This simplifies the search for the user.

Annexes

The Annexes have a new sorting.

The legal reason given to us by the Commission is that the numbering of the Annexes must follow the order of reference in the legal text.

Annex I is referred to in Article 6, Annex II in Article 7 and Annex III in Article 8 (but also in the definition in Article 3 No. 14).

Here the Commission could have made it easy for the market and at least brought Article 8 forward. Then Annex I MD would also have been Annex I MR.

However, since Annex XI is referenced in Article 11 (7) before Annex VI in Article 25 (3) and Annex VI in Article 25 (3) is referenced only after Annex VII in Article 25 (2), the order of the Annexes is probably more flexible, then the Commission let us believe. In this respect, the re-sorting of the attachments seems superfluous.

Division of content using the EU-Declaration of Conformity as an example

In the MD it is sometimes difficult to find all the content on a topic. For the EC declaration of conformity, you must look at the topic of instructions, for example, to know that you also must state "original" or "translation of the original".

An attempt was made to implement this more cleanly in the MR. However, this has not been successful in all respects.

For example, almost all the content of the EU-DoC can be found in Annex V Part A. However, the first section of the associated Article 21 requires:

"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."

This content of the EU-DoC is not listed in Annex V and must therefore be supplemented by the manufacturer in his EU-DoC.

In addition, Article 21 (2) requires

"The EU declaration of conformity [...] shall contain the elements specified in the relevant modules set out in Annexes VI, VIII, IX, and X."

But the requirement for naming the model of the machine from Annex VI 4.2. or Annex IX 5.2. is already included in Annex V. The requirement from Annex VIII 3.2. or Appendix X 5.2. to name the product is also not an addition.

Thus Article 21(2) only confuses at this point. What is important, however, is the requirement in the same paragraph:

"The EU declaration of conformity shall have the model structure set out in Annex V, Part A"

What looks like a list in Annex V is therefore a legal requirement for numbering. An addition "*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.*" must therefore be classified under point 10 "*Additional information*".

For Annex V 2. “name and address of the manufacturer” Article 10 (6) applies

"The address shall indicate a single point at which the manufacturer can be contacted."

It is therefore still not possible to only use Annex V to issue a legally compliant EU-DoC. For all other topics, too, one must not rely on all the requirements being summarized in one place.

Scope

Related products

Since there have been problems in the past with the term machinery in the narrow sense (only for products according to MD Article 1 a) and in the broader sense (for all products except PCM), the EU Commission originally wanted to introduce the generic term "machinery product" to simplify the legal text.

However, some states have opposed this due to alleged translation problems, so that the legal text now distinguishes between:

- Machinery
- related products
  and
- partly completed machinery

According to Article 2 (1), "related products" are all other products in the scope, except machinery and partly completed machinery.

Products within the scope of this Regulation

At the same time, the collective term "*products within the scope of this Regulation*" was introduced in Article 2 (1). However, this is not used consistently in the legal text. Instead, all product groups are listed individually at various points.

Confusion from new terms

In many places in the Regulation, the old text "*Machinery*" was supplemented with "*and related products*". In other places this seems to have been forgotten.

For example, the old exception in Article 2 (2) k is unchanged:

“This regulation does not apply to

k) seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;"

Since "*and related products*" was not added (forgotten) here, lifting accessories on these vessels and units are now within the scope of MR.

Partly completed machinery are now in scope even if the end product is not.

The definition of PCM in Article 3 No. 10 has been changed.

Among other things, the last condition in the definition has changed. Article 2 g) of the MD states:

"thereby forming machinery to which this Directive applies"

The MR now states:

"thereby forming machinery"

The red text above has been deleted, which now means that a PCM falls within the scope of the MR, even if the MR does not apply to the end-product.

In the exceptions in Article 2 (2) of the MR only machines and related products are mentioned (see above) and no PCM. Under the MD, the PCMs for these exempt machines and associated products were also exempt because the end-product is not a machinery "*to which this Directive applies*".

According to the new definition of PCM in the MR, this is no longer a factor. PCM are therefore formally in the scope even if the end-product is not. Thus, for the above-mentioned example of seagoing vessels in Article 2 (2) k, their PCM (e.g., the ship's motor) now also fall within the scope of the MR.

Partly completed machinery are formulated much more broadly.

In the MD in Article 2 g, the PCM is defined, among other things, as "*an assembly which is almost machinery*".

In Article 3 No. 10 of the MR, this has now been extended to "*an assembly which is not yet machinery*".

This shifts the boundary of the current interpretation of "components" vs. "partly completed machinery". In the future, many more "components" can be declared as PCMs and the harmonized market can thus be used.

Together with the improved safety of the PCM (see below), the EU internal market will be strengthened.

Machines without software are now also machinery.

The definition of the completed machinery was extended by Article 3 (1) f)

"an assembly as referred to in points (a) to (e) missing only the uploading of the software intended for the specific application foreseen by the manufacturer;"

Recital 19 of the MR clarifies that this also applies if the software "*is the subject of the conformity assessment procedure of the machinery*", i.e., is safety-relevant.

Thus, according to MR, machinery with the CE-mark may be sold where, for example, opening the protective doors does not trigger the switching off of the hazardous movements because the built-in door contacts are not yet queried in the control.

Safety components as spare parts are now more widely excluded.

The exception of the MD in Article 1 (2) a), which only refers to the manufacturer of the original machinery:

"safety components intended to be used as spare parts to replace identical components and supplied by the manufacturer of the original machinery;"

now applies to all manufacturers of products in the scope of the MR. The exception in Article 2 2 (a) now reads:

"safety components that are intended to be used as spare parts to replace identical components and are supplied by the manufacturer of the original machinery, related product or partly completed machinery;"

This means that the manufacturers of the built-in safety components can also supply "spare parts" for old safety components in the future without falling under the MR. This is particularly interesting where the EU type examination has already expired, and the product can no longer be sold according to MR.

The distribution of used products is now in the scope.

In Article 3 No. 21, the MR defines the distributor as:

"any natural or legal person in the supply chain, other *than* the manufacturer or the importer, who makes a product within the scope of this Regulation available on the market"

Making available on the market is defined in Article 3 No. 11 as:

"any supply of a product within the scope of 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"

Also, the "*Obligations of distributors*..." in Articles 15 and 16 only deal with "*making available on the market*" in their section (1).

Recital (10) of the MR states:

"This Regulation should cover products which are new to the Union market when placed on the market, and are either new products made by a manufacturer established in the Union or products, whether new or second-hand, imported from a third country."

This means that all products that are new to the EU market at a certain point in time or that have been imported into the EU from other EU countries fall within the scope of the MR. Once such products are sold by a third party (other than the manufacturer), that third party is to be considered a distributor, regardless of whether the product is new or used.

The distributor only must assess whether the product was state-of-the-art at the time it was "*placed on the market*" (Article 3 12.) or "*put into service*" (Article 3 13.). This will make it easier to trade used products in the EU in the future.

We have put this into more detail in our German paper:
Gebrauchtmaschinenhandel nach der neuen EU-Maschinenverordnung

Products that are imported from non-European countries for use no longer fall within the scope.

The MD manufacturer's "catch all" paragraph in Article 2(i) of the MD was 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;"

Remaining gaps in the regulations of the MR will thus no longer be closed in the future.

For the processing of imports from outside the Union, the "*importer*" has now been defined in Article 3 No. 20:

"any natural or legal person established within the Union who places a product within the scope of this Regulation from a third country on the Union market"

A natural or legal person is an importer if he "*places a product on the Union market*". It follows that according to Article 3 No. 12 the product must be made available. According to Article 3 No. 11, however, this only takes place if a "*supply of a product*" takes place.

However, if a person imports a machine or an associated product from another EU country and then "*puts it into service*" in their own company according to Article 3 13, they do not meet the definition of an "*importer*".

They also do not meet the definition of "*manufacturer*" under Article 3 No. 18 or "*distributor*" under Article 3 No. 21.

This loophole is present in all EU regulations that follow the NLF. The EU Market Surveillance Regulation does not cover such persons either.

However, the gap will still remain closed via MD until January 19, 2027. Until then, the European authorities have time to find a solution if necessary.

One possibility would be to close this gap in the course of adapting national law. However, this would not be in the spirit of a uniform internal market.

Products can be “not substantially modified” but be deemed new if later distributed.

MR now regulates the topic of "*substantial modification*". The standardization of this topic in Europe is urgent.

The definition of the substantial modification in the MR is easy to understand and should lead to a uniform assessment in practice.

However, the MR distinguishes between a "*substantial modification*" by the user, for which Article 18 applies, and a "modification" by an importer or distributor under Article 17.

Distributor, as shown above, are also those who distribute used products. If a user changes his product and finds out that it is not a "*substantial modification*" according to Article 3 No. 16 and therefore Article 18 does not apply, he may continue to use the product without applying the MD again. However, when the used product is handed over to third parties, he must later check this change in his role as distributor to determine whether it is a "modification" within the meaning of Article 17.

Since the bar for "modification" is much lower in Article 17:

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

they, as a distributor may now have to apply the MR to the product that is formally new according to Article 17.

In practice we will have a good definition of “*substantial modification*” for the operator, but only as long as that product never changes hands again.

National Expansion

The national authorities can add their own regulations to the MR.

Article 15 of the MD has been transferred to Article 5 of the MR. However, the wording was (deliberately?) changed by the Commission in its first draft. The text was not corrected in the further course of the negotiations.

Currently Article 15 of the MD states:

"This Directive shall not affect Member States' entitlement to lay down, in due observance of Community law, such requirements as they may deem necessary to ensure that persons, and in particular workers, are protected when using machinery, provided that this does not mean that such machinery is modified in a way not specified in this Directive."

Article 5 of the MR now 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 the modification of machinery or a related product in a way that is not compatible with this Regulation."

The current text of the MD prohibits Member States from imposing additional requirements on top of the MD or reducing requirements of the MD. The new text of the MR only prohibits a reduction in the requirements. Therefore, member states are now free to go beyond the requirements of the MR in their national law.

Conformity assessment

Annex I Part A

The Annex IV list of the MD is now found in Annex I of the MR.

For the products listed in Annex I Part A, MR requires an independent assessment by a notified body. Part B follows the provisions of the MD on Annex IV products.

Part A contains

- Removable mechanical transmission devices including their guards.
- Guards for removable mechanical transmission devices.
- Vehicle servicing lifts.
- Portable cartridge-operated fixing and other impact machinery.
- Safety components with self-improving AI
- The self-improving AI of machines that use AI for safety

Amendment to Annex I, before January 20, 2027

In the future, the Commission will have the option and the obligation to reassess the division between Annex I Part A and Part B and, if necessary, to change it. Article 6 (2) of the MR says on this:

"The Commission is empowered to adopt delegated acts in accordance with Article 47 to amend Annex I, after consulting the stakeholders concerned, [...]"

According to Article 54d, this applies from July 20, 2024, i.e., 2.5 years before the MR becomes applicable by economic operators. After this date, Annex I can be changed almost at will by the Commission. Article 6(3) requires the Commission to obtain prior "*views of experts*", but it ultimately has free decision-making powers. Since the Commission wanted to see significantly more products in part A in the negotiations for MR, it remains to be seen how this develops.

At least the transmission of accident data by the Member States, which must take place for the first time according to Article 6 (9) by July 20, 2025, should trigger a reassessment by the EU Commission.

A product would then have to be moved to Part A of Annex I if it, according to Article 6 (7)

"presents a serious inherent potential risk"

And one of several conditions applies, e.g., Article 6 (7) (a)

"there is a lack of harmonised standards or common specifications covering the relevant essential health and safety requirements;"

In the current Part B, however, there are product groups such as:

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

There is a high proportion of harmonized standards for these. However, for some products in these groups such a standard is missing. Thus, Article 6 (7) (a) is fulfilled for these groups.

In the reassessment, the only question that remains is whether these groups *"presents*

a serious inherent potential risk". As a result of answering this question,

- that with the first evaluation by the Commission these groups have to be moved to part A,
  or
- that these groups must be removed from Annex I.

It is not possible for these groups to remain in Annex I Part B.

Partly completed machinery must now be safe up to their interfaces.

Article 11 of the MR specifies requirements for manufacturers of PCMs.

The biggest change concerns the safety requirements.

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 insofar as 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."

In addition, the title of the "*Declaration of Incorporation*" was changed to "*EU Declaration of Incorporation*".

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

This is a very important and long overdue step. Currently, according to the MD, products can be sold without the buyer knowing what it left unsafe by the manufacturer. All these future MR regulations relating to PCM currently have to be covered by private contracts while the MD is still in effect.

Documentation

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

The MD limits the availability of the technical documentation for authorities to 10 years. This is also included in the MR's Articles 10 (3) and 11 (3).

"Manufacturers shall keep the technical documentation and the EU declaration of conformity at the disposal of the market surveillance authorities for at least 10 years after the machinery or the related product has been placed on the market or put into service."

However, a "reasonable request" is no longer required here. This is now regulated in MR's Article 10 (10) or 11 (10):

"Manufacturers shall, 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 or related products with this Regulation [...]."

This means that the authority can now access the manufacturer's documents for 10 years without a "reasoned request" and permanently with a "reasoned request".

However, such an unlimited access is already in force today, due to the EU Market Surveillance Regulation Article 4 No. 3 (b).

Documents can now be handed over completely electronically in B2B sales.

The instructions (Article 10 (7)), assembly instructions (Article 11 (7)) and the EU declarations (Article 10/11 (8)) can now be made available online in B2B sales.

The manufacturer "only" must provide the Internet address from which they can be obtained.

These addresses must be valid for at least ten years for PCM, but also for machines and related products "*during the expected lifetime of the machinery or related product*".

Instructions in B2C (not) always on paper

If the end customer is a non-professional user (B2C), the instructions for machinery and related products must be provided in paper form in accordance with Article 10 (7).

There is no such requirement for PCM in Article 11 (7). If a manufacturer sells PCM directly to non-professional user, it is sufficient according to MR to provide the instructions online. However, one must also analyse all other applicable legislation.

Digital means always online

If documents are only made available in digital form, they must always be available online as well. Article 10 (7) c requires:

"When the instructions for use are provided in digital format, the manufacturer shall:

(c) make them accessible online during the expected lifetime of the machinery or related product and for at least 10 years after the placing on the market of the machinery or related product."

According to the MD, the manufacturer himself decides on the format of the documents. These only must be available when they are needed. For example, parts of the instructions can be solely available on the display of the machine itself.

According to the MR, all digital downloads must also be available online permanently (for PCM only 10 years, see above). This must be considered when calculating a "reduction in cost".

Keeping a file online and accessible at the same URL for over 10 years and more needs to be planned.

- If you choose an external provider, you must expect that they will disappear from the market. If the URL was under their control, you may have lost it forever.
- If you use your own server, the URL must not change during a reorganisation of the webspace.
- If special formats are used, all legacy issues must be transferred into new formats when they die.

Software in the machine must be documented more intensively.

In Appendix III, in the new section 1.1.9., there are now requirements as to what must be logged in the machine's control system and for how long.

Even if this does not directly improve the safety of the machinery, these are specific requirements that are not currently given in the MD.

At this point, machinery manufacturers will have some catching up to do, since specific requirements of this type do not currently appear in any B standard.

The (semi) extended declaration of incorporation.

In the MD there is the problem that the declaration of incorporation only says:

"Caution unsafe! Don't turn it on until it's safe."

In the assembly instructions according to Annex VI of the MD only the following is to be stated:

"a description of the conditions which must be met with a view to correct incorporation

in the final machinery, so as not to compromise safety and health."

"Safety up to the interfaces" must currently be demanded in private contracts. See our German article: Erweiterte Einbauerklärung

In the MR an attempt was made to close this gap:

- Appendix III makes it clear that the manufacturer of a PCM has to carry out a risk assessment.
- With a few exceptions, the assembly instructions in Annex XI are the same as the instructions in Annex III 1.7.4.2.
- According to Annex XI f), the assembly instructions must specify all parts of Annex III that apply to the PCM.
  At the same time, the EU declaration of incorporation according to Annex V B 5. must specify all parts of Annex III that have been complied with.
  From this, of course, the important information can be derived, which parts have not yet been complied with.

Despite all this mandatory information, it will still be necessary in the future to privately purchase those parts of the risk assessment from which the remaining risks are precisely derived.

Extension of Annex I(II)

Now even more complete

Annex I of the MD fully describes all hazards that can occur at a machinery.

With Annex III of the MR, the goal was set to expand this complete list.

Of course, one could have detailed the sometimes very abstract demands. For example, the example list of ergonomic hazards in Annex III 1.1.6. added two more examples.

However, there is now also e.g., Appendix III 1.3.7. "*Risks related to moving parts*" which was supplemented with ergonomic requirements, which are already listed in Annex III 1.1.6.

Partly completed machinery and related products through the back door

Instead of relating Annex III directly to all "*products within the scope of this Regulation*" (Article 2 (1)), Annex III now contains Part B 5.

"These general principles shall apply to the risk assessment carried out by the manufacturer of partly completed machinery."

And in Annex III 1.1.1. states

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

This means that all parts of Annex III also apply to PCM.

Annex III Part B 4. contains:

"The first chapter is of general scope and applicable to all machinery or related products. The other chapters refer to certain sorts of more specific hazards. Nevertheless, it is essential to examine the whole of this Annex in order to be sure of meeting all the relevant essential health and safety requirements."

This means that those parts of Annex III that have not been mentioned must also be checked for application to related products.

All this could have been saved if the term defined in Article 2 (1) for "*products within the scope of this Regulation*" had been used throughout Annex III.

Security

In Annex III 1.1.9. the subject of security is now addressed in parallel with the

requirements in Annex III 1.2.1. For example, in 1.1.9. demands:

"The machinery or related product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery or related product or its configuration."

In 1.2.1. f) this is supplemented with:

"the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery or related product has been placed on the market or put into service is enabled for five years after such upload, exclusively to demonstrate the conformity of the machinery or related product with this Annex further to a reasoned request from a competent national authority."

AI: Unnecessary additions

The regulations in Annex III that have been made for artificial intelligence are largely superfluous.

Since machines according to MD must be safe in every phase of their life, special treatment of products evolving in the field is unnecessary. If one believes that this will be overlooked, it would have been entirely sufficient to point this out centrally.

But in order to sound as future-oriented as possible, AI was unreasonably "squeezed in" and thus "crushed" in many places.

So now in Annex III 1.2.1. 2nd b demanded that AI safety keeps their sensor data for one year. In this case, only lossless storage is permitted.

Due to the resulting enormous amounts of data, the most expensive thing about an AI in the near future would be the storage media required.

KI: Collateral damage "modification"

Unnecessary things can also lead to problems. Annex III 1.2.1. d now demands:

"no modifications are allowed to the settings or rules generated by the machinery or related product or by operators [...], where such modifications could lead to hazardous situations"

And in Annex III 1.2.1. 3rd c it is required:

"modifications to the settings or rules, generated by the machinery or related product or by operators [...] shall be prevented, where such modifications could lead to hazardous situations;"

In principle, changes can lead to "*hazardous situations"* if they affect the source code of the Safe-PLC. The code of a PLC is also affected if it is used for machinery's safety.

However, since the operator is defined in Annex III Part A d as "*the person or persons installing, operating, adjusting, maintaining, cleaning, repairing or moving machinery or a related product*" (in short, "all persons at the operator's") is defined, manufacturers will soon have to completely protect their safety-relevant program parts against changes. This can also prevent the operator from subsequently modifying the machinery.

Autonomous mobile Machinery: Unnecessary

Just as with the topic of AI, content was also sought for autonomous mobile machines (amM) that still needs to be regulated in addition to the current requirements of Annex I of the MD. However, since everything is already regulated in the MD, there are now inevitably unnecessary duplications in the MR.

amM are according to their definition in Annex III 3.1.1. completely secure at all times. This is also demanded in Annex III 3.3.

"For autonomous mobile machinery or related product, the control system shall be designed to perform the safety functions by itself as set out in this section, even when actions are ordered by using a remote supervisory function."

This means that both the. "*Supervisor*" listed in Annex III 3.1.1 d and the "*Supervisory function*" defined in e are not relevant for safety. The requirement for a "*Supervisory function*" in Annex III 3.2.4. can therefore be ignored. Finally, the general principle from Annex III Part B 2 apply here.

"The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery or related product in question when it is used under the conditions foreseen by the manufacturer or in foreseeable abnormal situations."

Unnecessary restrictions

In some cases, requirements in Annex III are unnecessarily restricted in the scope of application. In general, the above-mentioned restriction of the general principle from Annex III Part B 2 always apply. No further restriction is necessary.

For example, Annex III 1.2.1. contains the requirement:

"For wireless control, a failure of the communication or connection or a faulty connection shall not lead to a hazardous situation."

This requirement must also be implemented for wired controls.

Appendix III 3.3.2. demands:

"The movement of autonomous mobile machinery shall take into account the risks related to the area where it is intended to move and work."

Of course, all machinery must consider their "*area where it is intended to move and work*".

Also Annex III 3.5.1. "Batteries" has been extended for amM:

"The batteries with automatic charging for mobile machinery or related products, including autonomous mobile machinery or related products, shall be designed to prevent hazards referred to in sections 1.3.8.2 and 1.5.1, including the risks of contact or collision of the machinery or related product with a person or other machinery or related products when the machinery or related product moves autonomously to the charging station."

Again, this should apply to all movement of machinery, not just when returning for automatic charging.