

Machinery Product Regulation

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Changes in MPR Articles 1 to 21



The European Presidency has published the proposal of the Machinery Product Regulation on the 21st 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 this Regulation together with the appropriate Articles / Annexes of the Machinery Directive 2006/42/EC and the EU Regulation on market surveillance.

In 89 cases we have noticed an impact on the current market process and addressed it as such. Some cases are minor other are major. In another 39 cases, no change was discovered by us.

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

Due to the original text 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.

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 influence legal authorities is short. Thus we wanted to give you our results as soon as possible.

Major changes (excerpt)

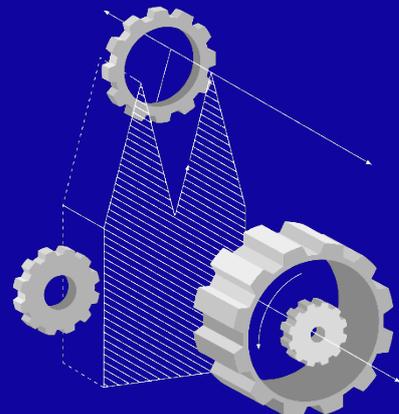
Distribution of used products is now in the scope.

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.



Major changes

Out of the 89 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 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 products that 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 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 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]

If any gaps remain in the MPR they 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 must move to part A in the first assessment.

The national authorities may expand the MPR with own regulations.

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

Currently it 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.”*

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 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 if they can use it. All those regulations of MPR regarding PCM must currently 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 3. (b).

Instructions may now be fully electronic, when selling B2B

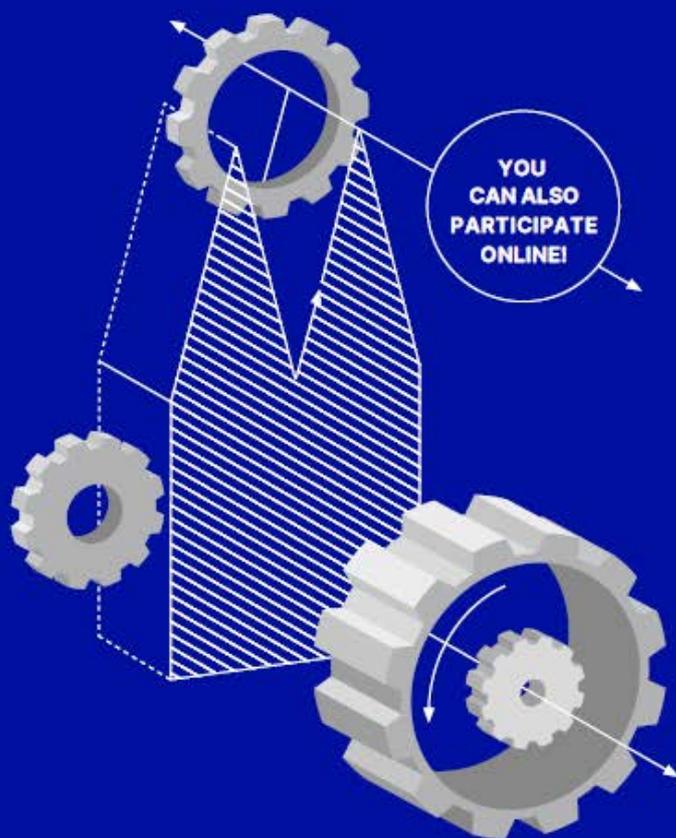
The instructions, as well as the EU Declarations, may now be provided as an internet address. [87] Such addresses must be valid for at least ten years.

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.

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Date: 21th July 2022

[1] Subject matter

Article 1

New / changed / no change:	new
Article of Proposal:	1

Proposal of EU-Council:

This Regulation lays down health and safety requirements for the design and construction of machinery, related products and partly completed machinery to allow their making available on the market or putting into service ensuring a high level of protection of the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment. It also establishes rules on the free movement of machinery, related products and partly completed machinery in the Union.

Impact:

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

[2] Scope

Article 2 1

New / changed / no change:	changed
Article of Proposal:	2 1
Old Article:	2

2006/42/EC:

For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f).

Proposal of EU-Council:

This Regulation applies to machinery and the following related products

(b) [...] (f)

Impact:

1. The term "machinery" is now distinguishable from all other products to which the MPR applies.

There are

- machinery
- related products
- partly completed machinery

2. The general term "machinery and related products" is now defined before any legal text. It now clearly applies to all provisions in Article 2.

[3] Scope

Article 2 1

New / changed / no change:	no change
Article of Proposal:	2 1
Old Article:	1 1

2006/42/EC:

1. This Directive applies to the following products:

- (a) machinery;
- (b) interchangeable equipment;
- (c) safety components;
- (d) lifting accessories;
- (e) chains, ropes and webbing;
- (f) removable mechanical transmission devices;

Proposal of EU-Council:

- (1) This Regulation applies to machinery and the following related products
- (b) interchangeable equipment;
- (c) safety components;
- (d) lifting accessories;
- (e) chains, ropes and webbing;
- (f) removable mechanical transmission devices;

Impact:

no change, other than grouping (see Article 2 1. [2])

[4] Scope

Article 2 1

New / changed / no change:	no change	
Article of Proposal:	2	1
Old Article:	1	1

2006/42/EC:

1. This Directive applies to the following products:

(g) partly completed machinery.

Proposal of EU-Council:

This Regulation also applies to partly completed machinery.

Impact:

no change, other than grouping (see Article 2 1. [2])

[5] Scope

Article 2 2a

New / changed / no change:	changed
Article of Proposal:	2 2a
Old Article:	1 2a

2006/42/EC:

The following are excluded from the scope of this Directive:

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

Proposal of EU-Council:

This Regulation does not apply to:

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

Impact:

The exclusion of safety components as spare parts from the original machine manufacturer has now been extended to the delivery of all products in the scope of the MPR, if they are supplied by their original manufacturer.

Previously, this exception only applied to manufacturers of "machinery". Now all spare parts from the original manufacturer of a product in the scope of MPR are excluded, if they are safety components. This also includes safety components for PCM.

See Article 2 1. [2]

The "spare parts" exemption is thus expanded.

[6] Scope

Article 2 2b

New / changed / no change:	no change
Article of Proposal:	2 2b
Old Article:	1 2b

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(b) specific equipment for use in fairgrounds and/or amusement parks;

Proposal of EU-Council:

(2) This Regulation does not apply to:

(b) specific equipment for use in fairgrounds or amusement parks;

Impact:

The word "and" was dropped. A purely editorial change.

The old problem remains that such equipment is often powered by electricity.

Since such equipment is not in the scope of the MD/MPR it is in the scope of the Low Voltage Directive.

Thus, this exemption makes no sense.

Another problem that remains is that fairground has multiple definitions:

<https://dictionary.cambridge.org/de/worterbuch/englisch/fairground>

"a large outside area used for a fair"

where fair can be

<https://dictionary.cambridge.org/de/worterbuch/englisch/fair>

"an outside event where you can ride on large machines for pleasure and play games to win prizes"

or

"a large show at which people who work in a particular industry meet, and sell and advertise their products"

[7] Scope

Article 2 2c

New / changed / no change:	changed
Article of Proposal:	2 2c
Old Article:	1 2c

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;

Proposal of EU-Council:

(2) This Regulation does not apply to:

(c) machinery and related products specially designed for use within or used in a nuclear installation and whose conformity with this Regulation may undermine the nuclear safety;

Impact:

This 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 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

Article 2 2d

New / changed / no change:	no change
Article of Proposal:	2 2d
Old Article:	1 2d

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(d) weapons, including firearms;

Proposal of EU-Council:

(2) This Regulation does not apply to:

(d) weapons, including firearms;

Impact:

no change

[9] Scope

Article 2 2e

New / changed / no change:	changed
Article of Proposal:	2 2e
Old Article:	1 2e -5

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(e) the following means of transport:

— means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport

Proposal of EU-Council:

(2) This Regulation does not apply to:

(e) means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport

Impact:

1. Other exclusions include "systems, components, separate technical units, parts and equipment designed and constructed for such vehicles". (see Article 2 2 f [11])

This is not stated here and thus it is up to interpretation.

2. "machinery" mounted on those vehicles are still in the scope of MPR.

3. "related products" and "partly completed machinery" mounted on those vehicles are not mentioned and are thus also excluded from MPR.

PCM were also (erroneously) excluded before, but "related products" were not.

See also the change in the last sentence of PCM in Article 3 10 [37].

[10] Scope

Article 2 2ea

New / changed / no change:	new
Article of Proposal:	2 2ea

Proposal of EU-Council:

(2) This Regulation does not apply to:

(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

Impact:

This exemption, like any others based on other Regulations and Directives that cover the relevant health and safety requirements is already covered by Article 8 [79] (former Article 3) and thus unnecessary.

[11] Scope

Article 2 2f

New / changed / no change:	changed
Article of Proposal:	2 2f
Old Article:	1 2e -3

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(e) the following means of transport:

— vehicles covered by Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles, with the exclusion of machinery mounted on these vehicles,

Proposal of EU-Council:

(2) This Regulation does not apply to:

(f) two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, that fall within the scope of application of Regulation (EU) No 168/2013, except for machinery mounted on those vehicles;

Impact:

1. It is made clear that systems, components, separate technical units, parts and equipment for these vehicles are excluded.

2. "machinery" mounted on those vehicles are in the scope of MPR.

3. "related products" and "partly completed machinery" mounted on those vehicles are not mentioned.

See also the change in the last sentence of PCM in Article 3 10 [37].

4. Only vehicles that fall within the scope of the referred EU Regulation are excluded.

It is not necessary to examine if the referred Regulation covers all EHSR, as is necessary with exemptions under Article 8. [79]

[12] Scope

Article 2 2fa

New / changed / no change:	changed
Article of Proposal:	2 2fa
Old Article:	1 2e -2

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(e) the following means of transport:

— motor vehicles and their trailers covered by Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers, with the exclusion of machinery mounted on these vehicles,

Proposal of EU-Council:

(2) This Regulation does not apply to:

(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

Impact:

same as Article 2 (2) (f) [11]

[13] Scope

Article 2 2fb

New / changed / no change:	changed
Article of Proposal:	2 2fb
Old Article:	1 2e -4

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(e) the following means of transport:

— motor vehicles exclusively intended for competition

Proposal of EU-Council:

(2) This Regulation does not apply to:

(fb) vehicles exclusively intended for competition

Impact:

Vehicles exclusively intended for competition no longer need a motor.

Thus e.g. wind driven cars can now also be exempted.

[14] Scope

Article 2 2g

New / changed / no change:	changed
Article of Proposal:	2 2g
Old Article:	1 2e -1

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(e) the following means of transport:

— agricultural and forestry tractors, with the exclusion of machinery mounted on those vehicles

Proposal of EU-Council:

(2) This Regulation does not apply to:

(g) agricultural and forestry tractors, as well as systems, components, separate technical units, parts and equipment designed and constructed for such tractors, that fall within the scope of application of Regulation (EU) No 167/2013, except for machinery mounted on those vehicles

Impact:

same as Article 2 (2) (f) [11]

5. Trailers and interchangeable towed equipment in the scope of Regulation (EU) No 167/2013 are only exempted, if covered under Article 8. [79]

[15] Scope

Article 2 2h

New / changed / no change:	no change
Article of Proposal:	2 2h
Old Article:	1 2f

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;

Proposal of EU-Council:

(2) This Regulation does not apply to:

(h) seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;

Impact:

1. Other exclusions include "systems, components, separate technical units, parts and equipment designed and constructed for such vehicles". (see Article 2 2 f [11])

This is not stated here and thus it is up to interpretation.

2. "machinery" on board of those vehicles are definitely not in the scope of MPR.

3. "related products" and "partly completed machinery" on board of those vehicles are not mentioned.

PCM were not covered before as well, but "related products" are now also no longer exempted.

[16] Scope

Article 2 2i

New / changed / no change:	no change
Article of Proposal:	2 2i
Old Article:	1 2g

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(g) machinery specially designed and constructed for military or police purposes;

Proposal of EU-Council:

(2) This Regulation does not apply to:

(i) machinery or related products specially designed and constructed for military or police purposes;

Impact:

no change

[17] Scope

Article 2 2j

New / changed / no change:	no change
Article of Proposal:	2 2j
Old Article:	1 2h

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(h) machinery specially designed and constructed for research purposes for temporary use in laboratories;

Proposal of EU-Council:

(2) This Regulation does not apply to:

(j) machinery or related products specially designed and constructed for research purposes for temporary use in laboratories;

Impact:

no change

[18] Scope

Article 2 2k

New / changed / no change:	no change
Article of Proposal:	2 2k
Old Article:	1 2i

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(i) mine winding gear;

Proposal of EU-Council:

(2) This Regulation does not apply to:

(k) mine winding gear;

Impact:

no change

[19] Scope

Article 2 2l

New / changed / no change:	no change
Article of Proposal:	2 2l
Old Article:	1 2j

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(j) machinery intended to move performers during artistic performances;

Proposal of EU-Council:

(2) This Regulation does not apply to:

(l) machinery or related products intended to move performers during artistic performances;

Impact:

no change

[20] Scope

Article 2 2m

New / changed / no change:	changed
Article of Proposal:	2 2m
Old Article:	1 2k

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(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

Proposal of EU-Council:

(2) This Regulation does not apply to:

(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

Impact:

These special products have been excluded already, if they fall within the scope of the Low Voltage Directive (LVD).

These exclusions are now extended to the scope of the Radio Equipment Directive (RED).

This change is necessary for the status quo, from before the RED. If products fall within the scope of the RED, they no longer fall within the scope of the LVD. Thus, currently they are not exempted from the Machinery Directive (MD).

In practice, this currently means that products without radio signals (e.g. Roomba without Wi-Fi) fall under the scope of the LVD and not the MD. The same product with a radio signal (e.g. Roomba with Wi-Fi) is subject to the RED and thus not the LVD, so the MD applies in addition to the RED.

This modified exception rectifies this problem.

[21] Scope

Article 2 2m i

New / changed / no change:	no change
Article of Proposal:	2 2m i
Old Article:	1 2k -1

2006/42/EC:

- household appliances intended for domestic use

Proposal of EU-Council:

(i) household appliances intended for domestic use which are not electrically operated furniture

Impact:

This change is only a clarification.

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

[22] Scope

Article 2 2m ii

New / changed / no change:	no change
Article of Proposal:	2 2m ii
Old Article:	1 2k -2

2006/42/EC:

- audio and video equipment

Proposal of EU-Council:

(ii) audio and video equipment;

Impact:

no change

[23] Scope

Article 2 2m iii

New / changed / no change:	no change
Article of Proposal:	2 2m iii
Old Article:	1 2k -3

2006/42/EC:

- information technology equipment

Proposal of EU-Council:

(iii) information technology equipment;

Impact:

no change

[24] Scope

Article 2 2m iv

New / changed / no change:	no change
Article of Proposal:	2 2m iv
Old Article:	1 2k -4

2006/42/EC:

- ordinary office machinery

Proposal of EU-Council:

(iv) ordinary office machinery, except additive printing machinery for producing three-dimensional products

Impact:

Small 3d-printers can be "office-machinery". With more and more cheap offers, they can be considered "ordinary" soon.

Thus "additive printing machinery" are exempted from the exemption, in order to keep them in the MPR.

Since 3d-printers were not considered "ordinary" before, this is no change in application.

[25] Scope

Article 2 2m v

New / changed / no change:	no change
Article of Proposal:	2 2m v
Old Article:	1 2k -5

2006/42/EC:

- low-voltage switchgear and control gear

Proposal of EU-Council:

(v) low-voltage switchgear and control gear;

Impact:

no change

[26] Scope

Article 2 2m vi

New / changed / no change:	no change
Article of Proposal:	2 2m vi
Old Article:	1 2k -6

2006/42/EC:

- electric motors

Proposal of EU-Council:

(vi) electric motors;

Impact:

no change

[27] Scope

Article 2 2n

New / changed / no change:	no change
Article of Proposal:	2 2n
Old Article:	1 2l

2006/42/EC:

2. The following are excluded from the scope of this Directive:

(l) the following types of high-voltage electrical equipment:

- switch gear and control gear,
- transformers.

Proposal of EU-Council:

(2) This Regulation does not apply to:

(n) the following high-voltage electrical products:

- (i) switch gear and control gear;
- (ii) transformers.

Impact:

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

[28] Definitions

Article 3 0

New / changed / no change:	changed
Article of Proposal:	3 0
Old Article:	2 0

2006/42/EC:

For the purposes of this Directive, 'machinery' designates the products listed in Article 1(1)(a) to (f).

The following definitions shall apply:

Proposal of EU-Council:

For the purposes of this Regulation, the following definitions shall apply:

Impact:

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

This has been moved to Article 2 1. [2] and one additional group "related products" has been created.

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

[29] Definitions

Article 3 1a-e

New / changed / no change:	no change
Article of Proposal:	3 1a-e
Old Article:	2 a

2006/42/EC:

(a) 'machinery' means:

- 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,
- an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion,
- an assembly referred to in the first and second indents, ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure,
- 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,
- 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;

Proposal of EU-Council:

(1)'machinery' means:

- (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;
- (b) an assembly referred to in point (a), missing only the components to connect it on site or to sources of energy and motion;
- (c) an assembly referred to points (a) and (b), ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure;
- (d) assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point (10) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;

(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;

Impact:

no change

[30] Definitions

Article 3 1f

New / changed / no change:	new
Article of Proposal:	3 1f

Proposal of EU-Council:

(f) an assembly as referred to in points (a), (b), (c), (d) and (e) missing only the upload of software intended for its specific application.

Impact:

Additionally to Article 3 1 (b) and (c) [29], machinery 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 [32] 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 Recital 17, 18, Article 3 1 (a), (f) and Article 3 10, but it is never defined. Already in the context of 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.

[31] Definitions

Article 3 2

New / changed / no change:	changed
Article of Proposal:	3 2
Old Article:	2 b

2006/42/EC:

(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

Proposal of EU-Council:

(2) 'interchangeable equipment' means a device which, after the putting into service of a machinery or an agricultural or forestry tractor, is assembled with that machinery or agricultural or forestry tractor by the operator in order to change its function or attribute to it a new function, in so far as that equipment is not a tool;

Impact:

"Interchangeable equipment" for related products is no longer within the scope of the Machine Product Regulation.

Although "interchangeable equipment" will be mainly manufactured for machinery, there is no reason to exclude fringe cases.

[32] Definitions

Article 3 3

New / changed / no change:	changed
Article of Proposal:	3 3
Old Article:	2 c

2006/42/EC:

(c) 'safety component' means a component

- which serves to fulfil a safety function,
- which is independently placed on the market,
- the failure and/or malfunction of which endangers the safety of persons, and
- which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

Proposal of EU-Council:

(3) 'safety component' means a component of physical, digital or mixed nature, including software, of products subject to this Regulation

which serves to fulfil a safety function and

which is independently placed on the market,

the failure or malfunction of which endangers the safety of persons

but

which is not necessary in order for the products subject to this Regulation to function or may be substituted by normal components in order for the products subject to this Regulation to function;

Impact:

1. Software can now be a safety component.
2. Now, a "safety component" can also exist for a partly completed machinery. (was never contested, but technically not in the scope of the MD today)

[33] Definitions

Article 3 3a

New / changed / no change:	new
Article of Proposal:	3 3a

Proposal of EU-Council:

(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

Impact:

The definition should be broad enough as to not cause any changes in the application of safety components

[34] Definitions

Article 3 4

New / changed / no change:	changed
Article of Proposal:	3 4
Old Article:	2 d

2006/42/EC:

(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;

Proposal of EU-Council:

(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;

Impact:

The last part "including slings and their components" differs from the old text. This change of a previously clear definition is unnecessary and may lead to wrong conclusions.

In theory, both 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).

[35] Definitions

Article 3 5, 6, 8

New / changed / no change:	no change
Article of Proposal:	3 5, 6, 8
Old Article:	2 e

2006/42/EC:

(e) 'chains, ropes and webbing' means chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;

Proposal of EU-Council:

(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;

Impact:

no change

[36] Definitions

Article 3 9

New / changed / no change:	changed
Article of Proposal:	3 9
Old Article:	2 f

2006/42/EC:

(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;

Proposal of EU-Council:

(9) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another machinery by joining them at the first fixed bearing. When it is placed on the market with the guard it shall be regarded as one item;

Impact:

no change

[37] Definitions

Article 3 10

New / changed / no change:	changed
Article of Proposal:	3 10
Old Article:	2 g

2006/42/EC:

(g) 'partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application. A drive system is partly completed machinery. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Directive applies

Proposal of EU-Council:

(10) 'partly completed machinery' means an assembly which is not yet machinery as it cannot in itself function so as to perform a specific application and which is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming a machinery;

Impact:

1. The term "almost" from "almost machinery" was replaced with "not yet".

Thus, it is no longer necessary to define at which point "almost" is reached.

2. The previous part of the sentence "but which cannot in itself perform a specific application" has been rewritten to "as it cannot in itself function so as to perform a specific application".

This is a clarification. PCM can frequently perform a specific application, but they cannot function safely.

3. The "Drive system" example has been deleted.

Deleting the example "drive system" 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.

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.

4. 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 later not in the scope by themselves.

[38] Definitions

Article 3 11

New / changed / no change:	new
Article of Proposal:	3 11

Proposal of EU-Council:

(11) 'making available on the market' means 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;

Impact:

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 also covers the entire retail chain with the economic actors concerned. In the future also distribution of used products 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.

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.

[39] Definitions

Article 3 12

New / changed / no change:	no change
Article of Proposal:	3 12
Old Article:	2 h

2006/42/EC:

(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

Proposal of EU-Council:

(12) 'placing on the market' means the first making available of a product subject to this Regulation on the Union market;

Impact:

no change

The term "whether for reward or free of charge" is now part of "making available on the market". see Article 11 [38]

[40] Definitions

Article 3 13

New / changed / no change:	no change
Article of Proposal:	3 13
Old Article:	2 k

2006/42/EC:

(k) 'putting into service' means the first use, for its intended purpose, in the Community, of machinery covered by this Directive;

Proposal of EU-Council:

(13) 'putting into service' means the first use, for its intended purpose, in the Union, of machinery or related products;

Impact:

no change

but for legal clarity it would have been nice to add "in the course of a commercial activity" here as well (See Article 3 11 [38])

[41] Definitions

Article 3 13a

New / changed / no change:	no change
Article of Proposal:	3 13a
Old Article:	2 m

2006/42/EC:

(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.

The essential health and safety requirements are set out in Annex I. Essential health and safety requirements for the protection of the environment are applicable only to the machinery referred to in section 2.4 of that Annex.

Proposal of EU-Council:

(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, as set out in Annex III;

Impact:

no change

[42] Definitions

Article 3 13b

New / changed / no change:	new
Article of Proposal:	3 13b

Proposal of EU-Council:

(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;

Impact:

new, but no impact

[43] Definitions

Article 3 14

New / changed / no change:

new

Article of Proposal:

3 14

Proposal of EU-Council:

(14) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

Impact:

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

[44] Definitions

Article 3 16

New / changed / no change:	new
Article of Proposal:	3 16

Proposal of EU-Council:

(16) 'substantial modification' means a modification of a machinery or related product, by physical or digital means after that machinery or related product has been placed on the market or put into service, which is not foreseen nor planned by the manufacturer, and affects its safety by creating a new hazard or by increasing an existing risk which requires:

- (i) additional guards or protective devices, whose processing modifies the existing safety control system, or
- (ii) additional protective measures to ensure the stability or mechanical strength of the machinery or related product;

Impact:

So far, the topic has only been part of different European and national interpretations.

The definition follows the explanation in the EU internal market guide "Blue Guide" in chapter 2.1.

However, the MPR limits the substantial modification to 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".

This approach differs from the German paper significantly, but might be much more practical.

What ever the final definition will be; a uniform, practicable view of the subject of "substantial modification" is urgently required within the framework of the internal market.

[45] Definitions

Article 3 17

New / changed / no change:	changed
Article of Proposal:	3 17
Old Article:	2 i

2006/42/EC:

(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 Directive shall be considered a manufacturer

Proposal of EU-Council:

(17) 'manufacturer' means any natural or legal person who manufactures a product subject to this Regulation, or who has a product subject to this Regulation designed or manufactured, and markets such a product under his or her name or trademark, or manufactures a product subject to this Regulation and puts it into service for his or her own use

Impact:

1. "Manufacturer" is no longer the person who designs the machinery product, but only the person who manufactures it.
3. "Manufacturer" is still the person who labels the machinery product with their brand.
4. A manufacturer "for his or her own use" is still a "manufacturer", but only if he manufactures the product himself.
e.g. if a person designs a product and has it manufactured, he will only become the manufacturer, if he markets it under his name. If he only uses it himself, the person manufacturing it becomes the manufacturer.
5. "non professional users" can become manufacturers. If they manufacture a product for their own use and put it into service, Article 3 13 [40] 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".
6. The part "In the absence of a manufacturer as defined above [...]" has been dropped.

It is made clear that the design office is fundamentally not a manufacturer within the meaning of the MPR. Currently, the manufacturer can also be the person who designs a product.

This also makes it formally clear that the design process, in which the risk assessment should be carried out and the technical documents created, can be outsourced to a third party who is not an economic operator in the sense of the MPR. In fact, this is not a change, as it has been the case before.

The old part "If there is no manufacturer in the sense of the above definition ..." was a "catch all" so that there always was a manufacturer. Now many economic actors who make machinery products available on the market are included in the MPR. However there are a few gaps left to put machinery in use without applying the MPR. (see Article 3 20 [49])

[46] Definitions

Article 3 17a

New / changed / no change:	no change
Article of Proposal:	3 17a

Proposal of EU-Council:

definition of "user" was added and later deleted

Impact:

Although the definition of "user" has been deleted, a lot of requirements on users remain in the text.

An indirect definition can be found in Article 28 4. where persons are listed:

"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. A "user" is not an installer or maintainer.

All mentions of "user" should be replaced by "operator".

[47] Definitions

Article 3 18

New / changed / no change:	new
Article of Proposal:	3 18

Proposal of EU-Council:

(18) 'instructions' means the information provided by the manufacturer when the machinery or related product is placed on the market or put into service to inform the user of the machinery or related product of the intended and proper use of that machinery or related product as well as information on any precautions to be taken when using or installing the machinery or related product, including information on the safety aspects;

Impact:

no impact

[48] Definitions

Article 3 19

New / changed / no change:	changed
Article of Proposal:	3 19
Old Article:	2 j

2006/42/EC:

(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;

Proposal of EU-Council:

(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;

Impact:

An authorised representative is no longer allowed to take over all responsibilities of the manufacturer, but only tasks defined in Article 11 [100].

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

[49] Definitions

Article 3 20

New / changed / no change:	new
Article of Proposal:	3 20

Proposal of EU-Council:

(20) 'importer' means 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;

Impact:

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 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 an importer for own use is not covered by this Regulation.

He 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]).

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

[50] Definitions

Article 3 21

New / changed / no change:	new
Article of Proposal:	3 21

Proposal of EU-Council:

(21) 'distributor' means 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;

Impact:

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 "new products". Thus any product subject to MPR that is sold (or gifted) after MPR takes effect leads to the seller being a "distributor".

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 (unintended) outcome leads to used products finally being handled in European law. Currently the sale of used products is handled in national law.

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.

(see also Article 3 11 [38])

[51] Definitions

Article 3 22

New / changed / no change:	new
Article of Proposal:	3 22

Proposal of EU-Council:

(22) 'economic operator' means the manufacturer, the authorised representative, the importer, the distributor, and the fulfilment service provider as defined in Regulation (EU) 2019/1020;

Impact:

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 also covers the entire retail chain with the economic actors concerned. This adjustment was made in 2014 for many other product directives.

The MPR additionally includes the fulfilment service provider as defined in Regulation (EU) 2019/1020.

[52] Definitions

Article 3 23

New / changed / no change:	new
Article of Proposal:	3 23

Proposal of EU-Council:

(23) 'technical specification' means a document that prescribes technical requirements to be fulfilled by machinery or related products;

Impact:

According to this definition, no technical specifications for partly completed machinery exists.

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

[53] Definitions

Article 3 23a

New / changed / no change:	new
Article of Proposal:	3 23a

Proposal of EU-Council:

(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;

Impact:

According to this definition, no common specifications for partly completed machinery exists.

"common specifications" are the "harmonised standards" equivalents of the commission.

[54] Definitions

Article 3 24

New / changed / no change:	no change
Article of Proposal:	3 24
Old Article:	2 I

2006/42/EC:

(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 regulations and of rules on Information Society services (4);

Proposal of EU-Council:

(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;

Impact:

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 EU-R in Article 2 (1) first sentence, is omitted.

[55] Definitions

Article 3 25

New / changed / no change:

new

Article of Proposal:

3 25

Proposal of EU-Council:

(25) 'CE marking' means a marking by which the manufacturer indicates that a machinery or related product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

Impact:

No effect, see also Article 20 [121]

[56] Definitions

Article 3 26

New / changed / no change:	new
Article of Proposal:	3 26

Proposal of EU-Council:

(26) 'accreditation' means accreditation as defined in Article 2, point (10) of Regulation (EC) No 765/2008;

Impact:

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

No consequences

[57] Definitions

Article 3 27

New / changed / no change:

new

Article of Proposal:

3 27

Proposal of EU-Council:

(27) 'national accreditation body' means a national accreditation body as defined in Article 2 point (11) of Regulation (EC) No 765/2008;

Impact:

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

No consequences

[58] Definitions

Article 3 28

New / changed / no change:	new
Article of Proposal:	3 28

Proposal of EU-Council:

(28) 'conformity assessment' means the process demonstrating whether the applicable essential health and safety requirements of this Regulation relating to machinery or related products have been fulfilled;

Impact:

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

No consequences

But there still is no "conformity assessment" for partly completed machinery.

[59] Definitions

Article 3 29

New / changed / no change:	new
Article of Proposal:	3 29

Proposal of EU-Council:

(29) 'conformity assessment body' means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;

Impact:

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

No consequences

[60] Definitions

Article 3 30

New / changed / no change:	new
Article of Proposal:	3 30

Proposal of EU-Council:

(30) 'notified body' means a conformity assessment body notified in accordance with Article 28 of this Regulation;

Impact:

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

No consequences

[61] Definitions

Article 3 31

New / changed / no change:	new
Article of Proposal:	3 31

Proposal of EU-Council:

(31) 'market surveillance authority' means a market surveillance authority as defined in Article 3, point (4) of Regulation (EU) 2019/1020;

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;

Impact:

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

No consequences

[62] Definitions

Article 3 32

New / changed / no change:	new
Article of Proposal:	3 32

Proposal of EU-Council:

(32) 'recall' means any measure aimed at achieving the return of a product subject to this Regulation that has already been made available to the 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;

Impact:

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

No consequences

That the word "end" is dropped, is necessary. Since partly completed machinery need not be supplied to the end-user but can also be supplied to another manufacturer.

[63] Definitions

Article 3 33

New / changed / no change:	new
Article of Proposal:	3 33

Proposal of EU-Council:

(33) 'withdrawal' means any measure aimed at preventing a product subject to this Regulation 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;

Impact:

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

No consequences

[64] Definitions

Article 3 33a

New / changed / no change:	new
Article of Proposal:	3 33a

Proposal of EU-Council:

(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;

Impact:

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.

[65] Free movement

Article 4 1

New / changed / no change:	no change
Article of Proposal:	4 1
Old Article:	6 1+2

2006/42/EC:

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.

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.

Proposal of EU-Council:

1. Member States shall not impede, for reasons relating to the aspects covered by this Regulation, the making available on the market of products subject to this Regulation or the putting into service of machinery or related products which comply with this Regulation.

Impact:

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

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.

[66] Free movement

Article 4 2

New / changed / no change:	no change
Article of Proposal:	4 2
Old Article:	6 3

2006/42/EC:

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. Furthermore, during demonstrations of such non-conforming machinery or partly completed machinery, adequate safety measures shall be taken to ensure the protection of persons.

Proposal of EU-Council:

2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the display of a product subject to this Regulation which does not comply with this Regulation, provided that a visible sign clearly indicates that it does not comply with this Regulation and will not be available on the market until it has been brought into conformity.

During demonstrations, adequate measures shall be taken to ensure the protection of persons.

Impact:

no change

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

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

Article 4a

New / changed / no change:	changed
Article of Proposal:	4a
Old Article:	15

2006/42/EC:

Installation and use of machinery

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.

Proposal of EU-Council:

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.

Impact:

A regulation that is similar in terms of content but partially deviating from the MD is proposed here. 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 rules could not demand more or less than the Directive.

Now, such additional rules can not demand less than the Regulation, but more.

Thus, this Article therefore is not conform with the Treaty on the Functioning of the European Union (TFEU), especially its Article 26 and Article 114.

[68] Machinery and related products listed in Annex I Article 5 1

New / changed / no change:	new
Article of Proposal:	5 1

Proposal of EU-Council:

1. Machinery and related products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Article 21(2) and 21(2a).

Impact:

The Annex I list does not include PCM, even if they fit in individual categories.

Only if they are include in the complete machinery or related product will they be part of the type examination.

[69] Machinery and related products listed in Annex I Article 5 2

New / changed / no change:	new
Article of Proposal:	5 2

Proposal of EU-Council:

2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I, after consultation with experts of Member states and relevant stakeholders representing all concerned sectors and interests in view of technical progress and knowledge or new scientific evidence by including in the list of machinery and related products in Annex I a new category of machinery or related product or withdrawing an existing category of machinery or related product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.

Impact:

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.

[70] Machinery and related products listed in Annex I

Article 5 2a

New / changed / no change:

new

Article of Proposal:

5 2a

Proposal of EU-Council:

2.a. A Member State which has concerns about a category of machinery or related product being listed or not listed in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof.

The Commission shall thoroughly assess the risks as referred to in paragraph 3 immediately after having being informed by a Member State.

After that assessment the Commission may initiate the procedure laid down in paragraph 2.

Impact:

[71] Machinery and related products listed in Annex I

Article 5 3

New / changed / no change:	new
Article of Proposal:	5 3

Proposal of EU-Council:

3. 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 shall be established based on the combination of the probability of occurrence of harm and the severity of that harm.

In determining the probability and severity of harm, the following criteria shall be taken into account, where relevant:

- (a') the nature of the hazard inherent to the function of the machinery or related product category, taking into account the intended use and reasonably foreseeable misuse;
- (a) the severity of harm by which a person would be affected, including the degree of reversibility of such harm;
- (b) the number of persons potentially affected by the harm;
- (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;
- (d) possibilities of avoiding or limiting harm;
- (h) in case of safety components, the likelihood of serious consequences for the safety of the persons exposed in the event of failure.

Impact:

The new provisions assumes that the list of Annex I machinery products (Annex IV of the MD) follows a risk-based approach and can then also be adapted / changed on this basis.

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

[72] Machinery and related products listed in Annex I

Article 5 4

New / changed / no change:	new
Article of Proposal:	5 4

Proposal of EU-Council:

4. When applying the criteria laid down in paragraph 3 the Commission may consider any of the following elements that shall be provided by the Member States in connection with market surveillance or as a result of the concerns referred to in the paragraph 2.a

- (a) indications of harm that have been caused in the past by machinery or related products which have been used for its intended use or any reasonably foreseeable misuse;
- (ba) information about safety defects detected in the course of market surveillance, and possible available material in the information systems administered by the Commission;
- (ca) known accidents and serious close calls, including characteristics of these accidents or close call;
- (d) data on accidents or damage to the health caused by the machinery or related product at least for the preceding four years.

Impact:

When a product is on the list and being on the list decreases accidents, these values should go down.

Thus expectations on the products has to change, depending on the product being part of Annex I A., Annex I B. or not being on the list. Otherwise products would move in and out of Annex I every five years.

Also the duration of being on such a list is important, to determine the percentage of products, the list applied to.

But here the Regulation asks for a minimum of four years. Does this mean that a re-evaluation can only happen every four years?

[73] Machinery and related products listed in Annex I

Article 5 4a

New / changed / no change:	new
Article of Proposal:	5 4a

Proposal of EU-Council:

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:

- (i) Lack of harmonised standards or common specifications covering the relevant essential health and safety requirements;
- (ii) Existence of residual risks including those which could be reduced by particular training or personal protective equipment according to the manufacturer and for which data and information set out in § 4 demonstrate the recurrence of similar serious or fatal accidents or damage to health in relation with these residual risks;
- (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;
- (iv) The degree of uncertainty of the existing risk assessment methods related to new categories of machinery or technologies.

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.

Impact:

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 it 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 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.

[74] Machinery and related products listed in Annex I Article 5 5

New / changed / no change:	new
Article of Proposal:	5 5

Proposal of EU-Council:

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.

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.

Impact:

Once a product is in Annex I A/B it will remain there for at least 5 years.

Drafting a new harmonized standard can take 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.

[75] Machinery and related products listed in Annex I

Article 5 6

New / changed / no change:	new
Article of Proposal:	5 6

Proposal of EU-Council:

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.

These implementing shall be adopted in accordance with the examination procedure referred to in Article 46(3).

The first implementing act shall be adopted not later than twelve months after the entry into force of this Regulation.

Impact:

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.

[76] Safety components

Article 6 1

New / changed / no change:	no change
Article of Proposal:	6 1
Old Article:	2 c

2006/42/EC:

An indicative list of safety components is set out in Annex V;

Proposal of EU-Council:

1. An indicative list of safety components is set out in Annex II.

Impact:

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

[77] Safety components

Article 6 2-4

New / changed / no change:	no change
Article of Proposal:	6 2-4
Old Article:	8 1+2

2006/42/EC:

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.

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).

Proposal of EU-Council:

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.

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.

Impact:

No change in content.

Also: Since this list only contains examples, there is no impact on such products.

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

Article 7

New / changed / no change:	changed
Article of Proposal:	7
Old Article:	4 1+2

2006/42/EC:

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.

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.

Proposal of EU-Council:

Machinery or related products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended use or under conditions which can reasonably be foreseen, they meet the essential health and safety requirements set out in Annex III.

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.

Impact:

In the MD this was an obligation only of the Member States. Now it can be understood that it is also addressed towards the economic operators.

[79] Specific Union harmonisation legislation

Article 8

New / changed / no change:	no change
Article of Proposal:	8
Old Article:	3

2006/42/EC:

Specific Directives

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.

Proposal of EU-Council:

Where, for a certain product subject to this Regulation, the risks addressed by the essential health and safety requirements set out in Annex III are wholly or partly covered by other more specific Union harmonisation legislation, this Regulation shall not apply to that product subject to this Regulation to the extent that that specific Union legislation covers such risks.

Impact:

Due to the broader term "product subject to this Regulation", this now also applies to PCM. This closed a "formal" gap.

[80] Obligations of manufacturers of machinery and related products

Article 10 1

New / changed / no change:	no change
Article of Proposal:	10 1
Old Article:	5 1a

2006/42/EC:

Placing on the market and putting into service

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;

Proposal of EU-Council:

1. When placing a machinery or a related product on the market or putting it into service, manufacturers shall ensure that it has been designed and constructed in accordance with the essential health and safety requirements set out in Annex III.

Impact:

no change

[81] Obligations of manufacturers of machinery and related products

Article 10 2 -(1)

New / changed / no change:	no change
Article of Proposal:	10 2 -(1)
Old Article:	5 1b 1d

2006/42/EC:

1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:

(b) ensure that the technical file referred to in Annex VII, part A is available;

(d) carry out the appropriate procedures for assessing conformity in accordance with Article 12;

Proposal of EU-Council:

2. Before placing a machinery or related product on the market or putting it into service, manufacturers shall draw up the technical documentation set out in part A of Annex IV and carry out the relevant conformity assessment procedure referred to in Article 21 or have it carried out.

[...]

Impact:

theoretically no change

Now the TD only needs to be drawn up, before in the MD it needed to be available.

[82] Obligations of manufacturers of machinery and related products

Article 10 2, 8

New / changed / no change:	changed
Article of Proposal:	10 2, 8
Old Article:	5 1 e 1 f

2006/42/EC:

1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:

(e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery;

(f) affix the CE marking in accordance with Article 16.

Proposal of EU-Council:

2. [...]

Where compliance of a machinery or related product with the essential health and safety requirements laid down in Annex III has been demonstrated by that conformity assessment procedure, manufacturers shall draw up the EU declaration of conformity in accordance with Article 18 and affix the CE marking in accordance with Article 20.

[...]

8. Manufacturers shall ensure that the machinery or related products is accompanied by the EU declaration of conformity set out in Part A of Annex V or shall provide the internet address at which it can be accessed in the instructions and information set out in section 1.7 of Annex III.

Digital EU declarations of conformity 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.

Impact:

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.

The requirement on affixing a CE mark is also covered by Article 20 2 [121]. Thus this requirement is handled at two different places.

[83] Obligations of manufacturers of machinery and related products

Article 10 3

New / changed / no change:	no change
Article of Proposal:	10 3
Old Article	5 1 b
Old Annex:	VII A 2.

2006/42/EC:

1. Before placing machinery on the market and/or putting it into service, the manufacturer or his authorised representative shall:

(b) ensure that the technical file referred to in Annex VII, part A is available;

Annex VII A

2. The technical file referred to in point 1 must be made available to the competent authorities of the Member States for at least 10 years following the date of manufacture of the machinery or, in the case of series manufacture, of the last unit produced.

[...]

Proposal of EU-Council:

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

Impact:

no change in content

The start time "following the date of manufacture of [...] the last unit produced" was dropped. This has no theoretical 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 "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.

There is a minuscule difference of the old "before placing on the market" and the new "has been placed on the market" without any real effect in praxis.

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.

[84] Obligations of manufacturers of machinery and related products

Article 10 4 -(1)

New / changed / no change:	no change
Article of Proposal:	10 4 -(1)
Old Annex:	VII A1.b

2006/42/EC:

(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.

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.

Proposal of EU-Council:

4. Manufacturers shall ensure that procedures are in place for machinery or related 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 or related product and changes in the harmonised standards or the common specifications referred to in Article 17 or other technical specifications by reference to which the conformity of the machinery or related product is declared shall be adequately taken into account.

[...]

Impact:

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 4. with adaptations)
2. no change
3. Documentation of these measures is still part of Technical Documentation (Annex IV m)

[85] Obligations of manufacturers of machinery and related products

Article 10 4 -(2)

New / changed / no change:	new
Article of Proposal:	10 4 -(2)

Proposal of EU-Council:

When deemed appropriate with regard to the risks presented by machinery or related products, manufacturers shall, in order to protect the health and safety of users, carry out sample testing of machinery or related products made available on the market and investigate. If necessary, manufacturers shall keep a register of complaints, of non-conforming machinery or related products and machinery or related products recalls, and shall keep distributors informed of any such monitoring.

Impact:

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 4.)

NLF "consumer" is replaced by "user". (see missing definition of user)

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

3. Tests must also be carried out for machinery products for own use.

[86] Obligations of manufacturers of machinery and related products

Article 10 5, 6

New / changed / no change:	changed
Article of Proposal:	10 5, 6
Old Annex:	I 1.7.3

2006/42/EC:

1.7.3. Marking of machinery

All machinery must be marked visibly, legibly and indelibly with the following minimum particulars:

- the business name and full address of the manufacturer and, where applicable, his authorised representative,
- designation of the machinery,
- the CE Marking (see Annex III),
- designation of series or type,
- serial number, if any,
- the year of construction, that is the year in which the manufacturing process is completed.

It is prohibited to pre-date or post-date the machinery when affixing the CE marking.

Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.

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.

Where a machine part must be handled during use with lifting equipment, its mass must be indicated legibly, indelibly and unambiguously.

Proposal of EU-Council:

5. Manufacturers shall ensure that the machinery or related product which they place on the market or put into service bears at least a designation of the machinery, series or type, the year of construction, that is the year in which the manufacturing process is completed, and, if any, batch or serial number allowing its identification, or, where the size or nature of the machinery or related product does not allow it, that the required information is provided on the packaging or in a document accompanying the machinery or related product.

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

machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related products. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by users and market surveillance authorities.

Impact:

1. Now a digital contact also needs to be provided, "if available".
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 same restrictions on language options as in the current MD remain.

3. The 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 fixing missing CE marks on machinery that have been illegally put on the market after 1995.

4. 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.

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)

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

[87] Obligations of manufacturers of machinery and related products

Article 10 7

New / changed / no change:	changed
Article of Proposal:	10 7
Old Article	5 1c
Old Annex:	I 1.7.1.

2006/42/EC:

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 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.

Proposal of EU-Council:

7. Manufacturers shall ensure that the machinery or related products are accompanied by the instructions and information set out in Annex III.

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

(a) mark on the machinery or related product and in an accompanying document how to access the digital instructions;

(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.

(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.

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 instructions in paper format free of charge.

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 .

The instructions and information shall be in a language which can be easily understood by users, as determined by the Member State concerned and shall be clear, understandable, intelligible and legible.

Impact:

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 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, 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.

2. Instructions can now be digital. They must be available online for 10 years. 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.

4. In case of non-professional users, 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".

[88] Obligations of manufacturers of machinery and related products

Article 10 9

New / changed / no change:	changed
Article of Proposal:	10 9
EU-Regulation on market surveillance, Article:	4

EU-Regulation on market surveillance:

Tasks of economic operators regarding products subject to certain Union harmonisation legislation

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:

(c) when having reason to believe that a product in question presents a risk, informing the market surveillance authorities thereof;

(d) cooperating with the market surveillance 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.

Proposal of EU-Council:

9. Manufacturers who consider or have reason to believe that a machinery or related product, which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that machinery or related products into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the machinery or related product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the machinery or related product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.

Impact:

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".

[89] Obligations of manufacturers of machinery and related products

Article 10 10

New / changed / no change:	changed
Article of Proposal:	10 10
EU-Regulation on market surveillance, Article:	4 3 b

EU-Regulation on market surveillance:

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:

(a) [...]

(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 the product in a language which can be easily understood by that authority;

Proposal of EU-Council:

10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery or related products with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks presented by the machinery or related products, which they have placed on the market or put into service.

Impact:

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.
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, these information have to be kept for at least as long as the product exists.

[90] Obligations of manufacturers of partly completed machinery

Article 10a 1

New / changed / no change:	changed
Article of Proposal:	10a 1
Old Annex:	IIV B (a) 3.- (i)

2006/42/EC:

Relevant technical documentation for partly completed machinery

It shall comprise the following:

(a) a construction file including:

- the risk assessment documentation showing the procedure followed, including:

(i) a list of the essential health and safety requirements applied and fulfilled,

Proposal of EU-Council:

1. When placing a partly completed machinery on the market, manufacturers shall ensure that it has been designed and constructed in accordance with the relevant essential health and safety requirements set out in Annex III.

Impact:

"The relevant ESHR" are much more than "a list of the EHSR applied and fulfilled". Now the manufacturer is obliged to make the PCM safe up to certain interfaces.

Before manufacturers of PCM could decide which EHRS to follow. Now, also according to Annex III 1.1.1, manufacturers of PCM need to apply all "possible" EHSR 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."

[91] Obligations of manufacturers of partly completed machinery **Article 10a 2**

New / changed / no change:	no change
Article of Proposal:	10a 2
Old Article:	13 1. (a) + (c)

2006/42/EC:

Procedure for partly completed machinery

1. The manufacturer of partly completed machinery or his authorised representative shall, before placing it on the market, ensure that:

(a) the relevant technical documentation described in Annex VII, part B is prepared;

(c) a declaration of incorporation described in Annex II, part 1, Section B has been drawn up.

Proposal of EU-Council:

2. Before placing a partly completed machinery on the market, manufacturers shall draw up the technical documentation set out in part B of Annex IV.

Where compliance of a partly completed machinery with the relevant essential health and safety requirements laid down in Annex III has been demonstrated in the technical documentation set out in Part B of Annex IV, manufacturers shall draw up the EU declaration of incorporation in accordance with Article 18a.

Impact:

no change here

but the contents of those documents have changed

[92] Obligations of manufacturers of partly completed machinery

Article 10a 3

New / changed / no change:	no change
Article of Proposal:	10a 3
Old Annex:	III 2. IV B

2006/42/EC:

Declarations

2. CUSTODY

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.

Relevant technical documentation for partly completed machinery

The relevant technical documentation must be available for at least 10 years following the date of manufacture of the partly completed machinery or, in the case of series manufacture, of the last unit produced, and on request presented to the competent authorities of the Member States. It does not have to be located in the territory of the Community, nor does it have to be permanently available in material form. It must be capable of being assembled and presented to the relevant authority by the person designated in the declaration for incorporation.

Proposal of EU-Council:

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.

Impact:

no change in meaning

[93] Obligations of manufacturers of partly completed machinery

Article 10a 4

New / changed / no change:	no change
Article of Proposal:	10a 4
Old Annex:	IV B (b)

2006/42/EC:

Relevant technical documentation for partly completed machinery

It shall comprise the following:

(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.

Proposal of EU-Council:

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 shall be adequately taken into account.

Impact:

No change in meaning,

but a clarification on the issue of changes in the state of the art, or the change of standards.

The old text also still remains in Annex IV B. (k). Thus this is now handled at two places. This could be skipped in Annex IV B. (k), or it needs a reference to this Article.

[94] Obligations of manufacturers of partly completed machinery

Article 10a 5

New / changed / no change:	new
Article of Proposal:	10a 5

Proposal of EU-Council:

5. Manufacturers shall ensure that the partly completed machinery which they place on the market bears at least the designation of the partly completed machinery, the year of construction, that is the year in which the manufacturing process is completed, model and series or type and, if any, batch or serial number or other element allowing its identification, or, where the size or nature of the partly completed machinery does not allow it, that the required information is provided on the packaging or in a document accompanying the partly completed machinery.

Impact:

Although regularly done in praxis, there was no formal requirement to outfit a partly completed machinery with a Marking according to old Annex I 1.7.3.

It makes sense to close this legal loophole.

[95] Obligations of manufacturers of partly completed machinery

Article 10a 6

New / changed / no change:	changed
Article of Proposal:	10a 6
EU Regulation on market surveillance, Article:	4

EU-Regulation on market surveillance:

Tasks of economic operators regarding products subject to certain Union harmonisation legislation

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.

Proposal of EU-Council:

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 incorporates the partly completed machinery into a machinery and market surveillance authorities.

Impact:

1. The information must be on the product if possible.
2. A digital contact must be provided, if it exists.
3. 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.

[96] Obligations of manufacturers of partly completed machinery

Article 10a 7

New / changed / no change:	changed
Article of Proposal:	10a 7
Old Article	13 2.
Old Annex:	VI

2006/42/EC:

Procedure for partly completed machinery

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.

Assembly instructions for partly completed machinery

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative.

Proposal of EU-Council:

7. Manufacturers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Annex X

When the assembly instructions are provided in digital format, the manufacturer shall:

- (a) mark on the partly completed machinery and in an accompanying document how to access the digital assembly instructions;
- (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.
- (c) make them accessible online not less than 10 years after the placing on the market of the partly completed machinery.

However, upon request of the person who incorporates the partly completed machinery, at the time of the purchase or up to 6 months after that purchase, assembly instructions shall be provided in paper format free of charge.

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.

Impact:

The content of the assembly instructions was heavily expanded upon (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.

[97] Obligations of manufacturers of partly completed machinery

Article 10a 8

New / changed / no change:	changed
Article of Proposal:	10a 8
Old Article:	13 2.

2006/42/EC:

Procedure for partly completed machinery

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.

Proposal of EU-Council:

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.

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.

Impact:

1. The "declaration of incorporation" has become an "EU declaration of incorporation"
2. It can now be provided in a digital format.

[98] Obligations of manufacturers of partly completed machinery

Article 10a 9

New / changed / no change:	changed
Article of Proposal:	10a 9
EU-Regulation on market surveillance, Article:	4

EU-Regulation on market surveillance:

Tasks of economic operators regarding products subject to certain Union harmonisation legislation

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:

(c) when having reason to believe that a product in question presents a risk, informing the market surveillance authorities thereof;

(d) cooperating with the market surveillance 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.

Proposal of EU-Council:

9. Manufacturers who consider or have reason to believe that a partly completed machinery which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk as regards the essential health and safety requirements, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.

Impact:

It is no longer necessary for the market surveillance authority to make a reasoned request. 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".

[99] Obligations of manufacturers of partly completed machinery

Article 10a 10

New / changed / no change:	changed
Article of Proposal:	10a 10
EU-Regulation on market surveillance, Article:	4 3 b

EU-Regulation on market surveillance:

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:

(a) [...]

(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 the product in a language which can be easily understood by that authority;

Proposal of EU-Council:

10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the partly completed machinery with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks as regards the essential health and safety requirements presented by the partly completed machinery, which they have placed on the market.

Impact:

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.
3. This is an addition to Article 10a 3. [92] 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 10a 3 [92]. However, since no time limit is specified here and no reference is made to Article 10 3, these information have to be kept for at least as long as the product exists.

[100] Authorised representatives

Article 11

New / changed / no change:	changed
Article of Proposal:	11
Old Article	2 j
Old Article:	5 (1)

2006/42/EC:

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:

5 (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;
- (b) ensure that the technical file referred to in Annex VII, part A is available;
- (c) provide, in particular, the necessary information, such as instructions;
- (d) carry out the appropriate procedures for assessing conformity in accordance with Article 12;
- (e) draw up the EC declaration of conformity in accordance with Annex II, part 1, Section A and ensure that it accompanies the machinery;
- (f) affix the CE marking in accordance with Article 16.

Proposal of EU-Council:

1. A manufacturer of a product subject to this Regulation may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 10(1) and Article 10a(1) and the obligation to draw up the technical documentation set out in Annex IV shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- (a) keep the technical documentation and the EU declaration of conformity of machinery and related products or the EU declaration of incorporation of partly completed machinery at the disposal of the national market surveillance authorities for ten years after the product has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the product subject to this Regulation;

(c) cooperate with the competent national authorities, at their request, on any actions taken to eliminate the risks presented by a product subject to this Regulation covered by the authorised representative's mandate.

Impact:

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".

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. [89] and Article 10a 10. [99])

The authorized representative has to work with the authority.

[101] Obligations of importers of machinery and related products

Article 12

New / changed / no change:	new
Article of Proposal:	12
Old Article	2 i
(EU) 2019/1020 -MSR-:	4 3

2006/42/EC:

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

EU-Regulation on market surveillance

Article 4

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:

(a) if the Union harmonisation legislation applicable to the product provides for an EU declaration of conformity or declaration of performance and technical documentation, verifying that the EU declaration of conformity or declaration of performance and technical documentation have been drawn up, keeping the declaration of conformity or declaration of performance at the disposal of market surveillance authorities for the period required by that legislation and ensuring that the technical documentation can be made available to those authorities upon request;

(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 the product in a language which can be easily understood by that authority;

(c) when having reason to believe that a product in question presents a risk, informing the market surveillance authorities thereof;

(d) cooperating with the market surveillance 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.

Proposal of EU-Council:

1. Importers shall place only compliant machinery or related products on the market.

2. Before placing a machinery or related product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 21 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation set out in Part A of Annex IV, that the machinery or related product bears the CE marking referred to in Article 19 and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 10(5) and (6).

Where an importer considers or has reason to believe that a machinery or related product is not in conformity with the applicable 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 or related product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

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 machinery or related product or, where that is not possible, on its packaging or in a document accompanying the machinery or related product. The contact details shall be in a language easily understood by users and market surveillance authorities.

4. Importers shall ensure that the machinery or related product is accompanied by the instructions and information set out in Annex III. The importer shall ensure that the instructions in paper format can be provided to the user in accordance with article 10.7.

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.

The instructions set out in Annex III shall be in a language which can be easily understood by users, as determined by the Member State concerned and shall be clear, understandable, intelligible and legible

5. Importers shall ensure that, while the machinery or related 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.

6. When deemed appropriate with regard to the risks presented by a machinery or related product, importers shall, in order to protect health and safety of persons, and where appropriate, domestic animals and property and, where applicable, the environment carry out sample testing of machinery or related products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery or related products and machinery or related products recalls, and shall keep distributors informed of any such monitoring.

7. Importers who consider or have reason to believe that a machinery or related product, which they have placed on the market, is not in conformity with this Regulation shall immediately take the corrective actions necessary to bring that machinery or related product into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the machinery or

related product presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the machinery or related product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.

8. Importers shall, for ten years after the machinery or related product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation set out in Part A of Annex IV can be made available to those authorities upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery or related products with this Regulation in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks presented by machinery or related products, which they have placed on the market.

Impact:

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".

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.

[102] Obligations of importers of partly completed machinery

Article 12a

New / changed / no change:	new
Article of Proposal:	12a
Old Article:	2 i

2006/42/EC:

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

Proposal of EU-Council:

1. Importers shall place only compliant partly completed machinery on the market.
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).

Where an importer considers or has reason to believe that a partly completed machinery is 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 relevant essential health and safety requirements, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

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 the person who incorporates the partly completed machinery and market surveillance authorities.

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

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.

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.

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 completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.
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.
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 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.

Impact:

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".

2. Currently in the MD importers are treated as manufacturers, if the manufacturer "does 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. Importers are not those persons who import in order to incorporate into their own products.

Such persons are also not manufacturers or distributors.

They are still liable for their own end-product comprising the imported PCM, thus the MPR indirectly applies. The imported PCM would then be treated as if the "not-importers" manufactured this imported product themselves.

[103] Obligations of distributors of machinery and related product

Article 13

New / changed / no change:	new
Article of Proposal:	13

Proposal of EU-Council:

1. When making a machinery or related product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.
2. Before making a machinery or related product available on the market, distributors shall verify that:
 - (a) the machinery or related product bears the CE marking;
 - (b) the machinery or related product is accompanied by the EU declaration of conformity set out in Part A of Annex V
 - (ba) The machinery or related product is accompanied by the instructions and information set out in Annex III , and that they are in a language which can be easily understood by users as determined by the Member State in which the machinery or related product is to be made available on the market. The distributor shall ensure that the instructions in paper format can be provided to the user in accordance with article 10.7.

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 paper format that are essential for putting the machinery or related product into service and for using it in a safe way.

 - (c) the manufacturer and the importer have complied with the requirements set out in Article 10(5) and (6) and Article 12(3) respectively.
3. Where a distributor considers or has reason to believe that a machinery or related product is not in conformity with the essential health and safety requirements set out in Annex III, the distributor shall not make the machinery or related product available on the market until it has been brought into conformity. Furthermore, where the machinery or related product presents a risk , the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities .
4. Distributors shall ensure that, while a machinery or related 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.
5. Distributors who consider or have reason to believe that a machinery or related product, which they have made available on the market, is not in conformity with this Regulation shall make sure that the corrective actions necessary to bring that machinery or related product into

conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the machinery or related product presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they have made the machinery or related product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.

6. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery or related product. They shall cooperate with that authority, at its request, on any actions taken to eliminate the risks presented by a machinery or related product, which they have made available on the market.

Impact:

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 dealers 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.

[104] Obligations of distributors of partly completed machinery

Article 13a

New / changed / no change:	new
Article of Proposal:	13a

Proposal of EU-Council:

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.
2. Before making a partly completed machinery available on the market, distributors shall verify that:
 - (a) the partly completed machinery is accompanied by the EU declaration of incorporation set out in part B of Annex V
 - (aa) the partly completed machinery is accompanied by the assembly instructions set 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
 - (b) the manufacturer and the importer have complied with the requirements set out in Article 10a (5) and (6) and Article 12a (3) respectively.
3. Where a distributor considers or has reason to believe that a partly completed machinery is not in conformity with the relevant essential health and safety requirements 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.
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.
5. Distributors who consider or have reason to believe that a partly completed machinery which they have made available on the market, is not in conformity with this Regulation shall make sure that the corrective actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the partly completed machinery presents a risk as regards applicable essential health and safety requirements, distributors shall immediately inform the competent national authorities of the Member States in which they have made the partly completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective actions taken.

6. Distributors 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. 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.

Impact:

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 are not covered by the MD.

The EU Regulation on market surveillance defines the "distributor" but there are no obligations in regard to its Article 4.

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

Article 14

New / changed / no change:	new
Article of Proposal:	14
Old Article:	2 i

2006/42/EC:

(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 Directive shall be considered a manufacturer;

Proposal of EU-Council:

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 and 10a where that importer or distributor places a product subject to this Regulation on the market under his or her name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.

Impact:

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", see here Article R 10.

2. 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) [45].

3. What is new is the mention of "modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected". This has to be viewed differently from "substantial modification" defined in Article 3 (16) [44] and handled in Article 15 [106].

It is in fact much stricter than any other requirement given in current national papers or the Blue Guide before. Already the chance that the EHSR were affected ("may be") leads to a new product with its own EU declaration.

[106] Other cases in which obligations of manufacturers apply

Article 15

New / changed / no change:	new
Article of Proposal:	15

Proposal of EU-Council:

A natural or legal person, that carries out a substantial modification of a machinery or related product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for that machinery or related product or, if the substantial modification has only an impact on the safety of a part of an assembly of machinery, for the affected machinery of this assembly as demonstrated in the risk assessment.

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.

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 obligations of the manufacturer set out in Article 10.

Impact:

1. Article 15 covers any person other than an importer or distributor, for which much stricter rules apply.

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.

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

3. A "substantial modification" of an assembly can be reduced to a machinery of that assembly, but no further. Recitals (23) wanted to reduce it also for related products.

Currently the German interpretation allows a reduction even down to partly completed machinery. This is more sensible, since most assemblies do not contain any "machinery" but only related products and partly completed machinery. Thus this "reduction of complexity" would never take effect.

4. Non professional users (consumers) as "natural persons" are not in the scope of Art. 15:

If they 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, but the last paragraph of Article 15 states that it does not apply to them.

5. 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 considered. The only law to apply in this case is the work safety directive, where the other companies on site need to consider the risks from this excavator.

6. 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.

7. The question of "substantial modification" has so far only been interpreted in the Blue Guide and national specifications. Therefore, covering this in the European law is important, no matter the content.

8. 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...

[107] Identification of economic operators

Article 16

New / changed / no change:	new
Article of Proposal:	16

Proposal of EU-Council:

1. Economic operators shall, on request, identify the following to the market surveillance authorities:
 - (a) any economic operator who has supplied them with a product subject to this Regulation;
 - (b) any economic operator to whom they have supplied a product subject to this Regulation.
2. Economic operators shall be able to present the information referred to in paragraph 1 for ten years after they have been supplied with the product subject to this Regulation and for ten years after they have supplied the product subject to this Regulation.

Impact:

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", see here Article R 10.
2. Paragraph 2 of the MPR goes beyond EC Decision No 768/2008/EC.
3. The suppliers of all products must be identifiable for ten years.
4. All customers who are economic operators must be identifiable for ten years.

While the first point should already be established in most businesses, point 4 will create problems.

How to do this in a cash business (e.g. hardware store) when some customers are economic operators?

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

[108] Presumption of conformity of products subject to this Regulation

Article 17 1

New / changed / no change:	changed
Article of Proposal:	17 1
Old Article:	7 2

2006/42/EC:

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.

Proposal of EU-Council:

1. A product subject to this Regulation which is in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those standards or parts thereof.

Impact:

no impact

New is a clarification that also partly followed standards can give partly presumption of conformity.

This has already been handled as such in praxis.

[109] Presumption of conformity of products subject to this Regulation

Article 17 2

New / changed / no change:	changed
Article of Proposal:	17 2
Old Article:	2 I

2006/42/EC:

(I) 'harmonised standard' means a non-binding technical specification adopted by a standardisation body, namely the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services

Proposal of EU-Council:

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.

Impact:

no impact

This is only a formal clarification. So far, the MD has had no such direct obligation. However, this has always resulted from the above-mentioned EU regulation.

[110] Presumption of conformity of products subject to this Regulation

Article 17 3

New / changed / no change:	new
Article of Proposal:	17 3

Proposal of EU-Council:

3. The Commission is empowered to adopt implementing acts establishing common specifications to cover the essential health and safety requirements set out in Annex III where the following conditions have been fulfilled:

- (a) no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;
- (b) the Commission has requested, pursuant to Article 10(1) of Regulation 1025/2012, one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements set out in Annex III
- (c) 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 deliverables t does not y comply with the request.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).

Impact:

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 gives the EU leverage against the standardization organizations.

[111] Presumption of conformity of products subject to this Regulation
Article 17 3a

New / changed / no change:	new
Article of Proposal:	17 3a

Proposal of EU-Council:

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.

Impact:

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

[112] Presumption of conformity of products subject to this Regulation
Article 17 3b

New / changed / no change:	new
Article of Proposal:	17 3b

Proposal of EU-Council:

3b. In the early preparation of the draft implementing act establishing 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.

Impact:

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.

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

Article 17 4

New / changed / no change:	new
Article of Proposal:	17 4

Proposal of EU-Council:

4. A product subject to this Regulation which is in conformity with the common specifications established by one or more implementing acts referred to in paragraph 3 or parts thereof shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those common specifications or parts thereof.

Impact:

Like harmonized standards, the common specifications of the EU Commission trigger the presumption of conformity.

[114] Presumption of conformity of products subject to this Regulation
Article 17 4a

New / changed / no change:	new
Article of Proposal:	17 4a

Proposal of EU-Council:

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.

Impact:

This process is not automatic. The common specification is still in effect until repealed.

[115] Presumption of conformity of products subject to this Regulation
Article 17 4b

New / changed / no change:	new
Article of Proposal:	17 4b

Proposal of EU-Council:

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.

Impact:

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". (At the time the common specification was first published?)

[116] Presumption of conformity of products subject to this Regulation
Article 17 5

New / changed / no change:	new
Article of Proposal:	17 5

Proposal of EU-Council:

5. Machinery and related products that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme adopted in accordance with Regulation (EU) 2019/881 and the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III, sections 1.1.9 and 1.2.1, as regards protection against corruption and safety and reliability of control systems in so far as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.

Impact:

This content is already covered by Article 8 [79] and is only a clarification here.

[117] EU declaration of conformity of machinery and related products

Article 18

New / changed / no change:	changed
Article of Proposal:	18
Old Annex:	II 1. A.

2006/42/EC:

The EC declaration of conformity must contain the following particulars:

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;

Proposal of EU-Council:

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.
2. The EU declaration of conformity shall have the model structure set out in part A of Annex V, and shall contain the elements specified in the relevant modules set out in Annexes VI, VIII, IX, and IXa and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the machinery or related product is placed on the market, is made available on the market or put into service.
3. Where a machinery or related product is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.
4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the machinery or related product with the requirements laid down in this Regulation.

Impact:

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, additional requirements are formulated in Annex V:

The first point is not yet a separate part of the required content of the EC declaration of conformity in Annex II 1 A of the Machinery Directive. However, this statement is already contained in its further declaration according to Annex V that the machinery complies with the

Machinery Directive. The first point is not listed separately in the proposed Annex V of the MPR, but the general explanation is.

The second point requires additional elements to be included in Annexes VI, VII, VIII and IX. 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 declaration begins.

[118] EU declaration of incorporation of partly completed machinery

Article 18a

New / changed / no change:	changed
Article of Proposal:	18a
Old Annex:	II B

2006/42/EC:

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.

The declaration of incorporation must contain the following particulars:

4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the Official Journal of the European Union;

Proposal of EU-Council:

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.
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.
3. Where a partly completed machinery is subject to more than one Union act requiring an EU declaration of conformity, the EU declaration of incorporation shall include a sentence declaring the conformity with such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.
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.

Impact:

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

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

no other change here

[119] General principles of the CE marking

Article 19

New / changed / no change:	no change
Article of Proposal:	19
Old Article:	16

2006/42/EC:

CE marking

1. The CE conformity marking shall consist of the initials 'CE' as shown in Annex III.
2. The CE marking shall be affixed to the machinery visibly, legibly and indelibly in accordance with Annex III.
3. The affixing on machinery of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both, shall be prohibited. Any other marking may be affixed to the machinery provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

Proposal of EU-Council:

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Remark:

Article 30 of Regulation (EC) No 765/2008:

General principles of the CE marking

1. The CE marking shall be affixed only by the manufacturer or his authorised representative.
2. The CE marking as presented in Annex II shall be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation, and shall not be affixed to any other product.
3. By affixing or having affixed the CE marking, the manufacturer indicates that he takes responsibility for the conformity of the product with all applicable requirements set out in the relevant Community harmonisation legislation providing for its affixing.
4. The CE marking shall be the only marking which attests the conformity of the product with the applicable requirements of the relevant Community harmonisation legislation providing for its affixing.
5. The affixing to a product of markings, signs or inscriptions which are likely to mislead third parties regarding the meaning or form of the CE marking shall be prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking is not thereby impaired.

6. Without prejudice to Article 41, Member States shall ensure the correct implementation of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

Impact:

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.

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

Article 20 1

New / changed / no change:	changed
Article of Proposal:	20 1
Old Article:	16 2

2006/42/EC:

2. The CE marking shall be affixed to the machinery visibly, legibly and indelibly in accordance with Annex III.

Proposal of EU-Council:

1. The CE marking shall be affixed visibly, legibly and indelibly to the machinery or related product. Where that is not possible or not warranted on account of the nature of the machinery or related product, it shall be affixed to the packaging and to the documents accompanying the machinery or related product.

Impact:

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.

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

Article 20 2

New / changed / no change:	no change
Article of Proposal:	20 2
Old Article:	5 1f

2006/42/EC:

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.

Proposal of EU-Council:

2. The CE marking shall be affixed before the machinery or related product is placed on the market or put into service.

Impact:

no change

This Requirement is already covered by the requirement of Article 10 2 [82].

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

Article 20 3

New / changed / no change:	changed
Article of Proposal:	20 3
Old Annex:	III

2006/42/EC:

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.

Proposal of EU-Council:

3. Where the conformity of machinery or related products is assessed in accordance with 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) , the CE marking shall be followed by the identification number of the notified body involved in that procedure.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.

Impact:

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

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

Article 20 4

New / changed / no change:	changed
Article of Proposal:	20 4
Old Annex:	III

2006/42/EC:

[...]

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.

Proposal of EU-Council:

4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or any other marking indicating a special risk or use.

Impact:

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.

A new label is required, which indicates a special risk or a special use. This should be located next to the CE marking.

However, no such special risk is defined in the MPR. Thus this part should be omitted from the MPR, since it leads to confusions.

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

Article 20 5

New / changed / no change:	changed
Article of Proposal:	20 5
Old Article:	17

2006/42/EC:

Non-conformity of marking

1. Member States shall consider the following marking not to conform:

(a) the affixing of the CE marking pursuant to this Directive on products not covered by this Directive;

(b) the absence of the CE marking and/or the absence of the EC declaration of conformity for machinery;

(c) the affixing on machinery of a marking, other than the CE marking, which is prohibited under Article 16(3).

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.

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.

Proposal of EU-Council:

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.

Impact:

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.

[125] Conformity assessment procedures for machinery and related products

Article 21 1

New / changed / no change:	no change
Article of Proposal:	21 1
Old Article:	12 1

2006/42/EC:

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.

Proposal of EU-Council:

1. The manufacturer of machinery or a related product shall apply one of the procedures for assessment of conformity referred to in paragraphs 2, 2a and 3.

Impact:

no change

[126] Conformity assessment procedures for machinery and related products

Article 21 2

New / changed / no change:	changed
Article of Proposal:	21 2
Old Article:	12 4

2006/42/EC:

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:

- (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;
- (b) the full quality assurance procedure provided for in Annex X.

Proposal of EU-Council:

2. Where the machinery or related product is listed in Annex I part A, the manufacturer shall apply one of the following procedures:

- (a) EU type-examination procedure (module B) set out in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;
- (b) Conformity based on full quality assurance (module H) set out in Annex IX;
- (c) Conformity based on unit verification (module G) set out in Annex IXa.

Impact:

The obligation for substantially modified "Appendix I A machinery or related product" has been added.

This was changed, because Annex I A machinery products now have to involve notified bodies.

[127] Conformity assessment procedures for machinery and related products

Article 21 2a

New / changed / no change:	changed
Article of Proposal:	21 2a
Old Article:	12 3

2006/42/EC:

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:

- (a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII;
- (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;
- (c) the full quality assurance procedure provided for in Annex X.

Proposal of EU-Council:

2a. Where the machinery or related product is listed in Annex I part B the manufacturer shall apply one of the following procedures:

- (a) Conformity with the internal production control procedure (module A) set out in Annex VI;
- (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;
- (c) Conformity based on full quality assurance (module H) set out in Annex IX;
- (d) Conformity based on unit verification (module G) set out in Annex IXa.

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.

Where the machinery or related product is listed in Annex I part B and has not been manufactured in accordance with the harmonized standards or common specifications specific for that category of machinery or related product and provided that those standards covering all the relevant essential health and safety requirements, the manufacturer shall apply one of the procedures referred to in paragraph 2.a(b),(c) or(d)

Impact:

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

However, the way the last paragraph is written, you only have to go to a notified body if product is in Annex I Part B AND no harmonised standard is used AND those standards cover all EHSR

while before it was

product is in Annex IV AND (no harmonised standard is used OR those standards do not cover all EHSR)

Thus, you only have to use harmonised standards, if those cover all EHSR. If no such standards exist, no notified body is needed.

This is somewhat covered by Article 5 5. which states that all such products need to be moved to Part A, but this will take 5 years and then the authorities have to implement the change.

[128] Conformity assessment procedures for machinery and related products

Article 21 3

New / changed / no change:	no change
Article of Proposal:	21 3
Old Article:	12 2

2006/42/EC:

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.

Proposal of EU-Council:

3. Where the machinery or related product is not listed in Annex I, the manufacturer shall apply the internal production control procedure (module A) set out in Annex VI.

Impact:

no change