

Machinery Product Regulation

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Changes in MPR Articles 1 to 23¹



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

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

We are presenting to you the first 23 Articles of this Regulation together with the appropriate Articles / Annexes of the Machinery Directive 2006/42/EC.

In 61 cases we have noticed an impact on the current market process and addressed it as such. Some cases are minor other are major.

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

----- Deutsch -----

Die Europäische Kommission hat am 21. April 2021 den Vorschlag der Maschinenproduktverordnung veröffentlicht.

Wir präsentieren Ihnen die ersten 23 Artikel dieses Entwurfs soweit möglich gegenübergestellt den entsprechenden Artikeln / Anhängen der Maschinenrichtlinie 2006/42/EG.

In 61 Fällen haben wir Auswirkungen auf den aktuellen Marktprozess festgestellt und als solche beschrieben. Einige Fälle sind geringfügig, andere schwerwiegend.

Referenzen in den von uns beschriebenen Auswirkungen werden als [Nummer] angegeben, entsprechend dem einschlägigen Kapitel.

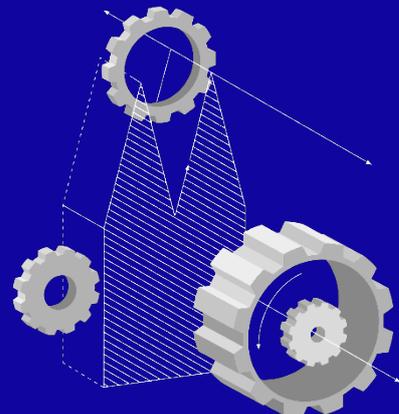
Major changes

[2] The partly completed machinery (PCM) is now included in the overall definition of the new term "machinery product".

This has led to a lot of confusion, because it has not been properly applied in all Articles.

[97][98] Annex I machinery (formerly Annex IV) now must be tested by a notified body, regardless of harmonized standards.

[8] ff. Among the exceptions from the MPR, vehicles face the most changes. Some are newly out, some are newly in.



¹ Market surveillance and notified bodies still to come

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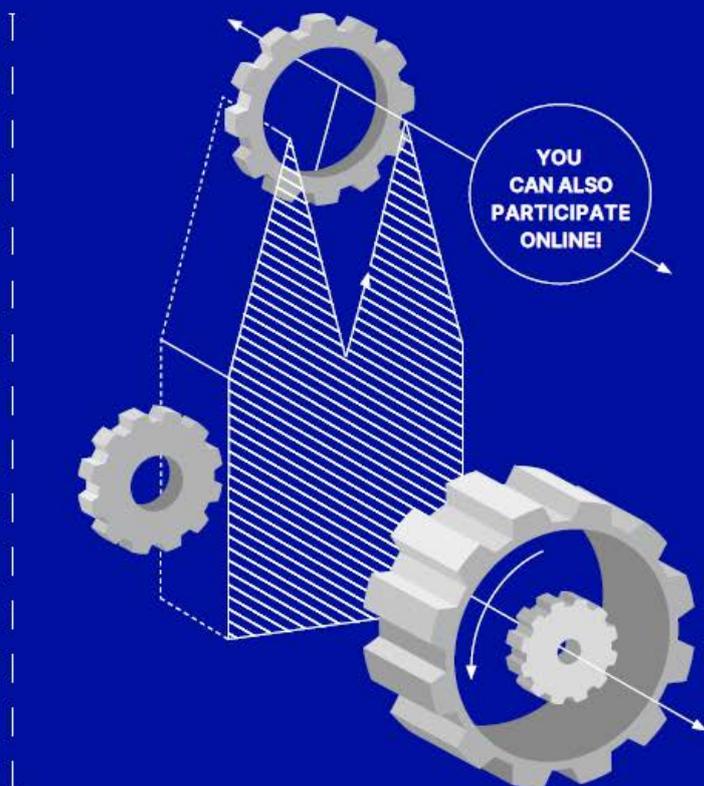
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[1] Subject matter

Article 1

New Article: 1

New / changed / moved / no change: new

New text:

This Regulation lays down requirements for the design and construction of machinery products to allow the making available on the market or putting into service of machinery products, and establishes rules on the free movement of machinery products in the Union.

Old text:

Impact / Motivation:

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

Einfluss / Motivation:

Dieser Text hat keine rechtliche Bedeutung. Er ist nur ein Vorwort.

[2] Scope

Article 2 1

New Article:	2 1
Old Article:	2
New / changed / moved / no change:	changed

New text:

This Regulation applies to the following machinery products

(a) [...] (g)

Old text:

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

Impact / Motivation:

1. The partly completed machinery (PCM) is thus covered by the generic term "machinery product" (previously: "machinery").
2. The term "machinery" is now distinguishable from the general term "machinery product".
3. The general term "machinery product" is now defined in Article 2 [2] before any legal text. It now clearly applies to all provisions in Article 2.

Einfluss / Motivation:

1. Die unvollständige Maschine (uvM) wird damit von dem Oberbegriff "Maschinenprodukt" (vorher: Maschine) erfasst.
2. Die Bezeichnung "Maschine" und der Sammelbegriff "Maschinenprodukt" können nun unterschieden werden.
3. Der allgemeine Begriff "Maschinenprodukt" wird jetzt in Artikel 2 [2] vor dem Rechtstext definiert. Er gilt jetzt eindeutig auch für alle Bestimmungen in Artikel 2.

[3] Scope

Article 2 1

New Article:	2 1
Old Article:	1 1
New / changed / moved / no change:	changed

New text:

(1) This Regulation applies to the following machinery products

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

Old text:

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;
- (g) partly completed machinery.

Impact / Motivation:

For the term "Machinery Product" see [2].

Slings (2 1. e) are now clearly in the scope of the Machinery Product Regulation. They are defined in Article 3 (7) [33].

Einfluss / Motivation:

Zum Oberbegriff „Maschinenprodukt“ siehe [2].

Schlingen sind nun eindeutig im Anwendungsbereich der Maschinenprodukteverordnung. Sie sind definiert in Artikel 3 (7) [33].

[4] Scope

Article 2 2a

New Article:	2 2a
Old Article:	1 2a
New / changed / moved / no change:	changed

New text:

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 product;

Old text:

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;

Impact / Motivation:

The exclusion of safety components as spare parts from the original machine manufacturer has now been extended to the delivery of all "machinery products" from their original manufacturer. Previously, this exception only applied to manufacturers of "machinery in the narrower sense". Now all spare parts from the original manufacturer of a "machinery product" are excluded, as far as they are safety components. This also includes safety components for PCM and for safety components themselves. See Article 2 [2]

The spare parts regulation is thus greatly expanded.

Einfluss / Motivation:

Der Ausschluss von Sicherheitsbauteilen als Ersatzteile des Originalmaschinenherstellers wurde jetzt auf die Lieferung aller „Maschinenprodukte“ von deren Originalhersteller ausgedehnt. Vorher galt diese Ausnahme nur für den Hersteller von „Maschinen im engeren Sinn“. Jetzt werden alle Ersatzteile vom Originalhersteller eines „Maschinenprodukts“ ausgenommen, soweit es sich um Sicherheitsbauteile handelt. Das schließt auch Sicherheitsbauteile für uvM und für Sicherheitsbauteile selbst ein. Siehe Artikel 2 [2]

Die Ersatzteilregelung wird damit stark ausgedehnt.

[5] Scope

Article 2 2b

New Article:	2 2b
Old Article:	1 2b
New / changed / moved / no change:	no change

New text:

(2) This Regulation does not apply to:

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

Old text:

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

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

Impact / Motivation:

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

A 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"

Einfluss / Motivation:

Das Wort "und" wurde gestrichen. Eine rein redaktionelle Änderung.

Ein bestehendes Problem ist, dass "fairground" sowohl ein Jahrmarkt als auch ein Messegelände ist.

[6] Scope

Article 2 2c

New Article:	2 2c
Old Article:	1 2c
New / changed / moved / no change:	no change

New text:

(2) This Regulation does not apply to:

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

Old text:

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;

Impact / Motivation:

This exception now only applies to machinery and not to other machinery products.

Einfluss / Motivation:

Diese Ausnahme gilt danach nur für Maschinen und nicht für die anderen Maschinenprodukte.

[7] Scope

Article 2 2d

New Article:	2 2d
Old Article:	1 2d
New / changed / moved / no change:	no change

New text:

(2) This Regulation does not apply to:

(d) weapons, including firearms;

Old text:

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

(d) weapons, including firearms;

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[8] Scope

Article 2 2e

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

New text:

(2) This Regulation does not apply to:

(e) vehicles which have as their only objective the transport of goods or persons by road, air, water or rail except for machinery mounted on those vehicles

Old text:

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

Impact / Motivation:

1. There is a new general exclusion of all vehicles that transport goods or persons on roads.
2. The exclusion for "means of transport [...] on rail networks" has been extended to "transport of goods or persons by rails".
3. The "means of transport" was specified as "transport of goods or persons".

This change to 1. was driven by the pedelec lobby. There is a desire here for a separate regulation for pedelecs. Until this regulation comes into being, however, pedelecs would then again be subject to national legislation.

This exception also applies to any other means of transport by road, such as busses and luggage transport on an airport apron. Industrial trucks (e.g. forklifts) would also be excluded, as they only transport (horizontally and vertically) and drive on internal roads. The term "road" is not limited to public roads, but includes roads in the broadest sense.

The expansion of the rail network (2.) to include rails has similar effects. E.g. cranes traveling on rails are now completely excluded.

These changes affect many machines. This would mean that many machinery products would be excluded from the Machinery Product Regulation. It can be doubted that this was intended.

Einfluss / Motivation:

1. Es gibt eine neue generelle Ausnahme für alle Fahrzeuge die Güter oder Personen auf Straßen transportieren.
2. Die Ausnahme der Transportmittel auf „Schienennetzen“ wurde auf „Transport von Gütern oder Personen auf Schienen“ erweitert.

3. Der „Transportzweck“ wurde spezifiziert als „Transport von Gütern oder Personen“.

Diese Änderung zu 1. wurde von der Pedelec-Lobby vorangetrieben. Hier besteht der Wunsch nach einer eigenen Vorschrift für Pedelecs. Bis zum Entstehen dieser Vorschrift würden Pedelecs dann allerdings wieder einzelstaatlicher Gesetzgebung unterliegen.

Unter diese Ausnahme fällt aber auch jedes andere Transportmittel auf Straßen, wie z.B. Busse und Gepäcktransport auf einem Flughafenvorfeld. Auch Flurförderzeuge wären damit ausgenommen, da sie nur (horizontal und vertikal) transportieren und auf innerbetrieblichen Straßen fahren. Der Begriff „Straße“ beschränkt sich insofern nicht auf öffentliche Straßen, sondern erfasst Straßen im weitesten Sinne.

Die Ausweitung des Schienennetzes (2.) auf Schienen hat ähnliche Auswirkungen. Z.B. sind jetzt auf Schienen verfahrbare Kräne, vollständig ausgeschlossen.

Die Änderungen wirken sich auf viele Maschinen aus. Damit würden viele Maschinenprodukten, aus der Maschinenproduktverordnung ausgenommen. Es darf bezweifelt werden, dass das so gewollt ist.

[9] Scope

Article 2 2f

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

New text:

(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;

Old text:

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,

Impact / Motivation:

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

2. The exclusion from the exception, machinery that is installed on these vehicles, is no longer applicable.

Such vehicles, including all machines mounted on them, are now excluded.

Since all vehicle exemptions stand on their own, the general exception of road vehicles according to Article 2 Paragraph 2 e [8] is extended for these vehicles with regard to the "machinery mounted on these vehicles".

Einfluss / Motivation:

1. Es wird klargestellt, dass Systeme, Komponenten, separate technische Einheiten, Teile und Ausrüstungen für diese Fahrzeuge ausgeschlossen sind.

2. Der Ausschluss der Ausnahme, von Maschinen, die auf diesen Fahrzeugen angebracht sind, ist entfallen.

Solche Fahrzeuge sind jetzt einschließlich aller darauf montierten Maschinen ausgeschlossen.

Da alle Fahrzeugausnahmen für sich alleine stehen, wird für diese Fahrzeuge in Bezug auf die „darauf angebrachten Maschinen“ der allgemeine Ausschluss von Straßenfahrzeugen nach Artikel 2 Absatz 2 Buchstabe e [8] erweitert.

[10] Scope Article 2 2g

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

New text:

(2) This Regulation does not apply to:

(g) agricultural and forestry vehicles, 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 167/2013

Old text:

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

Impact / Motivation:

1. It is made clear that systems, components, separate technical units, parts and equipment for these vehicles are excluded.
 2. The exclusion from the exception, machinery that is installed on these vehicles, is no longer applicable.
 3. Only vehicles that fall within the scope of the referred EU Regulation are excluded.
- (see also [9])

Such vehicles, including all machines mounted on them, are now excluded.

Since all vehicle exemptions stand on their own, the general exception of road vehicles according to Article 2 Paragraph 2 e [8] is extended for these vehicles with regard to the "machinery mounted on these vehicles".

Einfluss / Motivation:

1. Es wird klargestellt, dass Systeme, Komponenten, separate technische Einheiten, Teile und Ausrüstungen für diese Fahrzeuge ausgeschlossen sind.
 2. Der Ausschluss von Maschinen, die auf diesen Fahrzeugen angebracht sind, ist entfallen.
 3. Es sind nur noch die Fahrzeuge ausgenommen, in den Anwendungsbereich der genannten EU-Verordnung fallen.
- (siehe auch [9])

Solche Fahrzeuge sind jetzt einschließlich aller darauf montierten Maschinen ausgeschlossen.

Da alle Fahrzeugausnahmen für sich alleine stehen, wird für diese Fahrzeuge in Bezug auf die „darauf angebrachten Maschinen“ der allgemeine Ausschluss von Straßenfahrzeugen nach Artikel 2 Absatz 2 Buchstabe e [8] erweitert.

[11] Scope

New Article:

Old Article:

1 2e -2

New / changed / moved / no change:

deleted

New text:

-

Old text:

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,

Impact / Motivation:

This exception no longer applies.

However, vehicles on roads are not in the scope of the MPR, according to the provisions in Article 2 2e [9].

Since trailers are not mentioned in the general exception in Article 2 2e [9], such trailers are in the scope of the MPR, however, taking into account the provision for the application of special guidelines in Article 8 [67].

Einfluss / Motivation:

Diese Ausnahme ist weggefallen.

Die Fahrzeuge auf Straßen fallen allerdings nach den Bestimmungen in Artikel 2 2e [9] aus der MPVO heraus.

Da in der allgemeinen Ausnahme in Artikel 2 2e [9] allerdings Anhänger nicht erwähnt werden, fallen solche Anhänger jetzt in den Anwendungsbereich der MPVO, jedoch unter Beachtung der Regelung für die Anwendung spezieller Richtlinien in Artikel 8 [67].

[12] Scope

New Article:

Old Article:

1 2e -4

New / changed / moved / no change:

deleted

New text:

-

Old text:

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

(e) the following means of transport:

— motor vehicles exclusively intended for competition

Impact / Motivation:

This exception no longer applies.

Motor vehicles intended for competition that do not drive on roads [8] thus fall within the scope of the MPR. This applies, for example, to dirt bikes, off-road rally vehicles and similar products.

Einfluss / Motivation:

Diese Ausnahme ist weggefallen.

Kraftfahrzeuge für sportliche Wettbewerbe, die jedoch nicht auf Straßen fahren [8], fallen damit in den Anwendungsbereich der MPVO. Dies betrifft z.B. Dirtbikes, Rallye-Geländewagen und ähnliche Produkte.

[13] Scope

Article 2 2h

New Article: 2 2h

Old Article: 1 2f

New / changed / moved / no change: no change

New text:

(2) This Regulation does not apply to:

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

Old text:

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;

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[14] Scope

Article 2 2i

New Article: 2 2i

Old Article: 1 2g

New / changed / moved / no change: no change

New text:

(2) This Regulation does not apply to:

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

Old text:

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

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

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[15] Scope

Article 2 2j

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

New text:

(2) This Regulation does not apply to:

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

Old text:

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;

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[16] Scope

Article 2 2k

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

New text:

(2) This Regulation does not apply to:

(k) mine winding gear;

Old text:

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

(i) mine winding gear;

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[17] Scope

Article 2 2l

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

New text:

(2) This Regulation does not apply to:

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

Old text:

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

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

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[18] Scope

Article 2 2m

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

New text:

(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

Old text:

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

Impact / Motivation:

Special products that fall within the scope of the Low Voltage Directive and have therefore been excluded are now also excluded if they fall within the scope of the Radio Equipment Directive.

This change is necessary for the status quo. If these products fall within the scope of the Radio Equipment Directive, they no longer fall within the scope of the Low Voltage Directive and the exemption clause then comes to nothing.

In practice, this currently means that products without radio signals (e.g. Roomba without Wi-Fi) fall under the scope of the Low Voltage Directive and not the Machinery Directive. The same product with a radio signal (e.g. Roomba with Wi-Fi) is subject to the Radio Equipment Directive and not the Low Voltage Directive, so the machinery directive applies here.

The new exception rectifies this problem.

Einfluss / Motivation:

Spezielle Produkte, die in den Anwendungsbereich der Niederspannungsrichtlinie fallen und deshalb ausgenommen wurden, sind jetzt auch ausgenommen, wenn sie in den Anwendungsbereich der Funkanlagenrichtlinie fallen.

Diese Änderung ist notwendig für den Status Quo. Diese Produkte fallen, wenn sie in den Anwendungsbereich der Funkgeräte richtlinie fallen, nicht mehr in den Anwendungsbereich der Niederspannungsrichtlinie und die Ausnahmeregelung läuft dann leer.

In der Praxis führt dies derzeit dazu, dass Produkte ohne Funksignale (z. B. Roomba ohne WiFi) unter den Anwendungsbereich der Niederspannungsrichtlinie und nicht der Maschinenrichtlinie fallen. Dasselbe Produkt mit Funksignal (z. B. Roomba mit WiFi) unterliegt aber der Funkanlagenrichtlinie und nicht der Niederspannungsrichtlinie so dass hier die Maschinenrichtlinie greift.

Die neue Ausnahme behebt dieses Problem.

[19] Scope

Article 2 2m i

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

New text:

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

Old text:

- household appliances intended for domestic use

Impact / Motivation:

This change is only a clarification.

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

Einfluss / Motivation:

Diese Änderung ist nur eine Klarstellung.

(Elektrisch betriebene) Möbel gelten seit jeher nicht als Haushaltsgeräte.

[20] Scope

Article 2 2m ii

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

New text:

(ii) audio and video equipment;

Old text:

- audio and video equipment

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[21] Scope

Article 2 2m iii

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

New text:

(iii) information technology equipment;

Old text:

- information technology equipment

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[22] Scope

Article 2 2m iv

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

New text:
(iv) office machinery

Old text:
- ordinary office machinery

Impact / Motivation:

The term "ordinary" was dropped. Thus discussions on its meaning can now stop.

Now small 3d-printer are clearly in this category, since they are used in offices.

Still unclear is, how large, complex and unique office machinery can be. E.g. how large can a printer become, before it is no longer an office printer. I.e. the delimitation is still unclear.

Einfluss / Motivation:

Der Begriff "gewöhnlich" wurde gestrichen. Somit können Diskussionen über seine Bedeutung jetzt aufhören.

Jetzt gehören kleine 3D-Drucker eindeutig zu dieser Kategorie, da sie in Büros eingesetzt werden.

Noch unklar ist, wie groß, komplex und einzigartig Büromaschinen sein können. Z.B. wie groß kann ein Drucker werden, bevor er kein Bürodrucker mehr ist? D.h. die Abgrenzung ist nach wie vor unklar.

[23] Scope

Article 2 2m v

New Article:	2 2m v
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Old Article:	1 2k -5
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New / changed / moved / no change:	no change
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New text:

(v) low-voltage switchgear and control gear;

Old text:

- low-voltage switchgear and control gear

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[24] Scope

Article 2 2m vi

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

New text:

(vi) electric motors;

Old text:

- electric motors

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[25] Scope

Article 2 2n

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

New text:

- (2) This Regulation does not apply to:
- (n) the following high-voltage electrical products:
- (i) switch gear and control gear;
 - (ii) transformers.

Old text:

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.

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[26] Definitions

Article 3 0

New Article:	3 0
Old Article:	2 0
New / changed / moved / no change:	changed

New text:

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

Old text:

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

The following definitions shall apply:

Impact / Motivation:

see [2]

Einfluss / Motivation:

siehe [2]

[27] Definitions

Article 3 1a-e

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

New text:

(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 (7) 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;

Old text:

(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;

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[28] Definitions

Article 3 1f

New Article:

3 1f

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

Similar to Article 3 1 (b) and (c) [27], machines may also lack software that is required "for their specific application". That means special software for customer-specific use that is installed by the machine buyer. The limits for the software are the intended use.

This should not refer to the necessary safety software, but this is not excluded according to the EU proposal. In particular, a definition for the "specific application" is missing here in order to rule this out.

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 the specific application.

In the case of a system written in a high-level language (e.g. C), all software is definitely written for the "specific application" only.

Einfluss / Motivation:

Ähnlich wie in Artikel 3 1 (b) und (c) [27] darf bei Maschinen danach auch Software, die "für ihre bestimmte Anwendung" benötigt wird, fehlen. D.h. spezielle Software für die konkrete kundenspezifische Verwendung, die vom Maschinenkäufer aufgespielt wird. Die Grenzen für die Software liegen in der bestimmungsgemäßen Verwendung.

Das sollte sich nicht auf die notwendige Sicherheitssoftware beziehen, ist aber nach dem EU-Vorschlag nicht ausgeschlossen. Hier fehlt insbesondere eine Definition für die „bestimmte Anwendung“ um das auszuschließen.

Da es keine Definition für "bestimmte Anwendung" gibt, könnte interpretiert werden, dass das komplette Betriebssystem einer SPS fehlen darf, da die Maschine dieses für die bestimmte Anwendung benötigt.

Im Fall eines Systems, das in einer Hochsprache (z. B. C) geschrieben ist, ist die gesamte Software definitiv nur für die "bestimmte Anwendung" geschrieben.

[29] Definitions

Article 3 2

New Article:	3 2
Old Article:	2 b
New / changed / moved / no change:	changed

New text:

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

Old text:

(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

Impact / Motivation:

1. Since the word "tractors" has been deleted from the definition, interchangeable equipment for tractors no longer falls within the scope of the Machine Product Regulation.

Tractors, including their equipment, will be excluded from the scope of the Machine Product Regulation. [10]

Such "interchangeable equipment" for tractors would then possibly fall within the scope of other directives (e.g. radio equipment directive, if applicable) or be subject to national regulations.

2. Interchangeable equipment for PCM now fall within the scope of the Machine Product Regulation. See Article 2 [2]

Einfluss / Motivation:

1. Da das Wort "Traktoren" aus der Definition gestrichen wurden, fallen danach auswechselbare Ausrüstungen für Traktoren nicht mehr in den Anwendungsbereich der Maschinenproduktverordnung.

Traktoren sollen incl. ihrer Ausrüstungen vom Anwendungsbereich der Maschinenproduktverordnung ausgenommen werden. [10]

Solche „auswechselbare Ausrüstungen“ für Traktoren würden danach ggf. in den Anwendungsbereich anderer Richtlinien fallen (z. B. Funkanlagenrichtlinie, falls zutreffend) oder nationalen Regelungen unterliegen.

2. Auswechselbare Ausrüstung für uvM fallen danach in den Anwendungsbereich der Maschinenproduktverordnung. Siehe Artikel 2 [2]

[30] Definitions

Article 3 3

New Article:	3 3
Old Article:	2 c
New / changed / moved / no change:	changed

New text:

(3) 'safety component' means a physical or digital component, including software, of machinery

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 machinery to function or may be substituted by normal components in order for the machinery to function;

Old text:

(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.

Impact / Motivation:

1. Software can now be a safety component.
2. Safety components are limited to components for "machines". See Articles 2 [2] and [27] [28].

Since afterwards a "safety component" for another safety component is no longer a safety component in the sense of the MPR, software for a safety component is not a safety component. (e.g. the software for a laser scanner would not be a safety component)

Before the collective term "machinery product", which was newly defined in the MPR, the collective term "machine" included all products in the scope of the Machinery Directive, except PCM. Thus, safety components for "interchangeable equipment" and "removable mechanical transmission devices" would no longer be safety components in the future.

Einfluss / Motivation:

1. Software kann jetzt ein Sicherheitsbauteil sein.

2. Sicherheitsbauteile sind beschränkt auf Bauteile für „Maschinen“. Siehe Artikel 2 [2] sowie [27][28].

Da danach ein „Sicherheitsbauteil“ für ein anderes Sicherheitsbauteil kein Sicherheitsbauteil im Sinne der MPVO mehr ist, ist Software für ein Sicherheitsbauteil kein Sicherheitsbauteil. (z. B. wäre die Software für einen Laserscanner kein Sicherheitsbauteil)

Vor dem in der MPVO neu definierten Sammelbegriff „Maschinenprodukt“ umfasste der Sammelbegriff "Maschine" alle Produkte im Anwendungsbereich der Maschinenrichtlinie außer uvM. Somit wären Sicherheitsbauteile für „auswechselbare Ausrüstungen“ und „abnehmbare Gelenkwellen“ zukünftig keine Sicherheitsbauteile mehr.

[31] Definitions

Article 3 4

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

New text:

(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;

Old text:

(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;

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[32] Definitions

Article 3 5, 6, 8

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

New text:

(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;

Old text:

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

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[33] Definitions

Article 3 7

New Article:

3 7

New / changed / moved / no change:

new

New text:

(7) 'slings' means slings designed and constructed for lifting purposes as part of lifting machinery or lifting accessories;

Old text:

Impact / Motivation:

Slings that, when used as intended, become part of a lifting machine, should fall under the scope of the MPR. So far, only those slings that are load handling devices have come under the scope of the Machinery Directive. [31]

Einfluss / Motivation:

Schlingen, mit der bestimmungsgemäßen Verwendung Bestandteil einer Hebemaschine zu werden, sollen unter den Anwendungsbereich der MPVO fallen. Bisher fallen nur solche Schlingen unter den Anwendungsbereich der Maschinenrichtlinie, die Lastaufnahmemittel sind. [31]

[34] Definitions

Article 3 9

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

New text:

(9) 'removable mechanical transmission device' means a removable component for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing;

Old text:

(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;

Impact / Motivation:

The phrase "When it is placed on the market with the guard it shall be regarded as one product" has been omitted. This was just a clarification. Deleting this part of the definition does not change the fact that it is a product when it is made available on the market in an assembled state.

Einfluss / Motivation:

Der Satzteil "Wird die Vorrichtung zusammen mit der Schutzeinrichtung in Verkehr gebracht, ist diese Kombination als ein einziges Erzeugnis anzusehen" ist entfallen. Dies war lediglich eine Klarstellung. Das Löschen dieses Teils der Definition ändert nichts an der Tatsache, dass es sich um ein Produkt handelt, wenn es zusammengesetzt auf dem Markt bereitgestellt wird.

[35] Definitions

Article 3 10

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

New text:

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

Old text:

(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

Impact / Motivation:

1. The term "almost" was dropped from "almost machinery".
2. The previous part of the sentence "but which cannot in itself perform a specific application" has been rewritten to "but for the fact that it cannot in itself function so as to perform a specific application".
3. The "Drive system" example has been deleted.
4. PCM can now be used to create "machinery products", so now also for new PCM.

With the clarification that PCM are "machinery" in the sense of the MPR, it is made clear that the machine definition in Article 3 (1) (a) is also relevant for PCM. [27] That is, PCM are also put together for a "specific application". According to the definition, they cannot carry out this specific application "in itself", that is, on their own. To do this, they must first be assembled with other machinery, etc. or equipment.

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.

PCM have always been seen in the scope of the Machinery Directive if they were intended to be integrated into other PCM. To this extent, this change has no effect on practice.

Einfluss / Motivation:

1. Der Begriff "fast" wurde aus "fast eine Maschinen" gestrichen.

2. Der bisherige Satzteil "für sich genommen aber keine bestimmte Anwendung erfüllen kann" wurde geändert in "aber für die Tatsache, dass sie nicht für sich genommen funktionieren kann, um eine bestimmte Anwendung auszuführen" umgeschrieben.

3. Das Beispiel "Antriebssystem" wurde gelöscht.

4. UvM kann nun zur Bildung von "Maschinenprodukten" verwendet werden, also jetzt auch für neue uvM.

Mit der Klarstellung, dass uvM „Maschinen“ im Sinne der MPVO sind, wird deutlich gemacht, dass auch für uvM die Maschinendefinition in Artikel 3 Abs.1 (a) einschlägig ist. [27] D.h., uvM sind auch für eine „bestimmungsgemäße Verwendung“ zusammengefügt. Diese bestimmungsgemäße Verwendung können sie nach der Definition nur nicht „für sich genommen“, das heißt alleine ausführen. Sie müssen dazu erst mit anderen Maschinen, uvM oder Ausrüstungen zusammengebaut werden.

Das Löschen des Beispiels „Antriebssystems“ bedeutet nicht, dass Antriebssysteme zukünftig keine uvM mehr sind. Es ist nur unüblich in Rechtstexten Beispiele aufzulisten, so dass die Streichung konsequent ist.

UvM wurden schon immer im Anwendungsbereich der Maschinenrichtlinie gesehen, wenn sie dazu bestimmt waren in andere uvM integriert zu werden. Diese Änderung hat insofern keine Auswirkungen auf die Praxis.

[36] Definitions

Article 3 11

New Article:

3 11

New / changed / moved / no change:

new

New text:

(11) 'making available on the market' means any supply of a machinery product for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge

Old text:

Impact / Motivation:

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 term "commercial activity" makes it clear that the Machinery Product Regulation is not aimed at private individuals. This is already regulated in the AEU Treaty and therefore has no factual effects. That has always been the case, but it was not specified in the Machinery Directive itself.

Einfluss / Motivation:

Die MPVO folgt hier, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien". Damit wird auch die gesamte Handelskette mit den betroffenen Wirtschaftsakteuren erfasst. Diese Anpassung ist bereits 2014 bei vielen anderen Produktrichtlinien erfolgt.

Der Begriff "gewerbliche Tätigkeit" verdeutlicht, dass die Maschinenproduktverordnung sich nicht an Privatpersonen richtet. Dies ist bereits im AEU-Vertrag so geregelt und hat somit keine faktischen Auswirkungen. Das war schon immer so, aber es wurde nicht in der Maschinenrichtlinie selbst festgelegt.

[37] Definitions

Article 3 12

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

New text:

(12) 'placing on the market' means the first making available of a machinery product on the Union market

Old text:

(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

Impact / Motivation:

no change

The term "whether for reward or free of charge" is now part of "making available on the market". see [36]

Einfluss / Motivation:

Keine Änderung

Der Satzteil "entgeltliche oder unentgeltliche" ist jetzt Teil von "auf dem Markt bereitstellen". siehe [36]

[38] Definitions

Article 3 13

New Article: 3 13

Old Article: 2 k

New / changed / moved / no change: moved

New text:

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

Old text:

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

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[39] Definitions

Article 3 14

New Article:

3 14

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

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

Einfluss / Motivation:

Die Definition dient der Klarstellung, was unter dem in der MPVO verwendeten Begriff zu verstehen ist. Sie hat keinen Einfluss auf die Praxis.

[40] Definitions

Article 3 15

New Article:

3 15

New / changed / moved / no change:

new

New text:

(15) 'artificial intelligence system' means an artificial intelligence system as defined in Article 3(1) of Regulation (EU) .../... of the European Parliament and of the Council 28 +

Old text:

Impact / Motivation:

New definition included, as the MPR deals with the subject of AI.

Einfluss / Motivation:

Neu aufgenommene Definition, da die MPVO das Thema KI behandelt.

[41] Definitions

Article 3 16

New Article:

3 16

New / changed / moved / no change:

new

New text:

(16) 'substantial modification' means a modification of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen by the manufacturer and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements may be affected;

Old text:

Impact / Motivation:

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. This definition would cover a large part of the changes to machine products and possibly even if the safety of a machine is improved. Since the MPR includes the "manufacturer for his or her own use", it is not just about making modified machinery products available on the market. Machinery products are also in the scope that are modified by the employer in order to adapt them to new operational conditions or to the state of the art in the context of occupational safety.

Germany, Austria and Switzerland have their own interpretations that do not see certain modifications as "substantial modification". This definition would lead to an increase in the substantial modification and thus to an additional burden on the industry.

France has not yet seen any "substantial modification". All such cases are dealt with in the context of occupational health and safety. This would lead to an enormous increase in substantial modification in France and thus to an additional burden on industry.

A uniform, practicable view of the subject of "substantial modification" is urgently required within the framework of the internal market.

Einfluss / Motivation:

Das Thema ist bisher nur Bestandteil von unterschiedlichen europäischen und nationalen Interpretationen.

Die Definition folgt der Erklärung im EU-Binnenmarktleitfaden „Blue Guide“ in Kapitel 2.1. Diese Festlegung würde ein Großteil der Veränderungen von Maschinenprodukten erfassen und das ggf. auch dann, wenn die Sicherheit einer Maschine verbessert wird. Da die MPVO den „Eigenhersteller“ erfasst, geht es hier nicht nur um das Bereitstellen auf dem Markt von veränderten Maschinenprodukten. Es sind auch solche Maschinenprodukte erfasst, die durch den Arbeitgeber verändert werden um sie an neue betriebliche Gegebenheiten oder im Rahmen des Arbeitsschutzes an den Stand der Technik anzupassen.

Deutschland, Österreich und die Schweiz haben eigene Interpretationen, die bestimmte Änderungen nicht als „wesentliche Veränderung“ sehen. Diese Festlegung würde zu einer Zunahme der wesentlicher Veränderungen und damit zu einer Mehrbelastung der Industrie führen.

Frankreich kennt noch keine „wesentlichen Veränderungen“. Alle derartigen Fälle werden im Rahmen des Arbeitsschutzes abgehandelt. Dies würde zu einer enormen Zunahme wesentlicher Veränderungen in Frankreich und damit zu einer Mehrbelastung der Industrie führen.

Eine einheitliche praktikable Sichtweise des Themas "wesentliche Veränderung" ist im Rahmen des Binnenmarktes dringend erforderlich.

[42] Definitions

Article 3 17

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

New text:

(17) 'manufacturer' means any natural or legal person who manufactures machinery products or who has machinery products designed or manufactured, and markets those machinery products under his or her name or trademark or who designs and constructs machinery products for his or her own use;

Old text:

(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

Impact / Motivation:

1. PCM has been deleted as it is contained in Article 2 [2].
2. "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 designs AND constructs the product himself.
5. "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. Before that, the manufacturer was also the person who designed 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.

In this way, however, a manufacturer can outsource the design process to a third party "for his or her own use". This third party would then not be a "manufacturer". Since the manufacturer

then only constructs the machinery "for his or her own use", he would not be a manufacturer either.

The requirements for manufacturers in Article 10 (1) [68] are moreover almost exclusively aimed at manufacturers who make machinery products available on the market. In this respect, the "manufacturer" "for his or her own use" only needs to meet rudimentary requirements.

The old part "If there is no manufacturer in the sense of the above definition ..." is no longer required, as all economic actors who make machinery products available on the market are now included in the MPR. This sentence was necessary for imported machines, which are now covered by [45].

Einfluss / Motivation:

1. uvM wurde gestrichen, da sie in Artikel 2 [2] enthalten ist.
2. "Hersteller" ist nicht mehr die Person, die das Maschinenprodukt entwirft, sondern nur noch die Person, die es baut.
3. "Hersteller" ist immer noch die Person, die das Maschinenprodukt mit ihrer Marke kennzeichnet.
4. Ein Hersteller "für den Eigengebrauch" ist immer noch „Hersteller“, aber nur, wenn er das Produkt selbst entwirft UND baut.
5. "In Abwesenheit eines Herstellers wie oben definiert ..." wurde fallen gelassen.

Klargestellt wird, dass das Konstruktionsbüro grundsätzlich nicht Hersteller im Sinne der MPVO ist. Zuvor war der Hersteller auch die Person, die ein Produkt entworfen hat.

Formal wird damit auch klargestellt, dass der Entwurfsprozess, in dem auch die Risikobeurteilung durchgeführt und die technischen Unterlagen erstellt werden sollten, an einen Dritten ausgelagert werden kann, der nicht Wirtschaftsakteur im Sinne der MPVO ist. Faktisch ist das aber keine Änderung, da das schon bisher so war.

Somit kann aber ein Hersteller "für den Eigengebrauch" den Entwurfsprozess an einen Dritten auslagern. Dieser Dritte wäre dann kein "Hersteller". Da der Hersteller "für den Eigengebrauch" dann nur die Maschine danach baut, wäre auch er kein Hersteller.

Die Anforderungen an den Hersteller in Artikel 10 Absatz 1 [68] richten sich im Übrigen fast ausschließlich nur an solche Hersteller, die Maschinenprodukte auf dem Markt bereitstellen. Den "Hersteller" "für den Eigengebrauch" treffen insofern nur rudimentäre Anforderungen.

Der alte Teil "Wenn kein Hersteller im Sinne der vorstehenden Begriffsbestimmung existiert ..." ist nicht mehr erforderlich, da alle Wirtschaftsakteure, die Maschinen auf dem Markt bereitstellen, jetzt in der MPVO erfasst sind. Dieser Satz war für Importmaschinen notwendig, die jetzt aber von [45] abgedeckt werden.

[43] Definitions

Article 3 18

New Article:

3 18

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

no impact

Einfluss / Motivation:

kein Einfluss

[44] Definitions

Article 3 19

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

New text:

(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;

Old text:

(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;

Impact / Motivation:

An authorised representative is no longer allowed to take over all responsibilities of the manufacturer, but only tasks defined in Article 11 [78].

Einfluss / Motivation:

Ein Bevollmächtigter darf nicht mehr alle Aufgaben des Herstellers übernehmen, sondern nur noch die in Artikel 11 [78] festgelegten Aufgaben.

[45] Definitions

Article 3 20

New Article:

3 20

New / changed / moved / no change:

new

New text:

(20) 'importer' means any natural or legal person established within the Union who places machinery products from a third country on the Union market;

Old text:

Impact / Motivation:

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.

See also the deleted part in the old manufacturer definition "In the absence of a manufacturer as defined above ..." in [42]

Einfluss / Motivation:

Die MPVO folgt hier, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien". Damit wird auch die gesamte Handelskette mit den betroffenen Wirtschaftsakteuren erfasst. Diese Anpassung ist bereits 2014 bei vielen anderen Produktrichtlinien erfolgt.

Siehe auch der gelöschte Teil in der alten Herstellerdefinition "Wenn kein Hersteller im Sinne der vorstehenden Begriffsbestimmung existiert ..." in [42]

[46] Definitions

Article 3 21

New Article:

3 21

New / changed / moved / no change:

new

New text:

(21) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes machinery products available on the market;

Old text:

Impact / Motivation:

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.

Einfluss / Motivation:

Die MPVO folgt hier, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarkttrichtlinien". Damit wird auch die gesamte Handelskette mit den betroffenen Wirtschaftsakteuren erfasst. Diese Anpassung ist bereits 2014 bei vielen anderen Produktrichtlinien erfolgt.

[47] Definitions

Article 3 22

New Article:

3 22

New / changed / moved / no change:

new

New text:

(22) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

Old text:

Impact / Motivation:

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.

Einfluss / Motivation:

Die MPVO folgt hier, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien". Damit wird auch die gesamte Handelskette mit den betroffenen Wirtschaftsakteuren erfasst. Diese Anpassung ist bereits 2014 bei vielen anderen Produktrichtlinien erfolgt.

[48] Definitions

Article 3 23

New Article:

3 23

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

no impact

Einfluss / Motivation:

kein Einfluss

[49] Definitions

New Article:

Old Article:

2 m

New / changed / moved / no change:

deleted

New text:

Old text:

(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.

Impact / Motivation:

On the one hand, the definition served to clarify that these are legally binding requirements. On the other hand, it was made clear here that the Machinery Directive does not in principle make any environmental protection requirements.

The definition of GSA has been deleted.

This has no practical impact, as everything is already derived from the legal stipulations and the deletion of the definition does not change anything.

Einfluss / Motivation:

Die Definition diente einerseits der Klarstellung, dass es sich um rechtlich verbindliche Anforderungen handelt. Andererseits wurde hier klargelegt, dass die Maschinenrichtlinie grundsätzlich keine Umweltschutzanforderungen stellt.

Die Definition von GSA wurde gestrichen.

Dies hat keine praktischen Auswirkungen, da sich alles bereits aus den rechtliche Festlegungen ergibt und sich durch die Löschung der Definition nichts daran ändert.

[50] Definitions

Article 3 24

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

New text:

(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;

Old text:

(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 (4);

Impact / Motivation:

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.

Einfluss / Motivation:

Für diese Definition wird auf die Festlegungen in der entsprechenden EU Verordnung verwiesen. Durch die Einschränkung auf Buchstabe (c) entfällt allerdings der Teil "deren Einhaltung nicht zwingend ist", der in der EU-VO in Artikel 2(1) erster Satz enthalten ist.

[51] Definitions

Article 3 25

New Article:

3 25

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

No effect, see also Article 20 [90]

Einfluss / Motivation:

Keine Auswirkung, siehe auch Artikel 20 [90]

[52] Definitions

Article 3 26

New Article:

3 26

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

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

No consequences

Einfluss / Motivation:

Dies dient der Anpassung an die EG-VO 765/2008 "Akkreditierung und Marktüberwachung"

Keine Auswirkungen

[53] Definitions

Article 3 27

New Article:

3 27

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

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

No consequences

Einfluss / Motivation:

Dies dient der Anpassung an die EG-VO 765/2008 "Akkreditierung und Marktüberwachung"

Keine Auswirkungen

[54] Definitions

Article 3 28

New Article:

3 28

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

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

No consequences

Einfluss / Motivation:

Dies dient der Anpassung an die EG-VO 765/2008 "Akkreditierung und Marktüberwachung"

Keine Auswirkungen

[55] Definitions

Article 3 29

New Article:

3 29

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

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

No consequences

Einfluss / Motivation:

Dies dient der Anpassung an die EG-VO 765/2008 "Akkreditierung und Marktüberwachung"

Keine Auswirkungen

[56] Definitions

Article 3 30

New Article: 3 30

New / changed / moved / no change: new

New text:

(30) 'notified body' means a conformity assessment body notified in accordance with Article 26 of this Regulation;

Old text:

Impact / Motivation:

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

No consequences

Einfluss / Motivation:

Dies dient der Anpassung an die EG-VO 765/2008 "Akkreditierung und Marktüberwachung"

Keine Auswirkungen

[57] Definitions

Article 3 31

New Article:

3 31

New / changed / moved / no change:

new

New text:

(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;

Old text:

Impact / Motivation:

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

No consequences

Einfluss / Motivation:

Dies dient der Anpassung an die EG-VO 765/2008 "Akkreditierung und Marktüberwachung"

Keine Auswirkungen

[58] Definitions

Article 3 32

New Article:

3 32

New / changed / moved / no change:

new

New text:

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

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;

Old text:

Impact / Motivation:

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

No consequences

Einfluss / Motivation:

Dies dient der Anpassung an die EG-VO 765/2008 "Akkreditierung und Marktüberwachung"

Keine Auswirkungen

[59] Definitions

Article 3 33

New Article:

3 33

New / changed / moved / no change:

new

New text:

(33) 'withdrawal' means any measure aimed at preventing a machinery product in the supply chain from being made available on the market.

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;

Old text:

Impact / Motivation:

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

No consequences

Einfluss / Motivation:

Dies dient der Anpassung an die EG-VO 765/2008 "Akkreditierung und Marktüberwachung"

Keine Auswirkungen

[60] Free movement

Article 4 1

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

New text:

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

Old text:

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.

Impact / Motivation:

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

Since PCM are now to be covered by the collective term "machinery product", there is no longer any need for a separate regulation, so that No. 2 of the old text can be omitted.

Einfluss / Motivation:

Der Text ist anders geschrieben, aber der Inhalt ist der gleiche.

Da uvM jetzt von dem Sammelbegriff "Maschinenprodukt" abgedeckt werden sollen, bedarf es dafür keiner gesonderten Regelung mehr, so dass Nr. 2 des alten Textes entfallen kann.

[61] Free movement

Article 4 2

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

New text:

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

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

Old text:

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.

Impact / Motivation:

no change

Einfluss / Motivation:

keine Änderung

[62] High-risk machinery products Article 5

New Article:

5

New / changed / moved / no change:

new

New text:

1. High-risk machinery products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Article 21(2).

2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I in view of technical progress and knowledge or new scientific evidence by including in the list of high-risk machinery products a new machinery product or withdrawing an existing machinery product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.

3. A machinery product shall be included in the list of high-risk machinery products in Annex I if it poses a risk to human health taking into account its design and intended purpose. A machinery product shall be withdrawn from the list of high-risk machinery products in Annex I if it no longer poses such risk. The risk posed by a certain machinery product shall be established based on the combination of the probability of occurrence of harm and the severity of that harm.

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

(a) the degree to which each affected person would be impacted by the harm;

(b) the number of persons potentially affected;

Old text:

- (c) the degree to which potentially affected parties are dependent on the outcome produced by the machinery product;
- (d) the degree to which potentially affected parties are in a vulnerable position vis-à-vis the user of the machinery product;
- (e) the degree of reversibility of the harm produced by the machinery product;
- (f) the degree to which the machinery product has been used for a specific purpose;
- (g) indications of harm that have been caused in the past by machinery products which have been used for a specific purpose.

4. The Commission shall thoroughly assess the criteria laid down in paragraph 3 on the basis of available information. In particular the following information shall be communicated to the Commission by the Member States when it becomes available to them in connection with market surveillance or as a result of the concerns referred to in the fifth paragraph:

- (a) an assessment of the risks as referred to in paragraph 3;
- (b) a cost-effectiveness analysis;
- (c) a machinery accident analysis;
- (d) statistics on accidents caused by the machinery product for the preceding four years based, in particular information obtained from the Information and Communication System for Market Surveillance (ICSMS) information, safeguard clauses, Rapid Alert System (RAPEX) and the Machinery Administrative Cooperation Group reporting.

5.A Member State which has concerns about a machinery product being listed or not listed in Annex I shall immediately inform the

Commission of its concerns and provide reasons in support thereof.

Impact / Motivation:

The Annex I list now includes all machinery products of the categories named there and thus also PCM, as long as the individual categories are not limited to "machinery".

The new provisions obviously assume that the list of Annex I machinery products (formerly Annex IV) follows a risk-based approach and can then also be adapted / changed on this basis. According to the newly specified system, machines with a high number of accidents would have to be included in the list and - following this logic - if the accident rate fell again, these machines would be removed from the Annex. This is reminiscent of the closing / opening system with a rising / falling corona incidence. That did not work.

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 the committee according to Article 46 of the MPR is involved, as stipulated e.g. in the context of the EU Market Surveillance Ordinance.

The effects of future changes can be positive or negative for the industry:

1. If the list is changed, this has an enormous impact on products that are newly included, as a notified body must then always be involved in the conformity assessment process.
2. If products are removed from the list, the industry does not have to pay the costs for the notified body.

Einfluss / Motivation:

Die Anhang I Liste erfasst jetzt alle Maschinenprodukte der dort genannten Kategorien und damit auch uvM, soweit die einzelnen Kategorien nicht auf „Maschinen“ beschränkt sind.

Die neuen Bestimmungen gehen offensichtlich davon aus, dass die Liste der Anhang I Maschinenprodukte (früherer Anhang IV) einem risikobasiertem Ansatz folgt und auf dieser Basis dann auch angepasst / geändert werden kann. Dabei müssten nach der neu vorgegebenen Systematik Maschinen mit einem hohem Unfallgeschehen in die Liste aufgenommen werden und- dieser Logik folgend – wenn die Unfallrate dadurch wieder sinkt, diese Maschinen wieder aus dem Anhang entfernt werden. Das erinnert an das System Schließen / Öffnen bei steigender / sinkender Corona-Inzidenz. Das hat nicht funktioniert.

Die Liste der Maschinenprodukte in Anhang I kann später von der EU Kommission durch einen delegierten Rechtsakt geändert werden. Hierbei ist nicht vorgesehen, dass der Ausschuss nach Artikel 46 der MPVO beteiligt wird, wie das z.B. im Rahmen der EU-Marktüberwachungsverordnung festgelegt ist.

Die Auswirkungen zukünftiger Änderungen können für die Industrie positiv wie negativ sein:

1. Wenn die Liste geändert wird, hat dies enorme Auswirkungen auf Produkte, die neu aufgenommen werden, da im Konformitätsbewertungsprozess dann immer eine benannte Stelle beteiligt werden muss.

2. Wenn Produkte aus der Liste entfernt werden, entfallen für die Industrie die Kosten für die benannte Stelle.

[63] Safety components

Article 6 1

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

New text:

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

Old text:

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

Impact / Motivation:

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

Einfluss / Motivation:

keine Änderung, bist auf die Änderung der Nummer des Anhangs.

[64] Safety components

Article 6 2-4

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

New text:

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.

3. The Commission shall thoroughly assess the risks that require the inclusion of a new safety component in the list of safety components in Annex II or a withdrawal of a safety component from that list.

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.

Old text:

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).

Impact / Motivation:

No change in content.

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

Einfluss / Motivation:

Keine Änderung im Inhalt.

Außerdem: Da diese Liste nur Beispiele enthält, gibt es keine Auswirkungen auf solche Produkte.

[65] Requirements for machinery products

Article 7

New Article: 7

New / changed / moved / no change: new

New text:

Requirements for machinery products

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

Old text:

Impact / Motivation:

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".

However, the 1: 1 transfer of the text does not fit.

This requirement would also have to be met by machine products that do not need to be installed. That would mean that such machines are not allowed to be made available on the market.

These requirements also apply to PCM, but cannot be met by PCM.

Einfluss / Motivation:

Die MPVO folgt hier, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien".

Die 1:1 Übernahme des Textes passt aber nicht.

Diese Anforderung müsste auch von Maschinenprodukten erfüllt werden, die nicht installiert werden müssen. Das würde bedeuten, dass solche Maschinen nicht auf dem Markt bereitgestellt werden dürfen.

Diese Anforderungen gelten auch für uvM, können aber von uvM nicht erfüllt werden.

[66] Specific Union harmonisation legislation

Article 8

New Article:	8
Old Article:	3
New / changed / moved / no change:	moved

New text:

Specific Union harmonisation legislation

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

Old text:

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.

Impact / Motivation:

Due to the broader term "machinery product" (see [2]), this now also applies to PCM. This closed a "formal" gap.

Einfluss / Motivation:

Aufgrund des weiter gefassten Begriffs "Maschinenprodukt" (siehe [2]) gilt das jetzt auch für uvM. Damit wurde eine „formale“ Lücke geschlossen.

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

Article 9

New Article:

9

New / changed / moved / no change:

new

New text:

Regulation (EU) .../... of the European Parliament and of the Council

Where machinery products contain an artificial intelligence system, to which the essential health and safety requirements of Regulation (EU) .../... apply, this Regulation shall, in relation to that artificial intelligence system, only apply with regard to its safe integration into the overall machinery, so as not to compromise the safety of the machinery product as a whole.

Old text:

Impact / Motivation:

AI safety is excluded from the MPR, but is still dealt with in great detail in the rest of the regulation.

Furthermore: This provision is superfluous as Article 8 [66] already deals with this issue.

Einfluss / Motivation:

KI-Sicherheit ist von der MPVO ausgeschlossen, wird jedoch im Rest der Verordnung trotzdem sehr detailliert behandelt.

Außerdem: Diese Bestimmung ist überflüssig, da Artikel 8 [66] auch diesen Sachverhalt bereits behandelt.

[68] Obligations of manufacturers

Article 10 1

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

New text:

Obligation of manufacturers

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

Old text:

Placing on the marked 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;

Impact / Motivation:

1. The term "putting into service" is deleted here.
2. The requirement also applies to PCM
3. Manufacturers of machinery products for their own use are herewith not obliged to comply with this part of the MPR, with the exception of the EHSR requirements mentioned in [73], [76] and [77].

Einfluss / Motivation:

1. Der Begriff "Inbetriebnahme" wird hier gestrichen.
2. Die Anforderung gilt auch für uvM
3. Hersteller von Maschinenprodukten für die eigene Verwendung sind damit nicht verpflichtet, diesen Teil der MPVO einzuhalten, mit Ausnahme der in [73], [76] und [77] genannten Anforderungen bezüglich der GSA.

[69] Obligations of manufacturers

Article 10 2 -(1)

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

New text:

2. Before placing a machinery product on the market, manufacturers shall draw up the technical documentation referred to in Annex IV ('technical documentation') and carry out the relevant conformity assessment procedures referred to in Article 21 or Article 22 or have them carried out.

[...]

Old text:

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;

2. Before placing partly completed machinery on the market, the manufacturer or his authorised representative shall ensure that the procedure referred to in Article 13 has been completed.

Impact / Motivation:

Basically no change. It is formally unclear whether Annex IV A or Annex IV B is meant.

Einfluss / Motivation:

Grundsätzlich keine Änderung. Formal unklar ist, ob Anhang IV A oder Anhang IV B gemeint ist.

[70] Obligations of manufacturers

Article 10 2, 8

New Article:	10 2, 8
Old Article:	5 1e
New / changed / moved / no change:	changed

New text:

2. [...]

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

[...]

8. Manufacturers shall either provide the EU declaration of conformity with the machinery product or include in the instructions and information set out in section 1.7 of Annex III the internet address at which the EU declaration of conformity can be accessed.

Old text:

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;

Impact / Motivation:

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.

No requirements are set on how long the URL needs to be valid or how reliable it has to work. (e.g. the EU is changing their URLs every second month or delete content completely)

Einfluss / Motivation:

Die EU-Konformitätserklärung muss nicht mehr beigefügt werden. Stattdessen kann die URL dafür in die Betriebsanleitung aufgenommen werden.

Anhang III 1.7.4.2. c) wurde ebenfalls angepasst.

Es wird nicht festgelegt, wie lange die URL gültig sein muss oder wie zuverlässig sie funktionieren muss. (z. B. ändert die EU ihre URLs jeden zweiten Monat oder löscht Inhalte vollständig)

[71] Obligations of manufacturers

Article 10 3

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

New text:

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity, where relevant, at the disposal of the market surveillance authorities for ten years after the machinery product has been placed on the market. Where relevant, the source code or programmed logic included in the technical documentation shall be made available upon a reasoned request from the competent national authorities provided that it is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.

Old text:

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.

[...]

Impact / Motivation:

1. This provision does not apply to the manufacturer of machinery products for their own use.
2. The start time for the ten years "of the last unit produced" has been dropped.
3. Source code is mentioned specially.

The start time can be dropped, since the Machinery Product Regulation concerns itself no longer with the construction, but only with the manufacturing process (see [42]). Thus each product is treated singularly and not as a series.

The separate mentioning of source code is superfluous. If it is part of the technical documentation, it is already handled.

The EU declaration of conformity is no longer part of the technical documentation. However, based on this paragraph, it must still be made available to the market authorities.

Einfluss / Motivation:

1. Diese Bestimmung gilt nicht für den Hersteller von Maschinenprodukten für die eigene Verwendung.
2. Die Startzeit für die zehn Jahre ab "der zuletzt produzierten Einheit" wurde gelöscht.
3. Der Quellcode wird speziell erwähnt.

Die Startzeit kann gelöscht werden, da sich die Maschinenproduktverordnung nicht mehr mit der Konstruktion, sondern nur noch mit dem Herstellungsprozess befasst (siehe [42]). Somit wird jedes Produkt einzeln und nicht als Serie behandelt.

Die gesonderte Erwähnung des Quellcodes ist überflüssig. Wenn er Teil der Technischen Unterlagen ist, ist er bereits behandelt.

Die EU-Konformitätserklärung ist nicht mehr Bestandteil der Technischen Unterlagen. Sie muss jedoch aufgrund dieses Absatzes den Marktbehörden weiterhin zur Verfügung gestellt werden können.

[72] Obligations of manufacturers

Article 10 4 -(1)

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

New text:

4. Manufacturers shall ensure that procedures are in place for machinery products that are part of a series production to remain in conformity with this Regulation. Changes in the production process or in the design or characteristics of the machinery product and changes in the harmonised standards or the technical specifications referred to in Article 17 by reference to which the conformity of the machinery product is declared or by application of which its conformity is verified shall be adequately taken into account.

[...]

Old text:

(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.

Impact / Motivation:

1. This provision also applies to PCM.
2. The start time for the ten years "of the last unit produced" has been dropped.
see [71]
3. This provision also applies to manufacturers of machinery products for their own use.

Einfluss / Motivation:

1. Es werden auch uvM erfasst.
2. Die Startzeit für die zehn Jahre ab "der zuletzt produzierten Einheit" wurde gelöscht.
siehe [71]
3. Diese Bestimmung gilt auch für Hersteller von Maschinenprodukten für die eigene Verwendung.

[73] Obligations of manufacturers

Article 10 4 -(2)

New Article:

10 4 -(2)

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

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 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.

Machinery products that are manufactured for own use are not subject to the manufacturer's obligations under the Machine Product Regulation (see [68]), but must comply with Annex III when they are put into service.

Einfluss / Motivation:

1. Die MPVO folgt hier, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien".
2. Die Prüfung im Feld wurde zuvor grundsätzlich nicht gefordert, außer für Maschinen nach Anhang IX oder X. (durch benannte Stellen)
3. Es müssen danach auch Tests für selbst hergestellte Maschinenprodukte durchgeführt werden.

Selbst hergestellte Maschinenprodukte unterliegen nicht der Herstellerpflichten der Maschinenproduktverordnung (siehe [68]), müssen jedoch bei Inbetriebnahme Anhang III erfüllen.

[74] Obligations of manufacturers

Article 10 5, 6

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

New text:

5. Manufacturers shall ensure that the machinery products which they place on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the machinery product does not allow it, that the required information is provided on the packaging or in a document accompanying the machinery product.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and the email address at which they can be contacted on the machinery product or, where that is not possible, on its packaging or in a document accompanying the machinery product. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

Old text:

1.7.3. Marking of machinery

Impact / Motivation:

1. Now an email address also needs to be provided.
2. The language only needs to be easily understood.

But [75] reduces this choice, since this information is also part of Annex III 1.7.

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

Einfluss / Motivation:

1. Jetzt muss auch eine E-Mail-Adresse angegeben werden.

2. Die Sprache muss nur leicht verständlich sein.

[75] reduziert diese Auswahl jedoch, da diese Informationen auch Teil von Anhang III 1.7 sind.

3. Die Informationen dürfen sich auf der Verpackung befinden und müssen nicht auf dem Maschinenprodukt sein, sofern dies nicht möglich ist.

[75] Obligations of manufacturers

Article 10 7

New Article:	10 7
Old Article:	5 1c
New / changed / moved / no change:	changed

New text:

7. Manufacturers shall ensure that the machinery products are accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users, as determined by the Member State concerned. Such instructions and information shall be clear, understandable, intelligible and legible.

Old text:

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;

Impact / Motivation:

1. Formerly, instructions were given as an example for information, now all information listed in 1.7 is mandatory.
2. Basic requirements on instructions and information are given.
3. Language is supposed to be "easily understood by end-users, as determined by the Member State concerned".

The requirement on language is dropped from Annex III 1.7.

4. Instructions only need to be in "a" language and no longer in all official languages of that state.

Nearly all contents of 1.7 had to be provided before as well. Now, also the Sales literature defined in Annex III 1.7.4.3. has to be provided.

Before the language needed to be all official Community languages of the Member State. With only one language necessary this reduces the workload.

But 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 LVwG,SH; SächsSorbG; SWG; SVwVfG)

Einfluss / Motivation:

1. Bisher wurden Betriebsanleitungen als Beispiel für Informationen gegeben, jetzt sind alle in 1.7 aufgeführten Informationen obligatorisch.
2. Grundlegende Anforderungen an Betriebsanleitungen und Informationen werden festgelegt.
3. Die Sprache soll "für die Endnutzer leicht verständlich sein, wie vom betreffenden Mitgliedstaat festgelegt".

Das Erfordernis der Sprache wird aus Anhang III 1.7 gestrichen.

4. Die Betriebsanleitung muss nur in "einer" Sprache abgefasst sein und nicht mehr in allen Amtssprachen des Landes.

Fast alle Inhalte von 1.7 mussten schon zuvor bereitgestellt werden. Nun muss auch das in Anhang III 1.7.4.3. definierte Verkaufsprospekt bereitgestellt werden.

Zuvor musste die Sprache eine offizielle Gemeinschaftssprache des Mitgliedstaats sein. Wenn nur noch eine Sprache notwendig ist, reduziert sich der Aufwand.

Aber, diese Regelung ermöglicht es den Mitgliedstaaten, eine eigene Liste zulässiger Sprachen zu haben, was es ausländischen Herstellern erschweren würde, diese Listen in jedem Mitgliedstaat zu finden.

In Deutschland zählen zu den zugelassenen Sprachen auch Sorbisch, Niederdeutsch, Friesisch sowie Dänisch und Französisch.

(siehe LVwG,SH; SächsSorbG; SWG; SVwVfG)

[76] Obligations of manufacturers

Article 10 9

New Article:

10 9

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

1. The provision in the first sentence also applies to the manufacturer of machinery products for their own use.
2. However, the manufacturer for own use does not have to meet the EHSR [68].

Einfluss / Motivation:

1. Die Bestimmung im ersten Satz gilt auch für den Hersteller von Maschinenprodukten für die eigene Verwendung (Eigenhersteller).
2. Der Eigenhersteller muss aber die GSA nicht erfüllen [68].

[77] Obligations of manufacturers

Article 10 10

New Article:	10 10
Old Annex:	VII A 2. -(1)
New / changed / moved / no change:	changed

New text:

10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery product with the essential health and safety requirements set out in Annex III, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks posed by the machinery product, which they have placed on the market or put into service.

Old text:

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.

Impact / Motivation:

1. This is an addition to Article 10 3. [71] It only concerns the information on Annex III of the MPR, but no time limit is given.
2. This also applies to machine products manufactured for own use.
3. Paper or electronic form is now acceptable.
4. The language regulation for the documents to be sent to the authority is new.

So far, this information, along with the rest of the technical documentation, only has to be kept for ten years. A corresponding regulation can be found in Article 10 3 [71]. However, since no time limit is specified here and no reference is made to Article 10 3, they may have to be kept for at least as long as the machine exists.

This information must also be kept for machine products manufactured for own use, which contradicts with the fact that these do not have to comply with Annex III of the Machinery Product Regulation. (see [71])

The electronic form can be difficult for the authority to read if the information is provided in a format ten years old or older (e.g., a Harvard Graphics slide set).

Einfluss / Motivation:

1. Dies ist eine Ergänzung zu Artikel 10 3. [71]. Sie betrifft nur die Informationen zu Anhang III der MPVO, es wird jedoch keine zeitliche Begrenzung angegeben.
2. Dies betrifft auch selbst hergestellte Maschinenprodukte.
3. Papier- oder elektronische Form ist jetzt zulässig.
4. Neu ist die Sprachenregelung für die an die Behörde zu übersendenden Unterlagen.

Bisher müssen diese Informationen zusammen mit dem Rest der technischen Dokumentation nur zehn Jahre lang aufbewahrt werden. Eine entsprechende Regelung findet sich in Abs. 3 [71]. Da an dieser Stelle aber kein Zeitlimit angegeben ist und auch nicht auf Abs. 3 verwiesen wird, müssen sie ggf. mindestens so lange aufbewahrt werden, wie die Maschine existiert.

Diese Informationen müssen auch für selbst hergestellte Maschinenprodukte aufbewahrt werden, was im Widerspruch dazu steht, dass diese aber nicht Anhang III der Maschinenproduktverordnung erfüllen müssen. (siehe [71])

Die elektronische Form kann für die Behörde schwierig zu lesen sein, wenn die Informationen in einem zehn Jahre alten oder älteren Format bereitgestellt werden (z.B. als Harvard Graphics Foliensatz).

[78] *Authorised representatives*

Article 11

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

New text:

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

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

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 EU declaration of conformity and the technical documentation at the disposal of the national market surveillance authorities for ten years after the machinery product has been placed on the market;

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

(c) cooperate with the competent national authorities, at their request, on any measures taken to eliminate the risks posed by a machinery product covered by the authorised representative's mandate.

Old text:

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:

[...]

Impact / Motivation:

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.

The authorized representative has to work with the authority.

Einfluss / Motivation:

1. Die MPVO folgt hier, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien".
2. Die Aufgaben, die dem Bevollmächtigten übertragen werden können sind gegenüber der MRL stark eingeschränkt.

Der Bevollmächtigte muss die EU-Konformitätserklärung und die technischen Unterlagen und ggf. weitere Informationen für die Behörde bereithalten.

Der Bevollmächtigte muss ggf. mit der Behörde zusammenarbeiten.

[79] Obligations of importers

Article 12

New Article:	12
Old Article:	2 i
New / changed / moved / no change:	new

New text:

Obligations of importers

1. Importers shall only place on the market machinery products that comply with the essential health and safety requirements set out in Annex III.

2. Before placing a machinery product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 21 or Article 22 have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the machinery product bears the CE marking referred to in Article 19 and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 10(5) and (6).

Where an importer considers or has reason to believe that a machinery product is not in conformity with the essential health and safety requirements set out in Annex III, the importer shall not place it on the market until it has been brought into conformity.

Furthermore, where the machinery product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and the email

Old text:

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

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

4. Importers shall ensure that the machinery product is accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users, as determined by the Member State concerned.

5. Importers shall ensure that, while the machinery product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements set out in Annex III.

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

7. Importers who consider or have reason to believe that a machinery product, which they have placed on the market, is not in conformity with the essential health and safety requirements set out in Annex III shall immediately take the corrective measures necessary to bring that machinery product into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the machinery product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment,

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

8. Importers shall, for ten years after the machinery product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities. Where relevant, the source code or programmed logic included in the technical documentation shall be made available upon a reasoned request from competent national authorities provided that it is necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.

9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery product with the essential health and safety requirements set out in Annex III in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment posed by a machinery product, which they have placed on the market.

Impact / Motivation:

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. Formerly importers were treated as manufacturers, if the manufacturer "did not exist" (e.g. if the market surveillance could not get a hold of them).

Now there are concrete requirements on all importers.

Einfluss / Motivation:

1. Die MPVO folgt hier, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarkttrichtlinien".

2. Früher wurden Importeure als Hersteller behandelt, wenn der Hersteller "nicht existierte"(d.h. wenn die Marktüberwachung sie nicht erreichen konnte).

Jetzt gibt es konkrete Anforderungen an alle Importeure.

[80] Obligations of distributors

Article 13

New Article:

13

New / changed / moved / no change:

new

New text:

Obligations of distributors

1. When making a machinery product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making a machinery product available on the market, distributors shall verify that:

(a) the machinery product bears the CE marking;

(b) the machinery product is accompanied by the required documents and by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by end-users in the Member State in which the machinery product is to be made available on the market;

(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 product is not in conformity with the essential health and safety requirements set out in Annex III, the distributor shall not make the machinery product available on the market until it has been brought into conformity. Furthermore, where the machinery product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the

Old text:

distributor shall inform the manufacturer and the market surveillance authorities to that effect.

4. Distributors shall ensure that, while a machinery product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements set out in Annex III.

5. Distributors who consider or have reason to believe that a machinery product, which they have made available on the market, is not in conformity with the essential health and safety requirements set out in Annex III shall make sure that the corrective measures necessary to bring that machinery product into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the machinery product poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, distributors shall immediately inform the competent national authorities of the Member States in which they have made the machinery product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

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 product with the essential health and safety requirements set out in Annex III in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, posed by a machinery product,

which they have made available on the market.

Impact / Motivation:

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. These provisions also apply to the dealer of PCM.
3. The dealers were previously not covered by the MD.

Einfluss / Motivation:

1. Die MPVO folgt hier, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien" und erfasst auch diesen Wirtschaftsakteur. Damit sind für die komplette Handelskette Anforderungen bezüglich der Maschinenprodukte festgelegt.
2. Diese Bestimmungen gelten auch für den Händler von uvM.
3. Die Händler waren bisher nicht von der MRL erfasst.

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

Article 14

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

New text:

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 where that importer or distributor places a machinery product on the market under his or her name or trademark or carries out a substantial modification of a machinery product that has already been placed on the market or put into service.

Old text:

(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;

Impact / Motivation:

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.
3. This corresponds to the definition in Article 3 (17) [42].
4. What is new is the mention of the essential change, but this is only limited to the cases where such a change is made by the importer or dealer. This was previously interpreted by the "Blue Guide" for the internal market and, if necessary, regulated by national laws.

Since this is also regulated in Article 15, this article is completely superfluous.

Einfluss / Motivation:

1. Die MPVO folgt hier, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarkttrichtlinien" siehe hier Artikel R 10.

2. Es war schon immer so, dass die Person, die ihre Marke / ihren Namen auf ein Produkt setzt, zum Hersteller wird.

3. Dies korrespondiert mit der Definition in Artikel 3 Absatz 17 [42].

4. Neu ist die Erwähnung der wesentlicher Veränderung, die aber nur auf die Fälle beschränkt ist, wo eine solche Veränderung durch den Importeur oder Händler erfolgt. Dies wurde früher durch den Binnenmarktleitfaden „Blue Guide“ interpretiert und ggf. durch nationale Gesetze geregelt.

Da dies auch in Artikel 15 geregelt ist, ist dieser Artikel völlig überflüssig.

[82] Other cases in which obligations of manufacturers apply

Article 15

New Article:

15

New / changed / moved / no change:

new

New text:

Other cases in which obligations of manufacturers apply

A natural or legal person, other than the manufacturer, the importer or the distributor, that carries out a substantial modification of the machinery product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for the part of the machinery product that is affected by the modification or, if the substantial modification has an impact on the safety of the machinery product as a whole, for the entire machinery product.

Old text:

Impact / Motivation:

1. Article 15 closes the loophole created by Article 14 with regard to the substantial change in relation to the economic operators not covered by it.
2. So far, this has only been left to the interpretation in the Blue Guide and national specifications.

This also includes the manufacturer for own use, which then does not fall under all points of Article 10.

Einfluss / Motivation:

1. Artikel 15 schließt die von Artikel 14 geschaffene Lücke hinsichtlich der wesentlichen Veränderung in Bezug auf die dort nicht erfassten Wirtschaftsakteure.
2. Dies ist bisher lediglich der Interpretation im Blue Guide und nationalen Festlegungen überlassen.

Damit ist auch der Eigenhersteller erfasst, der dann aber nicht unter alle Punkte des Artikel 10 fällt.

[83] Identification of economic operators

Article 16

New Article:

16

New / changed / moved / no change:

new

New text:

Identification of economic operators

1. Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with a machinery product;

(b) any economic operator to whom they have supplied a machinery product.

2. Economic operators shall be able to present the information referred to in paragraph 1 for ten years after they have been supplied with the machinery product and for ten years after they have supplied the machinery product.

Old text:

Impact / Motivation:

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?

Einfluss / Motivation:

1. Die MPVO folgt im Absatz 1, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarkttrichtlinien" siehe hier Artikel R 7.

-
2. Die MPVO geht in Absatz 2 über der EG-Beschluss 768/2008/EG hinaus.
 3. Die Lieferanten aller Produkte müssen zehn Jahre lang identifizierbar sein.
 4. Alle Kunden die Wirtschaftsakteure sind müssen zehn Jahre lang identifizierbar sein.

Während der erste Punkt in den meisten Unternehmen bereits festgelegt sein sollte, wird Punkt 4 Probleme verursachen. Wie geht das in einem Bargeldgeschäft (z. B. einem Baumarkt), wenn hier Wirtschaftsakteure einkaufen?

[84] Presumption of conformity of machinery products

Article 17 1

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

New text:

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

Old text:

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.

Impact / Motivation:

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.

Einfluss / Motivation:

Keine Auswirkungen

Neu ist eine Klarstellung, dass auch teilweise befolgte harmonisierte Normen für diesen Teil eine Konformitätsvermutung auslösen können.

Dies wurde bereits in der Praxis schon so gelebt .

[85] Presumption of conformity of machinery products

Article 17 2

New Article:	17 2
Old Article:	2 I
New / changed / moved / no change:	changed

New text:

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.

Old text:

(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

Impact / Motivation:

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.

Einfluss / Motivation:

Keine Auswirkungen

Es handelt sich hier lediglich um eine formale Klarstellung. Die MRL hatte bisher keine solche direkte Verpflichtung. Diese ergab sich aber schon immer aus der o.a. EU-Verordnung.

[86] Presumption of conformity of machinery products

Article 17 3

New Article:

17 3

New / changed / moved / no change:

new

New text:

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

(a) no reference to harmonised standards covering the relevant essential health and safety requirements is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;

(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements and there are undue delays in the standardisation procedure or the request has not been accepted by any of the European standardisation organisations.

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

Old text:

Impact / Motivation:

If the standardization organizations do not carry out a standardization order in good time, the EU Commission can issue appropriate technical rules itself. The Member States must be involved in this. This gives the EU leverage against the standardization organizations.

Einfluss / Motivation:

Soweit die Normungsorganisationen einen Normungsauftrag nicht rechtzeitig durchführen, kann die EU-Kommission selbst entsprechende technische Regeln erlassen. Dabei müssen die

Mitgliedstaaten beteiligt werden. Damit erhält die EU ein Druckmittel gegenüber den Normungsorganisationen.

[87] Presumption of conformity of machinery products

Article 17 4

New Article:

17 4

New / changed / moved / no change:

new

New text:

4. A machinery product which is in conformity with the technical specifications or parts thereof shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those technical specifications or parts thereof.

Old text:

Impact / Motivation:

Like harmonized standards, the technical rules of the EU Commission trigger the presumption of conformity.

Einfluss / Motivation:

Die technischen Regeln der EU-Kommission lösen wie harmonisierte Normen die Konformitätsvermutung aus.

[88] Presumption of conformity of machinery products **Article 17 5**

New Article:

17 5

New / changed / moved / no change:

new

New text:

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

Old text:

Impact / Motivation:

This content is already covered by Article 8 [66] and is only a specification here.

Einfluss / Motivation:

Dieser Inhalt ist bereits von Artikel 8 [66] abgedeckt und hier lediglich eine Konkretisierung.

[89] EU declaration of conformity

Article 18

New Article:	18
Old Annex:	III 1. A.
New / changed / moved / no change:	moved

New text:

EU declaration of conformity

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

Old text:

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;

Impact / Motivation:

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. So no update is possible (and certainly not in paper form).

Einfluss / Motivation:

Die MPVO folgt im Absatz 1, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien" siehe hier Artikel 5 und R 10.

Für die Konformitätserklärung sind in Anhang V weitere Anforderungen formuliert:

Der erste Punkt ist bisher nicht separater Bestandteil der geforderten Inhalte der EG-Konformitätserklärung im Anhang II 1 A der MRL. Diese Aussage ist aber bereits in der weitergehenden Erklärung nach Anhang V, dass die Maschine der MRL entspricht, enthalten. In dem vorgeschlagenen Anhang V der MPV ist der erste Punkt auch nicht separat aufgeführt, wohl aber die allgemeine Erklärung.

Der zweite Punkt erfordert zusätzliche Elemente, die in den Anhängen VI, VII, VIII und IX aufgeführt sein sollen. In diesen Anhängen werden aber keine solche zusätzlichen Elemente beschrieben.

Der zweite Punkt erfordert auch eine kontinuierliche Aktualisierung der EU-Konformitätserklärung. Eine EU-Konformitätserklärung gilt jedoch nur für den Zustand des Produktes zum Zeitpunkt seines Inverkehrbringens. Es ist insofern kein Update möglich (und in Papierform schon gar nicht).

[90] General principles of the CE marking

Article 19

New Article:	19
Old Article:	16
New / changed / moved / no change:	moved

New text:

General principles of the CE marking

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

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

Old text:

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.

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 / Motivation:

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.

Einfluss / Motivation:

Die MPVO folgt im Absatz 1, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien" siehe hier Artikel R 11.

Die Anforderungen an die CE-Kennzeichnung sind jetzt in die entsprechende Verordnung ausgelagert.

[91] Rules for affixing the CE marking

Article 20 1

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

New text:

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

Old text:

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

Impact / Motivation:

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 it is "not possible" on the product.

Einfluss / Motivation:

Die MPVO folgt im Absatz 1, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien" siehe hier Artikel R 12.

Es ist jetzt zulässig, eine CE-Kennzeichnung nur auf der Verpackung zu haben, wenn dies auf dem Produkt "nicht möglich" ist.

[92] Rules for affixing the CE marking

Article 20 2

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

New text:

2. The CE marking shall be affixed before the machinery product is placed on the market.

Old text:

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.

Impact / Motivation:

The CE marking now needs to be affixed on all machinery products, including PCM.

This Article clashes with the MPR in Article 10 2 [70], where PCM do not get a CE marking.

Einfluss / Motivation:

Die CE-Kennzeichnung muss jetzt auf allen Maschinenprodukten, einschließlich uvM, angebracht werden.

Dieser Artikel steht im Widerspruch zu der MPVO in Artikel 10 2 [70], in der uvM keine CE-Kennzeichnung erhalten.

[93] Rules for affixing the CE marking

Article 20 3

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

New text:

3. For a machinery product in the conformity assessment of which a notified body participates in accordance with Annex IX, the CE marking shall be followed by the identification number of that notified body.

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

Old text:

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.

Impact / Motivation:

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

Einfluss / Motivation:

Der Hersteller darf die Nummer der benannten Stelle nicht mehr alleine anbringen.

[94] Rules for affixing the CE marking

Article 20 4

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

New text:

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

Old text:

[...]

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.

Impact / Motivation:

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.

Einfluss / Motivation:

Die MPVO folgt im Absatz 1, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarkttrichtlinien" siehe hier Artikel R 12.

Es wird eine neue Kennzeichnung vorgeschrieben, die auf ein besonderes Risiko oder eine besondere Verwendung hinweist. Diese soll sich neben der CE-Kennzeichnung befinden. In der MPVO ist jedoch kein solches besonderes Risiko definiert.

[95] Rules for affixing the CE marking

Article 20 5

New Article:	20 5
Old Article:	17
New / changed / moved / no change:	changed

New text:

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.

Old text:

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.

Impact / Motivation:

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.

Einfluss / Motivation:

Die MPVO folgt im Absatz 1, wie auch an anderen Stellen dem NLF, d.h., dem EG-Beschluss 768/2008/EG "Gemeinsamer Rechtsrahmen für Binnenmarktrichtlinien" siehe hier Artikel R 12.

Die alten spezifischen Forderungen werden hier als allgemeinere Forderung an die Mitgliedstaaten angegeben.

[96] Conformity assessment procedures for machinery products except partly completed machinery

Article 21 1

New Article:	21 1
Old Article:	12 1
New / changed / moved / no change:	no change

New text:

1. In order to certify the conformity of a machinery product with this Regulation, the manufacturer or its authorised representative and the person who has carried out a substantial modification to the machinery product, shall apply one of the procedures for assessment of conformity referred to in paragraphs 2 and 3.

Old text:

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.

Impact / Motivation:

1. "except partly completed machinery" is only mentioned in the title of the Article, but not in the legal text.
2. The conformity assessment must also be carried out for PCM. This also applies to PCMs that fall under Annex I (see following paragraphs).
3. It has been added that the economic operator who makes a substantial modification to a machinery product must also carry out a conformity assessment.

Einfluss / Motivation:

1. "mit Ausnahme von unvollständigen Maschinen" steht nur in der Überschrift des Artikels, aber nicht im Rechtstext.
2. Die Konformitätsbewertung muss auch für uvM durchgeführt werden. Das gilt auch für uvM, die unter Anhang I fallen (s. nachfolgende Absätze).
3. Neu aufgenommen wurde, dass auch derjenige Wirtschaftsakteur, der eine wesentliche Veränderung an einem Maschinenprodukt vornimmt, eine Konformitätsbewertung vornehmen muss.

[97] Conformity assessment procedures for machinery products except partly completed machinery **Article**

New Article:

Old Article:

12 3

New / changed / moved / no change:

deleted

New text:

Old text:

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.

Impact / Motivation:

This provision has been deleted. For machinery products according to Annex I, notified bodies must now always be involved.

Einfluss / Motivation:

Diese Bestimmung wurde gestrichen. Bei Maschinenprodukten nach Anhangs I müssen jetzt immer benannte Stellen beteiligt werden.

[98] Conformity assessment procedures for machinery products except partly completed machinery

Article 21 2

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

New text:

2. Where the machinery product is a high-risk machinery product listed in Annex I, the manufacturer or the manufacturer's authorised representative and the person who has carried out a substantial modification to the machinery product shall apply one of the following procedures:

(a) EU type-examination procedure (module B) provided for in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;

(b) Conformity based on full quality assurance (module H) set out in Annex IX.

Old text:

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.

Impact / Motivation:

The obligation for substantially modified "Appendix I machine products" has been added.

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

Einfluss / Motivation:

Neu aufgenommen wurde die Verpflichtung für wesentlich veränderte "Anhang I Maschinenprodukte".

Dies wurde geändert, da an Maschinenprodukten nach Anhangs I jetzt benannte Stellen beteiligt sein müssen.

[99] Conformity assessment procedures for machinery products except partly completed machinery

Article 21 3

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

New text:

3. Where the machinery product is not a high-risk machinery product listed in Annex I, the manufacturer or the manufacturer's authorised representative and the person who has made a substantial modification to the machinery product shall apply the internal production control procedure (module A) set out in Annex VI.

Old text:

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.

Impact / Motivation:

The conformity assessment must also be carried out for PCM.

Otherwise no change

Einfluss / Motivation:

Die Konformitätsbewertung muss auch für uvM durchgeführt werden.

Ansonsten keine Änderung

[100] Conformity assessment procedures for machinery products except partly completed machinery

Article 21 4

New Article:

21 4

New / changed / moved / no change:

new

New text:

4. Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment and reduce those fees proportionately to their specific interests and needs.

Old text:

Impact / Motivation:

Notified bodies shall work more cost-effectively for SMEs.

This is a binding specification.

The first problem is, which definition to follow when assessing small and medium enterprises.

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

Einfluss / Motivation:

Benannte Stellen müssen bei KMU kostengünstiger arbeiten.

Dies ist eine verbindliche Vorgabe.

Das erste Problem ist, welche Definition bei der Einordnung kleiner und mittelständischer Unternehmen zu beachten ist.

Es gibt auch keinen festen Satz, zu dem die Konformitätsbewertung für kleinere Unternehmen günstiger sein muss.

[101] Conformity assessment procedures for partly completed machinery

Article 22 1

New Article:	22 1
Old Article:	13 1
New / changed / moved / no change:	no change

New text:

Conformity assessment procedures for partly completed machinery

1. The manufacturer of partly completed machinery or the manufacturer's authorised representative shall, before placing partly completed machinery on the market, ensure that the following documents are drawn up:

(a) the relevant technical documentation that satisfies the requirements laid down in Annex IV, part B;

(b) assembly instructions that satisfy the requirements laid down in Annex X;

(c) the EU declaration of incorporation that has the model structure set out in Annex V.

Old text:

Verfahren für unvollständige Maschinen

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;

(b) assembly instructions described in Annex VI are prepared;

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

Impact / Motivation:

1. No change

2. This is not a conformity assessment procedure, but a manufacturer obligation. In this respect, this is an additional requirement to Article 10 [68 ff].

The information for the machinery manufacturer is still not very helpful, because it is insufficient for the machinery manufacturer's evaluation of integration.

Einfluss / Motivation:

1. Keine Änderung

2. Es handelt sich hier nicht um ein Konformitätsbewertungsverfahren, sondern um Herstellerpflichten. Insofern ist diese eine zusätzliche Anforderung zu Artikel 10 [68 ff].

Die Informationen für den Maschinenhersteller sind immer noch wenig hilfreich weil nicht ausreichend für die Bewertung der Integration durch den Maschinenhersteller.

[102] Conformity assessment procedures for partly completed machinery

Article 22 2

New Article:	22 2
Old Article:	13 2
New / changed / moved / no change:	no change

New text:

2. Where relevant, the manufacturer of partly completed machinery or the manufacturer's authorised representative shall make available to the competent national authority upon its request the source code or programmed logic included in the technical documentation referred to in paragraph 1, point (a), , provided that it is needed in order for that authority to be able to check compliance with the essential health and safety requirements set out in Annex III. The assembly instructions referred to in paragraphs 1, point (b), and the declaration of incorporation referred to in paragraph 1, point (c), shall accompany the partly completed machinery until it is incorporated into the final machinery product and shall afterwards form part of the technical file for that machinery product.

Old text:

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.

Impact / Motivation:

no change

The superfluous reference to the source code has also been added here. If the source code is part of the special technical documentation, it is already regulated that it is accessible to market surveillance. See also Article 10 No. 3 [71]

Einfluss / Motivation:

keine Änderung

Auch hier wurde der überflüssige Hinweis bezüglich des Quellcodes hinzugefügt. Wenn der Quellcode Teil der speziellen technischen Unterlagen ist, ist bereits geregelt, dass er der Marktüberwachung zugänglich ist. Siehe auch Artikel 10 Nr. 3 [71]

[103] Protection of persons during installation and use of machinery products

Article 23

New Article:	23
Old Article:	15
New / changed / moved / no change:	changed

New text:

Protection of persons during installation and use of machinery products

Member States may lay down requirements to ensure that persons, including workers, are protected when installing and using machinery products, provided that such rules do not allow for modification of a machinery product in a way that is not compatible with this Regulation.

Old text:

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.

Impact / Motivation:

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, in theory, has a huge impact. Before, rules had to be conform to the Directive. Now they are just not allowed to demand less than the Regulation.

However demanding more is forbidden by the AEU contract.

Einfluss / Motivation:

Hier wird eine zwar ähnliche, inhaltlich aber von der MRL teilweise abweichende Regelung vorgeschlagen. Entfallen ist der Teil "im Einklang mit dem Gemeinschaftsrecht".

Auch "vorausgesetzt, dies bedeutet nicht, dass solche Maschinen auf eine Weise geändert werden, die nicht in dieser Richtlinie festgelegt ist." wurde geändert in "vorausgesetzt, dass diese Vorschriften keine Änderung eines Maschinenprodukts in einer Weise zulassen, die nicht mit dieser Verordnung vereinbar ist".

Dies hat theoretisch einen enormen Einfluss. Vorher mussten die Regeln der Richtlinie entsprechen. Jetzt dürfen sie einfach nicht weniger als die Verordnung verlangen.

Es ist nach dem AEU Vertrag jedoch verboten, mehr zu fordern.