# Proposal for a Regulation of the European Parliament and of the Council on machinery products

## Key points

## Comments on the proposal

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**Annex: additional motivations, amendments and requests for clarifications on parts of the Machinery Directive existing text**

# Proposal for a Regulation of the European Parliament and of the Council on machinery products

## Comments

**The recitals**

*(15) …However, machinery mounted on such vehicles or mobile machinery intended for facilitating works such as in construction sites or warehouses e.g. dumpers and forklifts, have a machinery function and should therefore be covered by this Regulation…*

Recital (15) is welcomed in the above-mentioned version.

*(17) The evolution of the machinery sector has resulted in the growing use of digital means and software plays a more and more important role in the machinery design. Consequently, the definition of machinery should be adapted. In this respect, machinery missing only the upload of a software intended for the specific application of the machinery should fall under the definition of machinery and not under the definition of partly completed machinery. Furthermore, the definition of safety components should cover not only physical devices but also digital devices. In order to take into account the increasing use of software as a safety component, software that performs a safety function and is placed independently on the market should be considered a safety component.*

The definition of safety component has been modified to include non-physical components such as software.
Safety components are now physical devices but also digital devices.

In practise, how the EU declaration of conformity will be addressed on this type of "machinery product"?
The application and implementation of this new provision should be specified.

*(19) Where machinery products pose risks that are addressed by the essential health and safety requirements set out in this Regulation but are also wholly or partly covered by other more specific Union legislation, this Regulation should not apply to the extent that those risks are covered by that other Union legislation. In other cases, machinery products may pose risks that are not covered by the essential health and safety requirements set out in this Regulation.*

Recital (19) is welcomed in the above-mentioned version.

*(19) For artificial intelligence systems, the specific Union legislation on artificial intelligence should apply, since it contains specific safety requirements for high-risk artificial intelligence systems.*

The horizontal legal act on AI is welcomed as a proposal.
See related proposal for Annex I.

*(19) In order to avoid incoherence with regard to the type of conformity assessment and to avoid introducing requirements to perform two conformity assessments, those specific safety requirements should however be checked as part of the conformity assessment procedure set out in this Regulation. The essential health and safety requirements set out in this Regulation should in any case be applied in order to ensure, where applicable, the safe integration of the artificial intelligence system into the overall machinery, so as not to compromise the safety of the machinery product as a whole.*

The application of requirements concerning conformity assessment procedures from this regulation, although regulations are prescribed in a European legal act, is also welcomed as a proposal.

*(23) In order to ensure that machinery products, when placed on the market or put into service, do not entail health and safety risks for persons or domestic animals and do not cause harm to property and, where applicable, the environment, essential health and safety requirements should be set out which have to be met in order for the machinery products to be allowed on the market. Machinery products should comply with the essential health and safety requirements when placed on the market or put into service. Where such machinery products are subsequently modified, by physical or digital means, in a way that is not foreseen by the manufacturer and* ***that may imply that it no longer meets the relevant essential health and safety requirements****, the modification should be considered as substantial. For example, users may upload software in a machinery product that is not foreseen by the manufacturer and that may generate new risks. In order to ensure the compliance of such a machinery product with the relevant essential health and safety requirements, the person that carries out the substantial modification should be required to perform a new conformity assessment before placing the modified machinery product on the market or putting it into service. That requirement should only apply with respect to the modified part of the machinery product, provided that the modification does not affect the machinery product as a whole. In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to aspects of the machinery product that are not impacted by the modification. It should be up to the person who carries out the substantial modification to demonstrate that the modification does not have an impact on the machinery product as a whole.*

- The wording "may" is not appropriate.
A substantial modification generates new risks that implies that relevant essential health and safety requirements are no longer met.
Proposal:
Where such machinery products are subsequently modified, by physical or digital means, in a way that is not foreseen by the manufacturer and that ~~**may**~~ imply that it no longer meets the relevant essential health and safety requirements, the modification should be considered as substantial.

- The timetable for the application of this provision must be specified and clearly defined.
"*that it no longer meets the relevant essential health and safety requirements*"
In case of substantial modification of a machinery product, should we consider the respect of the EHSR of the machinery directive 2006/42/CE or of the new ESHR of the regulation on machinery product?
Proposal:
The respect of ESHR must be linked to the first making available of the machinery product on the market.

*(50) Manufacturers should be responsible for certifying the conformity of their machinery products with this Regulation. Nevertheless, for certain types of machinery products that have a higher risk factor, a stricter certification procedure requiring participation of a notified body should be required.*

With the addition of:
"*24. Software ensuring safety functions, including AI systems,*
*25. Machinery embedding AI systems ensuring safety functions*,"
in annex I, all machinery product embedding new technologies (safety component and machinery) will be considered high risk machines.
When placed on the market, the conformity assessment and certification procedure should be carried out by the manufacturers and not by a notified body.
Only the manufacturer has the appropriate technical competences to guarantee the safety of its machines, especially when safety related AI systems are integrated !

The Commission's proposal for a Regulation on Artificial Intelligence (AI) defines AI techniques and concepts in its Annex I.
The risks posed by some of these techniques and concepts can be reliably assessed using currently available and proven methods.
These include, for example, deductive, more knowledge-based (symbolic) techniques and concepts such as the statistical approaches and Bayesian estimation, search and optimisation methods mentioned in Annex I c) of the proposed AI regulation.

Such artificial intelligence (AI) techniques and concepts are already used today for safety-relevant functions of machines, evaluated and safely placed on the market without the involvement of notified bodies. It is therefore also not necessary in future to involve a notified body in the conformity assessment for the techniques and concepts listed in Annex I c) of the Commission proposal for a regulation on artificial intelligence.
Points 24. and 25. from Annex I of the Machinery Products Regulation should therefore be formulated in a more differentiated manner in order to take better account of such differences between AI techniques and concepts.

**The articles**

**Article 2**

*(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;*

It would have to be specified in the Machinery Regulation that the following applies to the subject of attachments/structures (e.g. loading cranes on trucks):
a) Trucks are not covered by the Machinery Regulation. This is considered to be correct. This applies to all vehicles that are subject to compulsory road registration and/or track vehicles.
b) Loading cranes on trucks and the like are subject to the Regulation which is considered correct.

Manufacturers must provide information on request as to whether machine mountings and the like are possible on their vehicles and with what specifications.

At the same time, the manufacturer of the mounting/machine must state what forces act on the corresponding superstructure vehicle.

This is of essential importance for the construction industry!

**Article 3 Definitions**

*(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;*

Safety components must not be limited to components for "machines", as this would mean, for example, that the software for a laser scanner would not be a safety component, which would contradict the actual intention.
Software must therefore be classified as a safety component in the Machinery Regulation.

**Article 3 Definitions**

*(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;*

In principle, a definition of "substantial modification" is useful.

However, it must be prevented in any case that every "modification/change/alteration" to a machine or to a machine product is equivalent to a substantial modification.
And this definition of substantial modification might lead to a massively increased numbers of those modifications.
New conformity assessments will become mandatory for digital modifications which are aimed to lead to an increased level of safety and will have an important impact on the employer's organisation.
In practise, for example, the digital modification/update of safety devices and the installation of safety devices which do not enable any additional functions, that inevitably lead to an increase of the level of safety of the machine, shall not be considered as substantial modifications, and shall not require the intervention of a third party.

Therefore, the definition/interpretation proven in practice should also be used in the future.
See: "BMAS, 01.03.2015 - IIIb5-39607-3 - in GMBl 2015, Nr. 10, S. 183-186 (https://www.bmas.de/DE/Arbeit/Arbeitsschutz/Produktsicherheit/interpretationspapier-wesentliche-veraenderung-von-maschinen.html) :
1. the machine is safe even after modification without additional protective measures.
There is no significant change.
2. the machine is no longer safe after the modification without additional protective measures. The new hazard or the increased risk can be eliminated or at least sufficiently minimised by simple protective devices.
There is no significant change.
3. the machine is no longer safe after the modification without additional protective measures and a sufficient risk reduction cannot be achieved by simple protective devices.
There is a significant change.

A separate annex should be created for this point, in which the prerequisites and implementation are clearly regulated.

Proposal:
*(16) 'substantial modification' means **a change of a specific application** 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 **or planned** for 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;*

This is of essential importance for the construction industry!

**Article 3 Definitions**

*(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;*

Proposal:
(17) 'manufacturer' means any natural or legal person who manufactures machinery products or who has machinery products designed or manufactured **or undertaken substantial modifications**, 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;

With the wording "*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",* this regulation is supported in principle if it is interpreted as follows:
It is essential that machinery products must be designed and built for own use.
This includes machines (some of which are unique) which are not designed and built-in series for the domestic market because, based on practical experience, no manufacturer usually undertakes the design and construction for this application. Consequently, other criteria for commissioning and use must apply here than for machinery products that are made available on the market or placed on the market.
This is very important to the construction industry!

**Article 5 in combination with Article 21**

Provided that manufacturers apply harmonised standards, manufacturers are currently allowed to carry out the conformity assessment procedure for machinery covered by Annex IV of Directive 2006/42/EC entirely on their own.

As this has not led to problems so far, this should continue to be possible for these products.
Art 21 should be amended in this respect.

**Article 7 Requirements for machinery products**

Proposal to add the following wording:
*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 **taking into account foreseeable misuse,** they meet the essential health and safety requirements set out in Annex III.*

This change is important to the construction industry!

**Article 23 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.*

The above-mentioned text of Art. 23 is interpreted to the effect that occupational health and safety is still not affected by this Machinery Regulation (internal market). This includes, among others, the OSH Framework Directive and the Directive on the Use of Work Equipment.

Member states can independently adopt transposition acts on the basis of these above-mentioned directives. It must be explicitly stated that member states cannot enact independent legal acts on the scope of application of the Machinery Regulation on the basis of Art. 23.

Only if the text of Art. 23 is interpreted in this way can it be approved.
Otherwise, the text would have to be amended accordingly.
This issue is of essential importance for the construction industry!

**Article 10 (3), Article 12 (8) and Article 22 (2)**

The proof and storage obligations - especially with regard to software products - are welcomed.

However, it would have to be clarified whether a period of 10 years is sufficient, as the life cycle of many (valuable) machines clearly exceeds 10 years.

**Article 20**

*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.*

This article needs precisions.
For machinery embedding AI systems ensuring safety functions, the machinery shall have additional CE marking.
In practice, how the end-user (the employer) will receive/manage the documents?

**Chapter IV CONFORMITY ASSESSMENT**

Notified authorities must be able to verify and establish conformity with regard to both hardware (machine) and software - especially with regard to software-based security functions and cyber security.
This requirement is to be regulated accordingly in the text of the regulation.
This issue is of essential importance for the construction industry!

# Annex to the proposal for a Regulation of the European Parliament and of the Council on machinery products

## Comments

- **ANNEX I / HIGH-RISK MACHINERY PRODUCTS**

*17. Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres.*

The vertical fall height must be corrected to 2 m accordingly.
Proposal:
Devices for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than ~~three~~ **two** metres.

This issue is of essential importance for the construction industry!

*Addition of :*
*24. Software ensuring safety functions, including AI systems.*
*25. Machinery embedding AI systems ensuring safety functions.*

The Commission's proposal for a Regulation on Artificial Intelligence (AI) defines AI techniques and concepts in its Annex I.
The risks posed by some of these techniques and concepts can be reliably assessed using currently available and proven methods.
These include, for example, deductive, more knowledge-based (symbolic) techniques and concepts such as the statistical approaches and Bayesian estimation, search and optimisation methods mentioned in Annex I c) of the proposed AI regulation.

Such artificial intelligence (AI) techniques and concepts are already used today for safety-relevant functions of machines, evaluated and safely placed on the market without the involvement of notified bodies. It is therefore also not necessary in future to involve a notified body in the conformity assessment for the techniques and concepts listed in Annex I c) of the Commission proposal for a regulation on artificial intelligence.

It could be not appropriate to consider all safety-related AI systems as high risk, by default.
Points 24. and 25. from Annex I of the Machinery Regulation should therefore be formulated in a more differentiated manner in order to take better account of such differences between AI techniques and concepts.

- **ANNEX II INDICATIVE LIST OF SAFETY COMPONENTS**

*Addition of :*
*18. Software ensuring safety functions, including AI systems.*

This is important for the construction industry.

- **ANNEX III / ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF MACHINERY PRODUCTS**

- **GENERAL PRINCIPLES**

*1. The manufacturer of a machinery product or his or her authorised representative shall ensure that a risk assessment is carried out in order to determine the health and safety requirements, which apply to the machinery product. The machinery product shall then be designed and constructed to prevent and minimise all relevant risks, taking into account the results of the risk assessment.*

Even if it is common to use "should", especially in standardization and legal text, the old text using "**must**" is more relevant and legible.
In the official German translation of the proposal, the word "muss" is already used - which is supported. It is important to ensure that this word continues to be used consistently in all languages in the text of the regulation.

- **GENERAL PRINCIPLES**

*(b) determine the risks resulting from interactions between machinery in order to achieve the same end that are arranged and controlled so that they function as an integral whole, thus forming a machinery product as defined in Article 3, point (1), point (d);*

Editorial comment: This step (b) should be one of the last steps of the RA and RR (not in "b" position)

- **GENERAL PRINCIPLES**

*(c) identify the hazards that may be generated by the machinery product and the associated hazardous situations, including hazards that may be generated during the lifecycle of the machinery product that are foreseeable at the time of placing of the machinery product on the market as an intended evolution of its fully or partially evolving behaviour or logic as a result of the machinery product designed to operate with varying levels of autonomy. In this respect, where the machinery product integrates an artificial intelligence system, the machinery risk assessment shall consider the risk assessment for that artificial intelligence system that has been carried out pursuant to the Regulation … of the European Parliament and of the Council+ on a European approach for Artificial Intelligence+ ; .*

The technology neutrality of the Machinery Directive with the risk assessment (RA) and risk reduction (RR) principles is well appreciated and these principles apply for all technologies, methods and approaches.
All the risks must be assessed in the manufacturer RA, and machine learning capabilities must be anticipated and predicted by the manufacturer before placing into the market.
This wording is too confusing.
The old text of MD was sufficient even with respect to AI hazards: "identify hazards that can be generated by the machinery and the associated hazardous situations"

The wording “fully or partially evolving behaviour or logic” is not significant because it represents an unavailable technology and a clear lack of experience.
As mentioned in the recital 45: “*the market for software (…) based on artificial intelligence is so far very small, which results in a lack of experience and data*”.
So, how the end user can be sure that this new requirement is adequate and sufficient?

- **1.1.2 Principles of safety integration**

*(e) A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions, and the machinery product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.*

This clear formulation of the addition of being able to test machinery products and their safety functions is welcome.

- **1.1.6 Ergonomics (e) and (f)**

*(e) adapting the human-machinery product interface to the foreseeable characteristics of the operators, including with respect to a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy;*
*(f) adapting a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy to respond to people adequately and appropriately (verbally through words and non-verbally through gestures, facial expressions or body movement) and to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner.*

These new requirements for ergonomics and interface are important points with respect to AI requirements and human-machinery working situations.

- **1.1.9 Protection against corruption**

*The machinery product shall be designed and constructed so that the connection to it of another device, via any feature of the connected device itself or via any remote device that communicates with the machinery product does not lead to a hazardous situation.*
*A hardware component for connection that is critical for the compliance of the machinery product with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption. The machinery product shall collect evidence of a legitimate or illegitimate intervention in the hardware component.*
*Software and data that are critical for the compliance of the machinery product with the relevant health and safety requirements shall be identified as such and shall be adequately protected against accidental or intentional corruption.*
*The machinery product shall identify the software installed on it that is necessary for it to operate safely, and shall be able to provide that information at all times in an easily accessible form.*
*The machinery product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery product or its configuration.*

This new aspect deals with the issue of cybersecurity and hacking.

However, this new paragraph 1.1.9 could also refer to 1.2.1.a: "*unintended external influences, including malicious attempts from third parties to create a hazardous situation*"
The execution of this requirement is very important for the users and therefore to be welcomed.

Proposal for 1.1.9:
*Software and data that are critical for the compliance of the machinery product with the relevant health and safety requirements shall be identified as such and shall be adequately protected against accidental or intentional corruption.*
*The machinery product shall identify the software installed on it that is necessary for it to operate safely, and shall be able to provide that information at all times in an easily accessible form.*
*The machinery product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery product or its configuration* ***and safe those protected against accidental or intentional tampering****.*

This is important for construction!

- **1.2.1. Safety and reliability of control systems**

*(d) the safety functions cannot be changed beyond the limits defined by the manufacturer in the machinery product risk assessment. The establishment of the limits of the safety functions shall be part of the risk assessment performed by the manufacturer, including any modifications to the settings or rules generated by the machinery product or by operators, covering also the learning phase, which cannot go beyond the limits addressed in the risk assessment;*

The limits of the safety functions are part of RA of the manufacturer.
Therefore, important machinery changes will be part of the substantial modification criteria.
With this wording, important changes or safety updates will be impossible without the original manufacturer.
Safety updates lead to an increased level of safety of the machine and are aimed to improve the machinery working conditions.
These situations should not be considered as substantial modifications.
See our comments on this in Art. 3 (16).

- **1.2.1. Safety and reliability of control systems**

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

This clause 1.2.1 (f) is addressed directly to the manufacturer or software provider.
In this respect, this must be specified in the text of the regulation.

Proposal:
*(f) the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery product has been placed on the market or put into service, is enabled for five years after such upload* ***by the manufacturers or software providers****, exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority;*

This is important for construction.

Additional question:
How guarantee that market surveillance and national authorities will be able to check, in all situations, the traceability of machinery safety?

- **1.2.1. Safety and reliability of control systems**

*(g) recording of data on the safety related decision-making process after the machinery product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection, exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority.*

This clause 1.2.1 (g) is addressed directly to the manufacturer or software provider.
In this respect, this must be specified in the text of the regulation.

Proposal:
*(g) recording of data on the safety related decision-making process after the machinery product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection* ***by the manufacturer or software providers,*** *exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority.*

This is important for construction.

- **1.2.1. Safety and reliability of control systems**

Control systems of machinery products with fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy shall be designed and constructed in such a way that:
(a) they shall not cause the machinery product to perform actions beyond its defined task and movement space;
(b) it shall be possible at all times to correct the machinery product in order to maintain its inherent safety.

The wording "designed to operate with varying levels of autonomy" is confusing.
Saying that, the machinery must be safe in any operating condition and in all levels of autonomy.
How can the end-user be sure that these machines will be made safe and placed on the market without any risks, whatever the level of autonomy?
There is a need for clarification.

- **1.2.1. Safety and reliability of control systems**

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

What is a "remote supervisory function"?
There is a need for a definition and a clarification on this point from the user side.

- **1.2.6. Failure of the power supply or communication network connection**

*The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply or communication network connection to the machinery product shall not lead to hazardous situations.*

With connected machinery, the communication network connection is an important item.

Since the failure of a communication link must also be taken into account in the text of the regulation, the above addition is necessary.

Proposal:
*The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply **or the failure or change of** communication network connection to the machinery product shall not lead to hazardous situations.*

- **1.3.7. Risks related to moving parts and psychological stress**

*The prevention of risks of contact leading to hazard situations and the psychological stress that may be caused by the interaction with the machine shall be adapted to:*
*(a) human-machine coexistence in a shared space without direct collaboration;*
*(b) human-machine interaction.*

The prevention of risks of contact for all situations of human-machine coexistence and interaction is a safety key requirement.
The safety and health requirements in 1.3.7 are in any case to be assessed by the manufacturers. Information on this is essential in the relevant operating instructions of the manufacturers.
The regulations in clause 1.3.7 are therefore to be welcomed and, if necessary, further specified.

- **1.3.7. Risks related to moving parts and psychological stress**

*The machinery product with fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy shall be adapted to respond to people adequately and appropriately (verbally through words or nonverbally through gestures, facial expressions or body movement) and to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner.*

This new requirement that AI machinery shall indicate its planned action is welcome.

- **1.5.13. Emissions of hazardous materials and substances**

*A machinery product shall be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided.*
*Where a risk cannot be eliminated, the machinery product shall be so equipped that hazardous materials and substances can be contained, **captured**, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.*

*Where the process is not totally enclosed during normal operation of the machinery product, the devices for containment **or capture, filtration or separation** and evacuation shall be situated in such a way as to have the maximum effect.*

This new requirement regarding hazardous substances is welcome.

What is intended by the text must be expressed more clearly.
Paragraph 3 should be deleted, as it counteracts the already concrete requirements of the previous regulations.

Proposal:
*A machinery product shall be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces **or sets free throughout intended use is avoided.***
*Where a risk cannot be eliminated, the machinery product shall be so equipped that hazardous materials and substances can be contained, **captured**, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.*
~~*Where the process is not totally enclosed during normal operation of the machinery product, the devices for containment or capture, filtration or separation and evacuation shall be situated in such a way as to have the maximum effect.*~~

- **1.6.2. Access to operating positions and servicing points**

*Machinery shall be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment, maintenance and cleaning of the machinery.*

The addition of « cleaning » access gives clarity regarding this important operation.
It is no longer considered as part of maintenance but as an identified task.

Translation:
The official German translation lacks the "cleaning".

- **1.6.2. Access to operating positions and servicing points**

*In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be dimensioned and adapted for the use of rescue equipment in such a way that a timely rescue of the persons is guaranteed.*

The new paragraph dealing with rescue of persons entering machinery is welcome.
The fact that accesses for the use of rescue equipment must be sufficiently dimensioned in future is important and correct.

- **1.7.4. Instructions**

*The instructions may be provided in a digital format. However, upon purchaser's request at the time of the purchase of the machinery product, the instructions shall be provided in paper format free of charge.*
*When the instructions are provided in digital format, the manufacturer shall:*

*(a) mark on the machinery product and in an accompanying paper how to access the digital instructions;*
*(b) clearly describe which version of the instructions corresponds to the machinery product model;*
*(c) be presented in a format that makes it is possible for the end user to download the instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machine. This requirement also applies to a machinery product where the instruction manual is embedded in the software of the machinery product. General principles for the drafting of instructions*

Machinery will be delivered with digital instructions only.
The digitalisation aspects are welcome.
This new requirement has an important impact on the relevance and availability of instruction manuals in the whole lifecycle of the machinery.

The wording "how to access the digital instructions" is not clear enough and need precisions in relation to longevity and availability.
Manufacturer's companies often update their websites.
It may be very difficult to find the instruction guide in the successive versions of each manufacturer's website.
There should be more requirements to ensure the accessibility of digital instructions over the lifecycle of the machinery products.

Proposal:
*The instructions may be provided in a digital format. However, upon purchaser's request at the time of the purchase of the machinery product, the instructions shall be provided in paper format free of charge.*
*When the instructions are provided in digital format, the manufacturer shall:*
*(a)mark on the machinery product and in an accompanying paper how to access the digital instructions;*
*(b)clearly describe which version of the instructions corresponds to the machinery product model;*
*(c)be presented in a format* ***over the whole lifecycle of the machinery product*** *that makes it is possible for the end user to download the instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machine. This requirement also applies to a machinery product where the instruction manual is embedded in the software of the machinery product. General principles for the drafting of instructions*

Editorial comment: Reword the (c) because it doesn't fit with the first sentence "the manufacturer shall…be presented in a format"

- **1.7.4.2. Contents of the instructions**

*1. Each instruction manual shall contain, where applicable, at least the following information:*

This point specifies the minimum details of the operating instructions, therefore the term "where applicable" is not appropriate.

Proposal:
*1. Each instruction manual shall contain,* ~~***where applicable***~~*, at least the following information:*

- **1.7.4.2.Contents of the instructions**

*(c) the EU declaration of conformity, or a document setting out the contents of the EU declaration of conformity, showing the particulars of the machinery product, not necessarily including the serial number and the signature, or the internet address where the EU declaration of conformity can be accessed.*

According to this proposal, EU declaration has not to be attached to the machinery.
This will have a huge impact on the availability of this key document of the machinery during all its lifetime and all successive uses in different construction jobsites.
The validity of the internet address should be specified.
The URL shall be active all the lifetime of the machinery.
There should be more requirements to ensure the accessibility of digital documents over the lifecycle of the machinery products.

- **1.7.4.2. Contents of the instructions**

*(w) where the machinery product design allows emissions of hazardous substances from the machinery product, the characteristics of the capturing, filtration or discharge device if such device is not provided with the machinery product, and any of the following:*
*i. the flow rate for the emission of hazardous materials and substances from the machinery product,*
*ii. the concentration of hazardous materials or substances around the machinery product coming from the machinery product or from materials or substances used with the machinery product,*
*iii. the effectiveness of the capturing or filtration device and the conditions to be observed to maintain its effectiveness over time.*
*The values referred to in the first subparagraph shall either be actually measured for the machinery product in question or established based on measurements in respect of a technically comparable machinery product, which is representative of the state of the art.*

This proposal is welcome.
For the user, only the actual measured value is important in (construction) practice and not the theoretical laboratory value of the machine!

- **2.2.1. General**

*(e) have a device or a connected exhaust system, with an extraction connection outlet or equivalent system to capture or reduce emissions of hazardous substances. This requirement does not apply where its application would result in the creation of a new risk, where the main function of the machinery is the spraying of hazardous substances and to emissions of internal combustion engines. The handles of portable machinery shall be designed and constructed in such a way as to make starting and stopping straightforward.*

This proposal is welcome.

- **2.2.1.1. Instructions**

*The instructions shall give the following information concerning vibrations, expressed as acceleration (m/s2), and transmitted by portable handheld and hand-guided machinery:*
*(a) the vibration total value from continuous vibrations to which the hand-arm system is subjected;*

*(b) the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected;*

This new requirement on the format of the vibration is welcome.

- **2.2.1.1 Instructions**

*The values referred to in the first subparagraph shall either be those actually measured for the machinery in question or those established on the basis of measurements in respect of a technically comparable machinery product, which is representative of the state of the art.*

For the user, only the actual measured value is important in (construction) practice and not the theoretical laboratory value of the machine!

Proposal:
The values referred to in the first subparagraph shall ~~**either**~~ be those actually measured for the machinery in question ~~**or those established on the basis of measurements in respect of a technically comparable machinery product, which is representative of the state of the art.**~~

- **3.1.1. Definitions**

*(b) 'Driver' means a person responsible for the movement of a machine, who may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control or may remotely supervise the autonomous mobile machinery product regardless of the distance and the means of control communication.*

With this new requirement, the driver/operator of an autonomous mobile machinery can now supervise and control it from anywhere.
This requirement gives flexibility on the main driving modes and the distance between the driver and the machinery.
The definition is supported.

Moreover, the operator is responsible for the movement of the machinery.
Monitoring and supervision will be more and more practiced.
If the machine is guided from a distance (short? mid? long distance?)(with direct or indirect vision?), from anywhere and with any means, the employer shall evaluate the impact of this new job organisation. This will have an impact on the design of the working area.

- **3.1.1. Definitions**

*(c) 'Autonomous mobile machinery' means a mobile machinery that has an autonomous mode, in which all the essential safety functions of the mobile machinery are ensured in its travel and working operations area without permanent interaction of an operator.*

This proposal is welcome.

- **3.2.2. Seating**

*….the machinery shall be designed or equipped with a restraint system so as to keep the persons in their seats or in the protective structure,*

The proposal of addition of "in the protective structure" is welcome.

An addition and precision regarding ergonomic principles should be added:
Proposal to add the sentence:
*The restraint system must be designed according to ergonomic principles.*

- **3.2.2. Seating**

*A visual or audible signal shall be provided at the driving position alerting the driver when the restraint system is not active.*

This specific requirement is a real great progress to improve safety and enhance the state of the art.
This proposal is welcome but not sufficient.

Moreover, a visual signal is not sufficient for the driver to be alerted.
Proposal:
A visual **and** an audible signal shall be provided at the driving position alerting the driver when the restraint system is not active.

- **3.2.4. Supervisory control function**

*Autonomous mobile machinery products shall have a supervisory control function specific to the autonomous mode. This function shall allow the operator to remotely receive information from the machine. The supervisory control function shall only allow actions to stop and to start remotely the machine. It shall be designed and constructed to allow those actions only when the driver can see directly or indirectly the machine's movement and working area and the protective devices are operational.*

All autonomous machinery require a supervisory control function, activated while driving with only a start and stop possible functions.
This proposal is welcome.

- **3.2.4. Supervisory control function**

*The information the driver receives from the machine when the supervisory control function is active shall enable the driver to have a complete and accurate view of the operation, movement and safe positioning of the machine in its travel and working area.*
*This information shall alert the driver of the occurrence of unforeseen or dangerous situations present or impending, which require driver's intervention.*
*If the supervisory control function is not active, the machinery shall not be able to operate.*

This paragraph is not precise enough.
The addition of the requirement:
"*The information the driver receives from the machine when the supervisory control function is active shall enable the driver to have a complete and accurate view of the operation, movement and safe positioning of the machine in its travel and working area.*"
stresses the responsibility of the manufacturer to ensure that the driver can see the complete working area.
In practise, the manufacturer may not be able to give this information.
The working situations can't be anticipated by the manufacturer
How this requirement could be correctly applied?

- **3.3.2. Starting/moving**

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

This requirement is welcome.

- **3.3.3. Travelling function**

*Autonomous mobile machinery products shall comply with any of the following conditions:*
*(a) it shall move and operate in an enclosed zone fitted with a peripheral protection system comprising guards or protective devices;*

This requirement is welcome for the safety travelling functions of the autonomous mobile machinery.

Moreover, as the machinery shall move in an enclosed zone, this proposal is not clear enough on the obligations of the manufacturer and the end user.
Protective devices must be installed.
Can we consider the machine incomplete without these protection systems?
Are peripheral safety devices part of the machinery ?
If they are, they shall be provided by the manufacturer.
Otherwise, this requirement introduces obligations and responsibilities for the employer to protect the working area of all autonomous mobile machineries.
In this case, there is an important impact on the organisation of the working area : the employer shall find appropriate professional suppliers of protection systems, specialised in autonomous mobile machinery.

*(b) it shall be equipped with devices intended to detect any human, domestic animal or any other obstacle in its vicinity, where those obstacles could give rise to a risk to health and safety of persons or of domestic animals or to safe operation of the machinery product.*
*The movements of mobile machinery products connected with one or more trailers or towed equipment, including autonomous mobile machinery products, connected with one or more trailers or towed equipment, shall not give rise to risks for persons, domestic animals or any other obstacle in the danger zone of such machinery products and trailers or towed equipment.*

The machinery shall be equipped with devices intended to detect any human or any other obstacle in its vicinity, and this requirement is welcome.
In practice, users must also ensure the protection of the animals mentioned.

- **3.3.5. Control circuit failure**

*For autonomous mobile machinery, a failure in the steering system shall not have an impact on the safety of the machinery.*

This proposal is not sufficient and is different from the one presented by the Commission in November 2020 ("*For autonomous mobile machinery, a failure in the steering system shall stop any movements of the machinery.*")

Proposal to add the following sentence:
*For autonomous mobile machinery, a failure in the steering system shall not have an impact on the safety of the machinery.*
***In case of a failure of the steering system a safe stop of the machinery shall be ensured.***

- **3.5.1. Batteries**

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

The reference to 1.3.8.2 is not appropriate.

- **3.5.3 Emissions of hazardous substances**

*Ride-on mobile machinery having spraying of products as the main function shall be equipped with filtration cabs or equivalent safety measures.*

This proposal is welcome.

- **3.5.4. Risk of contact with live overhead power lines**

*Depending on the height of the machinery products, mobile machinery product shall, where relevant, be designed, constructed and equipped, so as to prevent the risk of contact with an energised overhead power line or the risk of creating an electric arc between any part of the machinery or an operator driving the machinery and an energised overhead power line.*
*When the risk of contact or electric arc with an energised overhead power line cannot be fully avoided, mobile machinery products shall be designed, constructed and equipped in such a way that all hazards of an electrical nature are prevented or can be prevented in the event of contact or electrical arc with an energized power line.*

This proposal is welcome.

- **3.6.3.1. Vibrations**

*The instructions shall give the following information concerning vibrations, expressed as acceleration (m/s2), transmitted by the machinery to the hand-arm system or to the whole body:*
*(a) the vibration total value from continuous vibrations to which the hand-arm system is subjected;*
*(b) the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected;*

This proposal is welcome.

- **3.6.3.3. Autonomous mobile machinery products**

*The instructions for use of autonomous mobile machinery products shall specify the characteristics of its intended travel, working areas and danger zones.*

Here is a translation error in the official German version, which must be corrected.
It must be “Betriebsanleitung” in stead of “Gebrauchsanweisung”.

- **4.1.2.3. Mechanical strength**

*Machinery, lifting accessories and their components shall be capable of withstanding the stresses to which they are subjected during their lifetime*

The addition of “during their lifetime” is welcome.
It is important for the construction sector.

- **4.1.3. Fitness for purpose**

*Where the machinery cannot be assembled in the manufacturer's premises or in the premises of his or her authorised representative, the appropriate measures shall be taken at the place of use by the manufacturer, or by his or her authorised representative or by another subject on the manufacturers’ behalf. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.*

We support this proposal.

In German language it is "Gebrauchstauglichkeit" instead of "Zwecktauglichkeit". This would have to be corrected.

- **6.2. CONTROL DEVICES**

*If there is no risk of persons or objects on the carrier colliding or falling and no other risks due to the upward and downward movements of the carrier, control devices authorising automatic stops at preselected positions may be used instead of hold-to-run type control devices*

No opinion.

- **ANNEX IV**

Point A (n) and point B (l)
We support these proposals.

# Annex

# Machinery Directive existing text

# Additional motivations, amendments and requests for clarifications

- **1.1.2 Principles of safety integration**

*(b) In selecting the most appropriate methods, the manufacturer or his authorised representative must apply the following principles, in the order given:*
*- eliminate or reduce risks as far as possible (inherently safe machinery design and construction),*
*- take the necessary protective measures in relation to risks that cannot be eliminated,*
*….*

Proposal:
In selecting the most appropriate methods, the manufacturer or his or her authorised representative shall apply the following principles, in the order given:
- eliminate or reduce risks as far as possible (inherently safe machinery product design and construction);
- take the necessary protective measures in relation to risks that cannot be eliminated; **Hazard control is to be carried out at the source of the hazard.**

This issue is of essential importance for construction!

- **1.1.2 Principles of safety integration**

Proposal of an additional subitem:
**1.1.2. (f) The manufacturer must take appropriate measures to ensure that users are notified or warned in a timely and effective manner when security-relevant software updates are necessary or cyber risks exist.**

This issue is essential for construction industry!
(Note: It may be necessary to insert the subject matter in another place in the Machinery Regulation).

Proposal of an additional subitem:
**1.1.2. (g) For each safety-relevant software change, the operator must be provided with comprehensible documentation. (Note: General principles regarding language versions from Annex III, item 1.7.4. instruction handbooks are also to be applied here).**

This issue is essential for construction industry!
(Note: It may be necessary to insert the subject matter in another place in the Machinery Regulation).

Proposal of an additional subitem:
**1.1.2. (h) For machinery whose safety depends on software, the manufacturer must ensure stable software support over the life cycle of the machinery products.**

This issue is essential for construction industry!
(Note: It may be necessary to insert the subject matter in another place in the Machinery Regulation).

- **1.2.1. Safety and reliability of control systems**

*(e) reasonably foreseeable human errors during operation shall not lead to hazardous situations;*

For similar types of machines (lifting platforms, wheel loaders, excavators, rollers, etc.), the actuator assignment for travel and working movements and operation in an emergency must be harmonised. Standards are to be drawn up on the basis of Article 17 of Chapter III.

This issue is of essential importance for construction!

- **1.2.2 and 3.3.1 (control devices (warning signal))**

There is a lack of consistency on control devices and warning signal requirements :
- 1.2.2. Control devices, 6th indent :
*If neither of these possibilities is applicable, before the machinery product starts, an acoustic and/or visual warning signal shall be given. The exposed persons shall have time to leave the danger zone or prevent the machinery starting up.*
- 3.3.1. Control devices, 6th indent :
*The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing*.

-> Would it be possible to make this requirement clearer, as a general EHSR and not a specific situation?

Proposal:
-> keep 1.2.2. and add the 6th indent of 3.3.1
-> delete the 6th indent of 3.3.1:
The new wording will be :
- 1.2.2. Control devices, 6th indent :
*If neither of these possibilities is applicable, before the machinery product starts, an acoustic and/or visual warning signal shall be given. The exposed persons shall have time to leave the danger zone or prevent the machinery starting up.*
***Acoustic and/or visual warning signals apply only in the case of reversing*.**

- **1.5.15. Risk of slipping, tripping or falling**

*Parts of the machinery product where persons are liable to move about or stand shall be designed and constructed in such a way as to prevent persons slipping, tripping or falling on or off these parts.*
*Where appropriate, these parts shall be fitted with handholds that are fixed relative to the user and that enable them to maintain their stability.*

Constructive technical measures of the manufacturer have priority over the use of " Personal Protective Equipment " against falls from a height (PPE).

Proposal to add the following sentence:

**These constructive technical measures of the manufacturer have priority. In the case of unavoidable use of personal protective equipment against falls from a height (PPE), which must be specified by the manufacturer, the stability of the machine must also be guaranteed in the event of a fall due to the energy of the fall.**

- **1.7.4. Instructions**

*The instructions accompanying the machinery product shall be either 'Original_instructions' or a 'Translation of the original instructions', in which case the translation shall be accompanied by the original instructions.*

The operating instructions only fulfil their purpose for safe operation of the machines if they can be understood by the users without doubt and without barriers. A prerequisite for this is the official translation by the manufacturer, which is his responsibility.

Proposal:
**The manufacturer's instructions accompanying the machinery product must, in addition to the original, also be provided in the official language of the Union country where the machinery is placed on the market, made available on the market and put into service by the manufacturer.**

- **1.7.4. Instructions**

*By way of exception, the maintenance instructions intended for use by specialised personnel mandated by the manufacturer or his or her authorised representative may be supplied in only one official language of the Union which the specialised personnel understand.*

The above paragraph is agreed with the exception that provided that the regulation is understood as targeting the so-called application technicians of the manufacturers and not the users.

- **1.7.4. Instructions**

**Additional requirements:**

The new provisions for a digital instruction handbook should also apply to the assembly instructions and declaration of incorporation for partly completed machinery. They are at least as useful there as for complete machines.

Many products that will be subject to the Machinery Regulation can also be purchased in the DIY store, such as a circular saw. Not every user will be able to download the digital instruction handbook (immediately). In some cases, it will also not be possible for the paper version to be supplied immediately by the manufacturer. To prevent this from leading to many users putting products into operation without having read the manufacturer's safety instructions, it is important that essential information for commissioning and safe use is always supplied in short form on paper.

- **1.7.4.2. Contents of the instructions**

*(h) warnings concerning ways in which the machinery product shall not be used that experience has shown might occur;*

This addition corresponds to the meaning of the Regulation and should therefore be specified.
This issue is of essential importance for the construction industry!

Proposal:
(h) warnings concerning ways in which the machinery product shall not be used that experience has shown ~~**might occur**~~; **when used as intended or in a reasonably foreseeable manner, taking into account any foreseeable misuse**

- **1.7.4.2. Contents of the instructions**

*(k) instructions for the putting into service and use of the machinery product and, if necessary, instructions for the training of operators;*

For the German translation it needs to be made sure that the paragraph does not refer to "Ausbildung" as apprentice instead of "Unterweisung" as instruction according to the OSH Framework Directive, which is the intended meaning.

- **1.7.4.2. Contents of the instructions**

*(m) instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided;*

Already implemented in the existing Machinery Directive but the following addition focuses to the meaning of the Regulation and should therefore be specified.

Proposal:
(m) instructions on the protective measures to be taken by the user in **the case of intended use or reasonably foreseeable use, taking into account foreseeable misuse,** including, where appropriate, the personal protective equipment to be provided;

- **1.7.4.2. Contents of the instructions**

*(o)the conditions in which the machinery product meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;*

Machine crashes are serious events that must be prevented at all costs. Therefore, this point must be added, as only the manufacturer, as the designer of the machine, has this information and must state it as precisely as possible.
This fact is essential for the construction sector!

Proposal:
(o) the conditions, **load conditions and load positions**, in which the machinery product meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns **on condition of intended use or reasonably foreseeable use and taking into account foreseeable misuse;**

- **1.7.4.2. Contents of the instructions**

*(u) ….. These values shall be either those actually measured for the machinery product in question or those established on the basis of measurements taken for a technically comparable machinery product, which is representative of the machinery product to be produced.*

For the user, only the actual sound level is important in (construction) practice and not the theoretical laboratory value of the machine.
Particularly in the case of noise-reducing machine products, concrete information must be provided in the operating instructions and not just "where appropriate".

Proposal:
(u) These values shall be ~~**either**~~ those actually measured for the machinery product in question ~~**or those established on the basis of measurements taken for a technically comparable machinery product, which is representative of the machinery product to be produced.**~~
With respect to noise reduction machinery products, the instructions shall specify ~~**, where appropriate,**~~ how to correctly assemble and install that equipment (see also section 1.7.4.2(1), point (j)).

- **3.2.1. Driving position**

The words "foreseeable conditions of use" are to be changed to "under intended or reasonably foreseeable use" to express what is intended.

The word "where appropriate" should be deleted in any case, as insufficient direct vision must always be compensated for by the manufacturer.

Proposal:
*Visibility from the driving position shall be such that the driver can, in complete safety for himself or herself and the exposed persons operate the machinery and its tools* ~~***in their foreseeable conditions of use***~~ ***when used as intended or under reasonably foreseeable use****. ~~**Where necessary,**~~ appropriate devices shall be provided to remedy risks due to inadequate direct vision.*
*Machinery on which the driver is transported shall be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.*
*The driving position of ride-on drivers shall be designed and constructed in such a way that a driver's cab may be fitted, provided this does not increase the risk and there is room for it. The cab shall incorporate a place for the instructions needed for the driver.*

- **3.2.2. Seating**

The existing regulation text does not yet adequately address the significant rolling or tipping risk of many types of mobile machinery.

Proposal to add the following sentence:
**If there is a significant risk of rolling or tipping, the machine must not be able to move if the restraint system is not active.**

- **3.3.1. Control devices**

Proposal:
*The driver shall be able to actuate all control devices required to operate the machinery from the driving position, except for functions, which can be safely actuated only by using control devices located elsewhere. These functions include, in particular, those for which operators other than the driver are responsible or for which the driver has to leave the driving position in order to control them safely.*
*Where there are pedals* ***and other operating elements****, they shall be so designed, constructed and fitted as to allow safe operation by the driver with the minimum risk of incorrect operation. They shall have a slip-resistant surface and be easy to clean.*
*Where their operation can lead to hazards, notably dangerous movements, the control devices, except for those with pre-set positions, shall return to the neutral position as soon as they are released by the operator.*
*In the case of wheeled machinery, the steering system shall be designed and constructed in such a way as to reduce the force of sudden movements of the steering wheel or the steering lever caused by shocks to the guide wheels.*
*Any control that locks the differential shall be so designed and arranged that it allows the differential to be unlocked when the machinery is moving.*
*The sixth paragraph of section 1.2.2, concerning acoustic and/or visual warning signals, applies only in the case of reversing.*

- **3.6.3.1. Vibrations**

*… These values shall be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery, which is representative of the machinery to be produced.*

For the user, only the actual measured value is important in (construction) practice and not the theoretical laboratory value of the machine!
Proposal:
These values shall be ~~**either**~~ those actually measured for the machinery in question ~~**or those established on the basis of measurements taken for technically comparable machinery, which is representative of the machinery to be produced.**~~

- **3.6.2 Marking**

*The following must be shown legibly and indelibly on all machinery:*
*- nominal power expressed in kilowatts (kW),*
*- mass of the most usual configuration, in kilograms (kg);*
*and, where appropriate:*
*- maximum drawbar pull provided for at the coupling hook, in Newtons (N),*
*- maximum vertical load provided for on the coupling hook, in Newtons (N).*

This paragraph needs clarification.
Proposal:
The following shall be shown legibly and indelibly on all machinery products:
(a)nominal power expressed in kilowatts (kW);
(b)mass of the most usual configuration, in kilograms (kg);
and, ~~**where appropriate**~~ **if the machine is equipped with a trailer device, additionally:**
(a)maximum drawbar pull provided for at the coupling hook, in Newtons (N);
(b)maximum vertical load provided for on the coupling hook, in Newtons (N).

- **Proposal for annex I (amending old Appendix IV)**

Appendix IV covers all products listed in the Directive's scope of application.
Safety components fall into category III.
The classification is made in 3 risk categories (similar to PPE EU Regulation 2016/425).
If the machine is designed and a risk assessment is carried out, a residual risk remains at the end. The classification into the 3 risk categories results from the remaining residual risk. All operating states / life cycles / life phases must be taken into account (maintenance, servicing, assembly, disassembly, operation, ...). The basis for determining risks and the remaining residual risks is Appendix I of the Directive. Reasonably foreseeable misuse must also be included.
Furthermore, the residual risks are to be defined based on the contents of other directives such as the Low Voltage Directive, EMC, cybersecurity, etc.
Risks cumulating from this are to be defined.
The remaining residual risks are again used for classification.
**Category I**
Category I includes all residual risks with minor injury potential such as:
a) superficial mechanical injuries
b) contact with slightly aggressive working substances
c) brief contact with hot surfaces whose temperature does not exceed 60 °C;
….
**Category II**
Category II includes all residual risks that are not listed under Category I or Category III;
**Category III**
Category III includes all residual risks which may lead to very serious consequences such as death or irreversible damage to the health of operators and third parties.

The following conformity assessment procedures shall be applied for each of the risk categories set out in Appendix I:
(a) Category I: internal production control in accordance with Appendix VIII.
(b) Category II: Full quality assurance in accordance with Appendix X
(c) Category III: EU type-examination according to Appendix IX
or application / taking into account the harmonised standards
e.g.: in the case of a circular saw, work must be carried out on the open circular saw blade, which automatically places it in category III.

EUROPEAN CONSTRUCTION INDUSTRY FEDERATION

**Machinery Directive – revision**
**FIEC comments on the proposed revision**

FIEC, the European Construction Industry Federation, welcomes the revision of the Machinery Directive, which takes into account recent technological developments.
These new aspects such as hazardous substances and cybersecurity are particularly welcome.

Regarding the notion of substantial modification, FIEC considers that this concept will create multiple interpretations and only a change of specific application shall be considered as a substantial modification. The digital modification/update of safety devices and the installation of safety devices which lead to an increase of the safety level of the machine) shall not be considered as substantial modifications and shall not require the intervention of a third party.

For machinery embedding AI systems ensuring safety functions, the machinery shall have additional CE marking. So it will be necessary to clarify what will be the process for the end-user.

FIEC thinks that clarifications are required regarding EU declaration of conformity (digital devices especially) and the timetable for the application of this provision must be specified and clearly defined.

Moreover, it should be noted that storing all data for five years is a real economic and organizational challenge for the end-user during the lifetime of the machinery. The question is therefore to ensure how that market surveillance and national authorities will be able to check, in all situations, the traceability of machinery safety.

At least, it is crucial to ensure in practice the availability of the key document of the machinery during all its lifetime and all successive uses in different construction sites (through an updated website for instance).

6 August 2021