AMENDMENTS

101 - 438

Draft report
Ivan Štefanec
(PE697.614v02-00)

Machinery products

Proposal for a regulation
Amendment 101  
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Title 1

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**Justification**

*The term "machinery products" does not have a direct translation into other languages, such as Spanish, and could complicate the writing and understanding of the proposal. In this sense, it could be more appropriate to refer only to "machinery", as it is in the current Directive.*

Amendment 102  
Marcel Kolaja, David Cormand

Proposal for a regulation
Recital 6 a (new)

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| *(6a)* Notes that it is in the public interest to harmonise the environmental standards for powering some of the relevant machinery products, such as electrical bicycles. Calls on the Commission to explore in cooperation with the manufactures the possibility of a unique charger for electrical bicycles placed on the market, with the view to ensure common health and safety requirements for charging across the EU.


Amendment 103
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba
Proposal for a regulation
Recital 10

(10) Where there is a possibility that the machinery products will be used by a consumer, that is to say, a non-professional operator, the manufacturer should take account of the fact that the consumer does not have the same knowledge and experience with handling machinery products in the design and construction of the products. The same applies where a machinery product is normally used to provide a service to a consumer. The same applies where a machinery product is normally used to provide a service to a consumer.

(10) Where there is a possibility that the machinery products will be used by a consumer, that is to say, a non-professional operator, the manufacturer should take account of the fact that the consumer does not have the same knowledge and experience with handling machinery products in the design and construction of the products and consider the safety impact. The same applies where a machinery product is normally used to provide a service to a consumer. While consumers do not necessarily purchase machinery products, machinery products are still being used by them.

Amendment 104
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba
Proposal for a regulation
Recital 15

(15) Since the purpose of this Regulation is to address the risks stemming from the machinery function and not the transport of goods or persons, it should not apply to vehicles which only objective is the mere transport of goods or persons on road, by air, on water or on rail networks,

(15) Since the purpose of this Regulation is to address the risks stemming from the machinery function and not the transport of goods, persons or domestic animals, it should neither apply to vehicles which only objective is the mere transport of goods, or domestic animals on road, by
regardless of the speed limits. 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. Since agricultural and forestry vehicles and two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, fall within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council and Regulation (EU) No 168/2013 of the European Parliament and of the Council respectively, they should be excluded from the scope of this Regulation.

Equally, non-type-approved, off-road and competition vehicles, as well as e-bikes, e-scooters and similar means of transport should be covered by this Regulation.

Since agricultural and forestry vehicles and two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, are approved according to Regulation (EU) No 167/2013 of the European Parliament and of the Council and Regulation (EU) No 168/2013 of the European Parliament and of the Council respectively, they should be excluded from the scope of this Regulation.


Amendment 105
Svenja Hahn, Sandro Gozi, Stéphanie You-Courtin, Karen Melchior
Proposal for a regulation
Recital 15

Text proposed by the Commission

(15) Since the purpose of this Regulation is to address the risks stemming from the machinery function and not the transport of goods or persons, it should not apply to vehicles which only objective is the mere transport of goods or persons on road, by air, on water or on rail networks, regardless of the speed limits. 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. Since agricultural and forestry vehicles and two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, fall within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council and Regulation (EU) No 168/2013 of the European Parliament and of the Council respectively, they should be excluded from the scope of this Regulation.

Amendment

(15) Since the purpose of this Regulation is to address the risks stemming from the machinery function and not the transportation function of goods or persons, it should not apply to vehicles approved for the transport of goods or persons or animals on road, by air, on water or on rail networks, regardless of the speed limits. 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. Equally, non-type-approved, off-road and competition vehicles, as well as e-bikes, e-scooters and similar means of transport should be covered by this Regulation. Since agricultural and forestry vehicles and two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, fall within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council and Regulation (EU) No 168/2013 of the European Parliament and of the Council respectively, they should be excluded from the scope of this Regulation when approved according to Regulation (EU) No 167/2013 and Regulation (EU) No 168/2013 respectively.


20 Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and...
market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52).

**Amendment 106**
Kateřina Konečná

Proposal for a regulation
Recital 15

*Text proposed by the Commission*

(15) Since the purpose of this Regulation is to address the risks stemming from the machinery function and not the transport of goods or persons, it should not apply to vehicles which only objective is the mere transport of goods or persons on road, by air, on water or on rail networks, regardless of the speed limits. 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. Since agricultural and forestry vehicles and two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, fall within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council and Regulation (EU) No 168/2013 of the European Parliament and of the Council respectively, they should be excluded from the scope of this Regulation.

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**Amendment**

(15) Since the purpose of this Regulation is to address the risks stemming from the machinery function and not the transport of goods or persons, it should not apply to vehicles which only objective is the mere transport of goods or persons on road, by air, on water or on rail networks, regardless of the speed limits. 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, as well as specific equipment for use in fairgrounds or amusement parks, together with e-bikes, e-scooters and similar means of transport. Since agricultural and forestry vehicles and two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, fall within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council and Regulation (EU) No 168/2013 of the European Parliament and of the Council respectively, they should be excluded from the scope of this Regulation.

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19 Regulation (EU) No 167/2013 of the


Amendment 107
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 16

Text proposed by the Commission

(16) Household appliances intended for domestic use which are not electrically operated furniture, audio and video equipment, information technology equipment, office machinery, low-voltage switchgear and control gear and electronic motors fall within the scope of Directive 2014/35/EU of the European Parliament and of the Council and should therefore be excluded from the scope of this Regulation. Some of those products are progressively incorporating Wi-Fi functions, e.g. washing machines, and are therefore covered by Directive 2014/53/EU of the European Parliament and of the Council as radio equipment. Those products should also be excluded from the scope of this Regulation.

Amendment

(16) Household appliances intended for domestic use which are not electrically operated furniture, audio and video equipment, information technology equipment, office machinery, low-voltage switchgear and control gear and electronic motors fall within the scope of Directive 2014/35/EU of the European Parliament and of the Council and should therefore be excluded from the scope of this Regulation with the exception of mechanical safety of those appliances, which should be part of this Regulation. Some of those products are progressively incorporating Wi-Fi functions, e.g. washing machines, and are therefore covered by Directive 2014/53/EU of the European Parliament and of the Council as radio equipment. Those products should also be excluded from the scope of this Regulation.


Amendment 108
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Recital 16

Text proposed by the Commission
(16) Household appliances intended for domestic use which are not electrically operated furniture, audio and video equipment, information technology equipment, office machinery, low-voltage switchgear and control gear and electronic motors fall within the scope of Directive 2014/35/EU of the European Parliament and of the Council21 and should therefore be excluded from the scope of this Regulation. Some of those products are progressively incorporating Wi-Fi functions, e.g. washing machines, and are therefore covered by Directive 2014/53/EU of the European Parliament and of the Council22 as radio equipment. Those products should also be excluded from the scope of this Regulation.

Amendment
(16) Household appliances intended for domestic use which are not electrically operated furniture, audio and video equipment, information technology equipment, office machinery, low-voltage switchgear and control gear and electric motors fall within the scope of Directive 2014/35/EU of the European Parliament and of the Council21 and should therefore be excluded from the scope of this Regulation, except for the mechanical safety of appliances, where applicable. Some of those products are progressively incorporating Wi-Fi functions, e.g. washing machines, and are therefore covered by Directive 2014/53/EU of the European Parliament and of the Council22 as radio equipment. Those products should also be excluded from the scope of this Regulation.
(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

Amendment 109
Adriana Maldonado López, Clara Aguilera, María Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Recital 17

Text proposed by the Commission

(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 if the safe use of this machinery does not depend on this software. 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,
should be considered a safety component. software that performs a safety function and is placed independently on the market should be considered a safety component.

Amendment 110
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Recital 19

Text proposed by the Commission

(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. For example, machinery products incorporating a Wi-Fi function or an artificial intelligence system may pose risks not addressed by the essential health and safety requirements set out in this Regulation, as this Regulation does not deal with risks specific to such systems. 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. 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

Amendment

(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. For example, machinery products incorporating a Wi-Fi function or an artificial intelligence system may pose risks not addressed by the essential health and safety requirements set out in this Regulation, as this Regulation does not deal with risks specific to such systems. 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 that pose significant risks to the health and safety or fundamental rights of persons. 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
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.

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.

Amendment 111
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Recital 21

Text proposed by the Commission
(21) The evolution of the state of the art in the machinery sector has an impact on the classification of high-risk machinery products. In view of properly reflecting all high-risk machinery products, criteria should be established for the assessment by the Commission of which machinery products should be included in the list of high-risk machinery products.

Amendment
(21) The evolution of the state of the art in the machinery sector has an impact on the classification of machinery products that potentially pose a high risk. In view of properly reflecting all machinery products potentially posing a high risk, criteria should be established for the assessment by the Commission of which machinery products should be included in Annex I of this Regulation, containing the list of machinery products that potentially pose a high risk.

Amendment 112
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Recital 24

Text proposed by the Commission
(24) In the machinery sector, around 98% of the companies are small or medium sized enterprises (SMEs). In order to

Amendment
(24) In the machinery sector, around 98% of the companies are small or medium sized enterprises (SMEs). In order to avoid
reduce the regulatory burden on SMEs, notified bodies should adapt the fees for conformity assessments and reduce them proportionately to the specific interests and needs of SMEs.

unnecessary burdens on SMEs, notified bodies should simplify and facilitate procedures and adapt the fees for conformity assessments and reduce them proportionately to the specific interests and needs of SMEs.

Amendment 113
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Recital 29

Text proposed by the Commission

(29) The manufacturer or the manufacturer’s authorised representative should also ensure that a risk assessment is carried out for the machinery product, which the manufacturer wishes to place on the market. For this purpose, the manufacturer should determine which of the essential health and safety requirements that are applicable to the machinery product and in respect of which measures must be taken to address the risks that the machinery product may present. Where the machinery product integrates an artificial intelligence system, the risks identified during the risk assessment should include those risks that may appear during the machinery product’s lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy. In this respect, where the machinery product integrates an artificial intelligence system, the risk assessment for the machinery product should consider the risk assessment for that artificial intelligence system that has been carried out pursuant to Regulation (EU) .../... of the European Parliament and of the Council23.

Amendment

(29) The manufacturer should also ensure that a risk assessment is carried out for the machinery product, which the manufacturer wishes to place on the market. For this purpose, the manufacturer should determine which of the essential health and safety requirements that are applicable to the machinery product and in respect of which measures must be taken to address the risks that the machinery product may present. Where the machinery product integrates an artificial intelligence system, the risks identified during the risk assessment should include those risks that may appear during the machinery product’s lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy. In this respect, where the machinery product integrates an artificial intelligence system, the risk assessment for the machinery product should consider the risk assessment for that artificial intelligence system that has been carried out pursuant to Regulation (EU) .../... of the European Parliament and of the Council23.

23 + OJ: Please insert in the text the number
Amendment 114
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Recital 29

Text proposed by the Commission

(29) The manufacturer or the manufacturer’s authorised representative should also ensure that a risk assessment is carried out for the machinery product, which the manufacturer wishes to place on the market. For this purpose, the manufacturer should determine which of the essential health and safety requirements that are applicable to the machinery product and in respect of which measures must be taken to address the risks that the machinery product may present. Where the machinery product integrates an artificial intelligence system, the risks identified during the risk assessment should include those risks that may appear during the machinery product’s lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy. In this respect, where the machinery product integrates an artificial intelligence system, the risk assessment for the machinery product should consider the risk assessment for that artificial intelligence system that has been carried out pursuant to Regulation (EU) .../... of the European Parliament and of the Council\(^23\).

Amendment

(29) The manufacturer or the manufacturer’s authorised representative should also ensure that a risk assessment is carried out for the machinery product, which the manufacturer wishes to place on the market. For this purpose, the manufacturer should determine which of the essential health and safety requirements that are applicable to the machinery product and in respect of which measures must be taken to address the risks that the machinery product may present. Where the machinery product integrates an artificial intelligence system, the risks identified during the risk assessment should include those risks that may appear during the machinery product’s estimated lifetime due to an intended evolution of its behaviour to operate with varying levels of autonomy. In this respect, where the machinery product integrates an artificial intelligence system, the risk assessment for the machinery product should consider the risk assessment for that artificial intelligence system that has been carried out pursuant to Regulation (EU) .../... of the European Parliament and of the Council\(^23\).

\(^23\) + OJ: Please insert in the text the number of the Regulation contained in document ...
(29) The manufacturer or the manufacturer’s authorised representative should also ensure that a risk assessment is carried out for the machinery product, which the manufacturer wishes to place on the market. For this purpose, the manufacturer should determine which of the essential health and safety requirements that are applicable to the machinery product and in respect of which measures must be taken to address the risks that the machinery product may present. Where the machinery product integrates an artificial intelligence system, the risks identified during the risk assessment should include those risks that may appear during the machinery product’s lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy. In this respect, where the machinery product integrates an artificial intelligence system, the risk assessment for the machinery product should consider the risk assessment for that artificial intelligence system that has been carried out pursuant to Regulation (EU) .../... of the European Parliament and of the Council\textsuperscript{23}.

\textsuperscript{23} OJ: Please insert in the text the number of the Regulation contained in document ... .
**Justification**

*Artificial Intelligence is a technology whose paradigms and applications are rapidly changing and expanding. Because of this, AI legislation and standards are expected to undergo a large integration and modification within the timeframe in which the Machinery Regulation will be in force. For this reason, a guideline (a more “dynamic” document compared to the Regulation) considering the AI evolutions and applications related to machinery. Similarly to the Machine Directive, a more comprehensive guideline for the Machinery Directive is expected, in which AI can also be included.*

**Amendment 116**  
**Marco Campomenosi, Alessandra Basso**

**Proposal for a regulation**  
**Recital 29**

**Text proposed by the Commission**

(29) The manufacturer or the manufacturer’s authorised representative should also ensure that a risk assessment is carried out for the machinery product, which the manufacturer wishes to place on the market. For this purpose, the manufacturer should determine which of the essential health and safety requirements that are applicable to the machinery product and in respect of which measures must be taken to address the risks that the machinery product may present. Where the machinery product integrates an artificial intelligence system, the risks identified during the risk assessment should include those risks that may appear during the machinery product’s lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy. **In this respect, where the machinery product integrates an artificial intelligence system, the risk assessment for the machinery product should consider the risk assessment for that artificial intelligence system that has been carried out pursuant to Regulation (EU) .../... of the European Parliament and of the Council**²³.

**Amendment**

(29) The manufacturer or the manufacturer’s authorised representative should also ensure that a risk assessment is carried out for the machinery product, which the manufacturer wishes to place on the market. For this purpose, the manufacturer should determine which of the essential health and safety requirements that are applicable to the machinery product and in respect of which measures must be taken to address the risks that the machinery product may present. Where the machinery product integrates an artificial intelligence system, an appropriate guideline should be developed, in order to correctly evaluate possible further risks that may appear during the machinery product’s lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy. **The guideline defining risk assessment procedures for the machinery including AI should also take into account the risk assessment (and related terminology and risk levels) for artificial intelligence system that has been carried out pursuant to Regulation (EU) .../... of the European Parliament and of the Council**²³.
Amendment 117
Adriana Maldonado López, Clara Aguilera, María Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Recital 31

Text proposed by the Commission

(31) It is essential that, before drawing up the EU declaration of conformity, the manufacturer or the manufacturer’s authorised representative established in the Union prepares a technical construction file, which they should be required to make available to national authorities or notified bodies on request. Detailed plans of subassemblies used for the manufacture of the machinery product should only be required as part of the technical construction file where knowledge of such plans is essential for assessing conformity with the essential health and safety requirements set out in this Regulation.

Amendment

(31) It is essential that, before drawing up the EU declaration of conformity, the manufacturer prepares a technical documentation as referred to in Annex IV, which they should be required to make available to national authorities or notified bodies on request. Detailed plans of subassemblies used for the manufacture of the machinery product should only be required as part of the technical documentation where knowledge of such plans is essential for assessing conformity with the essential health and safety requirements set out in this Regulation.

Amendment 118
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Recital 34

Text proposed by the Commission

(34) When placing machinery products

Amendment

(34) When placing machinery products
on the market, the importer should indicate on the machinery product his or her name, registered trade name or registered trade mark and the postal address at which he or she can be contacted. Exceptions should be provided for in cases where the size or nature of the machinery product does not allow it. This includes cases where the importer would have to open the packaging to put his or her name and address on the machinery product.

or. en

Amendment 119
Kateřina Konečná
Proposal for a regulation
Recital 40

Text proposed by the Commission

(40) In the absence of relevant harmonised standards, the Commission should be able to establish technical specifications for the essential health and safety requirements. Recourse to technical specifications should be used as a fall back solution to facilitate the manufacturer’s obligation to comply with the health and safety requirements, for instance when the standardisation process is blocked due to a lack of consensus between stakeholders or there are undue delays in the establishment of a harmonised standard. Such delays could for example occur when the required quality is not reached.

Amendment

(40) In the absence of relevant harmonised standards, the Commission should be able to establish technical specifications for the essential health and safety requirements on an exceptional basis and in due respect of the standardisation organisations’ role and functioning. Recourse to technical specifications should be used as a fall back solution to facilitate the manufacturer’s obligation to comply with the health and safety requirements, for instance when the standardisation process is blocked due to a lack of consensus between stakeholders or there are undue delays in the establishment of a harmonised standard. Such delays could for example occur when the required quality is not reached.

or. en
(45) The list of high-risk machinery in Annex I to Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of that machinery. Nevertheless, the machinery sector embraces new ways of designing and constructing machinery products that may imply high risks, regardless of such intended use or any reasonably foreseeable misuse. For example, software ensuring safety functions of machinery based on artificial intelligence, embedded or not in the machinery product, should be classified as a high-risk machinery product due to the characteristics of artificial intelligence such as data dependency, opacity, autonomy and connectivity, which might increase very much the probability and severity of harm and seriously affect the safety of the machinery product. Furthermore, the market for software ensuring safety functions of machinery products based on artificial intelligence is so far very small, which results in a lack of experience and data. Therefore, the conformity assessment of software ensuring safety functions based on artificial intelligence should be carried out by a third party.

Amendment 121
Kateřina Konečná
Proposal for a regulation
Recital 45
The list of high-risk machinery in Annex I to Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of that machinery. Nevertheless, the machinery sector embraces new ways of designing and constructing machinery products that may imply high risks, regardless of such intended use or any reasonably foreseeable misuse. For example, software ensuring safety functions of machinery based on artificial intelligence, embedded or not in the machinery product, should be classified as a high-risk machinery product due to the characteristics of artificial intelligence such as data dependency, opacity, autonomy and connectivity, which might increase very much the probability and severity of harm and seriously affect the safety of the machinery product. **Furthermore, the market for software ensuring safety functions of machinery products based on artificial intelligence is so far very small, which results in a lack of experience and data.** Therefore, the conformity assessment of software ensuring safety functions based on artificial intelligence should be carried out by a third party.

**Amendment**

(45) The list of high-risk machinery in Annex I to Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of that machinery. Nevertheless, the machinery sector embraces new ways of designing and constructing machinery products that may imply high risks, regardless of such intended use or any reasonably foreseeable misuse. For example, software ensuring safety functions of machinery based on artificial intelligence, embedded or not in the machinery product, should be classified as a high-risk machinery product due to the characteristics of artificial intelligence such as data dependency, opacity, autonomy and connectivity, which might increase very much the probability and severity of harm and seriously affect the safety of the machinery product. Therefore, the conformity assessment of software ensuring safety functions based on artificial intelligence should be carried out by a third party.

**Justification**

In this context, we do not think that the current size of the market for software would be relevant in view of the conformity assessment, especially as this might change in the upcoming future.

**Amendment 122**

Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Recital 45 a (new)
Text proposed by the Commission

(45a) Nevertheless, provisions set out in Articles 5(1) and 21(2) of this Regulation should only apply to AI systems with a self-determining and evolving behaviour during normal operation. On the contrary, these provisions should not apply to conventional software incapable to learn or evolve, and programmed only to execute certain automated functions of machinery products.

Or. en

Justification

Provisions for AI systems given by this Regulation should apply only to AI systems capable of evolving autonomously during their lifecycle. Static/deterministic software without any capability to evolve or take decisions, with a code programmed to execute certain automated functions of the machine, should not fall into AI definition or apply AI requirements.

Amendment 123
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Recital 45 a (new)

Text proposed by the Commission

(45a) Nevertheless, provisions set out in Articles 5(1) and 21(2) of this Regulation should only apply to AI systems with self-determining, evolving behaviour during normal operation. On the contrary, they should not apply to conventional software not capable to learn or evolve and programmed only to execute certain automated functions of machinery products.

Or. en

Justification

I propose that provisions for AI systems given by Machinery Regulation should apply only to
“real” AI systems, which means capable of evolving autonomously during their lifecycle. On the contrary, other ‘static’ (deterministic) software without any capability to evolve or take decisions, with a code programmed to execute certain automated functions of the machine (for example automatic levelling of a combine header) should not fall into AI definition. This conventional software will apply all relevant health and safety requirements, but the ones on AI appear, in our opinion, inappropriate. The legislation should be clear on this point, avoiding possible misunderstandings or diverging interpretations.

Amendment 124
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Recital 45 a (new)

Text proposed by the Commission

Amendment

(45a) Nevertheless, provisions set out in Articles 5(1) and 21(2) of this Regulation should apply only to AI systems with self-determining, evolving behaviour during normal operation. On the contrary, they should not apply to conventional software not capable to learn or evolve and programmed only to execute certain automated functions of machinery products.

Or. en

Amendment 125
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Recital 46 a (new)

Text proposed by the Commission

Amendment

(46a) The harmonised standards relevant to this Regulation should take into account the requirements of Directive (EU) 2019/882 (European Accessibility Act) and the United Nations Convention on the Rights of Persons with Disabilities4a

Amendment 126
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Recital 50

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<td>(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.</td>
<td>(50) Manufacturers are responsible to make sure that a conformity assessment of their machinery products is carried out in accordance with this Regulation.</td>
</tr>
</tbody>
</table>

Amendment 127
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Recital 50

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(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</td>
<td>(50) Manufacturers should be responsible for the conformity assessment of their machinery products as specified by this Regulation. Nevertheless, for certain types of machinery products that have a</td>
</tr>
</tbody>
</table>
risk factor, a stricter certification procedure requiring participation of a notified body should be required.

higher risk factor, a stricter certification procedure requiring participation of a notified body should be required.

Amendment 128
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Recital 56

Text proposed by the Commission

(56) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the machinery to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries.

Amendment

(56) Conformity assessment bodies frequently subcontract parts of their tasks linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the machinery to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also tasks carried out by subcontractors and subsidiaries.

Justification

Linguistic change

Amendment 129
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Recital 65
(65) In order to take into account technical progress and knowledge or new scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the list of high-risk machinery products and the indicative list of safety components. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Or. en

Amendment 130
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Recital 76 a (new)

Text proposed by the Commission

(76a) The harmonised standards relevant to this Regulation should take into account the United Nations Convention on the Rights of Persons with Disabilities


Or. en
Amendment 131
Kateřina Konečná

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission
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.

Amendment
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 ensuring a high level of protection for EU workers and citizens.

Or. en

Justification
One of the main reasons to introduce the machinery directive was to reduce the number of occupational accidents and illness. Therefore, we would welcome this inclusion here.

Amendment 132
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission
(d) lifting accessories;

Amendment
(d) lifting accessories, including lifting appliances whose speed is not greater than 0.15 m/s;

Or. en

Justification
EHSR 6.2 on control devices includes slow lifts
Amendment 133
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 2 – paragraph 1 – point d

Text proposed by the Commission
(d) lifting accessories;

Amendment
(d) lifting accessories; including lifting appliances whose speed does not exceed 0.15 m/s;

Or. en

Amendment 134
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 1 – point g a (new)

Text proposed by the Commission
(ga) specific equipment for use in fairgrounds or amusement parks;

Amendment
(ga) non type approved road vehicles including pedal cycles with pedal assistance;

Or. en

Amendment 135
Svenja Hahn, Sandro Gozi, Stéphanie Yon-Courtin, Karen Melchior

Proposal for a regulation
Article 2 – paragraph 1 – point g a (new)

Text proposed by the Commission
(ga) non type approved road vehicles including pedal cycles with pedal assistance;

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

Or. en
Amendment 136
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 2 – paragraph 1 – point g a (new)

Text proposed by the Commission

Amendment

(ga) equipment to be used in fairgrounds or amusement parks;

Or. en

Amendment 137
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 2 – paragraph 1 – point g a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 138
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 1 – point g b (new)

Text proposed by the Commission

Amendment

(gb) vehicles which have as their objective the transport of goods or persons by road, not covered by Regulation (EU) No 168/2013;

Or. en
Justification

It would be important to also include e-bikes, e-scooters and similar means of transport

Amendment 139
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 2 – paragraph 1 – point g b (new)

Text proposed by the Commission
(gb) vehicles which have as their objective the transport of goods or persons by road, not falling within the scope of application of Regulation (EU) No 168/2013;

Or. en

Amendment 140
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 2 – paragraph 2 – point b

Text proposed by the Commission
(b) specific equipment for use in fairgrounds or amusement parks;

Amendment
deleted

Or. en

Amendment 141
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 2 – point b
(b) specific equipment for use in fairgrounds or amusement parks; deleted

Amendment 142
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 2 – paragraph 2 – point b

Texto propuesto por la Comisión
Amendamento

(b) equipamento específico para uso em feiras ou parques de atrativos;

Amendamento 143
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 2 – point e

Texto propuesto por la Comisión
Amendamento

(e) vehículos que tienen como único objetivo el transporte de mercancías o personas por carretera, aire, agua o ferrocarril excepto para maquinaria montada en esos vehículos;

Amendamento 144
Svenja Hahn, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Article 2 – paragraph 2 – point e
(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;

(e) vehicles which have as their only objective the transport of goods, animals or persons by air, water or rail except for machinery mounted on those vehicles; the manufacturers of vehicles shall provide information on fastening, statics, mass/forces and similar important product details that affect the safe functioning when mounting machinery on the vehicle to end users upon request.

Amendment 145
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 2 – paragraph 2 – point e

Text proposed by the Commission

(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;

Amendment

(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; vehicles which have as their only objective the transport persons by air, water or rail except for machinery mounted on those vehicles;

Or. en

Amendment 146
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 2 – paragraph 2 – point e
Text proposed by the Commission

(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;

Amendment

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

Amendment 147
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 2 – paragraph 2 – point f

Text proposed by the Commission

(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;

Amendment

(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 are approved according to Regulation (EU) No 168/2013 except for machinery mounted on those vehicles;

Amendment 148
Svenja Hahn, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 2 – paragraph 2 – point f

Text proposed by the Commission

(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;

Amendment

(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, approved according to Regulation (EU) No 168/2013 except for machinery mounted on those vehicles;
Amendment 149
Salvatore De Meo, Andrea Caroppo, Krzysztof Hetman

Proposal for a regulation
Article 2 – paragraph 2 – point g

Text proposed by the Commission

(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;

Amendment

(g) agricultural and forestry *tractors*, 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, *with the exclusion of machinery mounted on those vehicles*;

Justification

The proposed amendment is necessary to align this text with the wording of the current Machinery Directive 2006/42/EC. Therefore, the amendment is needed to ensure legal certainty and to clarify which agricultural vehicles falls under the scope of the Machinery Product Regulation and which are not covered.

Amendment 150
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Article 2 – paragraph 2 – point g

Text proposed by the Commission

(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;

Amendment

(g) agricultural and forestry *tractors*, 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, *with the exclusion of machinery mounted on those vehicles*;
Justification

The text of the proposed amendment is aligned with the wording of current Machinery Directive 2006/42/EC. Amendment is needed to ensure legal certainty and clarify which agricultural vehicles are covered by the Machinery Product Regulation and which are not.

Amendment 151
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Article 2 – paragraph 2 – point g

Text proposed by the Commission

(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;

Amendment

(g) agricultural and forestry tractors, 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, with the exclusion of machinery mounted on those vehicles;

Amendment 152
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 2 – paragraph 2 – point g

Text proposed by the Commission

(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;

Amendment

(g) agricultural and forestry vehicles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, that are approved according to Regulation (EU) No 167/2013, except for machinery mounted on those vehicles;
Amendment 153
Svenja Hahn, Vlad-Marius Botoş, Sandro Gozi, Stéphanie Yon-Courtin, Karen Melchior

Proposal for a regulation
Article 2 – paragraph 2 – point g

Text proposed by the Commission

(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;

Amendment

(g) agricultural and forestry vehicles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, that are approved according to Regulation (EU) No 167/2013, except for machinery mounted on those vehicles;

Or. en

Amendment 154
Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation
Article 2 – paragraph 2 – point g

Text proposed by the Commission

(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;

Amendment

(g) agricultural and forestry tractors, as well as systems, components, separate technical units, parts and equipment designed and constructed for them that fall within the scope of application of Regulation (EU) No 167/2013;

Or. en

Amendment 155
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Sandro Gozi, Stéphanie Yon-Courtin, Karen Melchior

Proposal for a regulation
Article 2 – paragraph 2 – point g a (new)
(ga) motor vehicles and their trailers as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, that are approved according to Regulation (EU) No 2018/858, except for machinery mounted on those vehicles;

Amendment 156
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 2 – paragraph 2 – point g a (new)

(ga) motor vehicles and their trailers as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, that are approved according to Regulation (EU) No 2018/858, except for machinery mounted on those vehicles;

Amendment 157
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 2 – paragraph 2 – point g b (new)

(gb) motor vehicles exclusively intended for competition;
Amendment 158
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 2 – paragraph 2 – point g b (new)

*Text proposed by the Commission*  
(\textit{gb}) motor vehicles exclusively intended for competition;

*Or. en*

Amendment 159
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 2 – paragraph 2 – point g c (new)

*Text proposed by the Commission*  
(\textit{gc}) assemblies of CE marked pressure equipment within the meaning of Directive 2014/68/EU;

*Or. en*

Amendment 160
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 2 – paragraph 2 – point m – point i

*Text proposed by the Commission*  
(i) household appliances intended for domestic use which are not electrically operated furniture;

*Or. en*
Amendment 161
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 2 – paragraph 2 – point m – point i

Text proposed by the Commission

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

Amendment

(i) household appliances intended for domestic use which are not electrically operated furniture, excluding their mechanical safety;

Or. en

Amendment 162
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 1 – point d

Text proposed by the Commission

(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;

Amendment

(d) assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point (10) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;

Or. en

Amendment 163
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Article 3 – paragraph 1 – point 1 – point f

Text proposed by the Commission

(f) an assembly as referred to in points

Amendment

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

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

(f) an assembly as referred to in points (a), (b), (c), (d) and (e) missing only the upload of a software intended for the specific application foreseen by the manufacturer and which is the subject of the conformity assessment procedure of the machinery product.

Or. en

Amendment 164
Svenja Hahn, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 3 – paragraph 1 – point 1 – point f

Text proposed by the Commission

Amendment

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

(f) an assembly as referred to in points (a), (b), (c), (d) and (e) missing only the upload of a software intended for its specific application, if the safe use does not depend on this software.

Or. en

Amendment 165
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 1 – point f

Text proposed by the Commission

Amendment

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

(f) an assembly as referred to in points (a), (b), (c), (d) and (e) missing only the upload of a software intended for its specific application, if the safe use does not depend on this software.

Or. en
Amendment 166
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 2

Amendment

Text proposed by the Commission

(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;

Amendment

(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 or herself in order to change its function or attribute to it a new function, in so far as that equipment is not a tool;

Or. en

Amendment 167
Ivan Štefanec

Proposal for a regulation
Article 3 – paragraph 1 – point 3

Amendment

Text proposed by the Commission

(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;

Amendment

(3) ‘safety component’ means a physical or digital component, including software, of a machinery product which is designed or intended 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. In the case of software of machinery serves to fulfil a safety function, the required hardware is covered by the conformity assessment procedure and specified in the instructions;

Or. en
Amendment 168
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Article 3 – paragraph 1 – point 3

Text proposed by the Commission

(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;

Amendment

(3) ‘safety component’ means a physical or digital component, including software, of a machinery product, except partly completed machinery, which is designed or intended 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;

Or. en

Amendment 169
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 3

Text proposed by the Commission

(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;

Amendment

(3) ‘safety component’ means a physical or digital component, including software, of a machinery product, except partly completed 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;
Amendment 170
Carlo Fidanza

Proposal for a regulation
Article 3 – paragraph 1 – point 3

Text proposed by the Commission

(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;

Amendment

(3) ‘safety component’ means a physical or digital component, including software, of a machinery product which is designed or intended 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;

Or. en

Amendment 171
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 12

Text proposed by the Commission

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

Amendment

(12) ‘placed on the market’ means the first making available of a machinery product on the Union market;

Or. en

Amendment 172
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior
Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission

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

Amendment

(13) ‘putting into service’ means the first use, for its intended purpose, in the Union, of a machinery product except for partly completed machinery;

Or. en

Amendment 173
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission

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

Amendment

(13) ‘putting into service’ means the first use, for its intended purpose, in the Union, of a machinery product, excluding partly completed machinery;

Or. en

Amendment 174
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(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;

Amendment

(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, and that only applies to artificial intelligence systems with self-determining, evolving behaviour or logic during normal operation;
Proposal for a regulation
Article 3 – paragraph 1 – point 16

Text proposed by the Commission

(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;

Amendment

(16) ‘substantial modification’ means a modification of a machinery product, except for partly completed machinery, 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 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. A substantial modification is given if the remaining risk is increased by the modification of the machine under the application of all necessary protective measures;
**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;

**change of the specific application** of a machinery product, except partly completed machinery, 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;

**Or. en**

**Justification**

The proposal is to clarify this definition by introducing an objective criterion, easy to check and much more precise to illustrate the transformation of a machinery, i.e. a modification that leads to a new application. This proposal will also avoid overlaps between the Product legislation (placing products on the market) and the social Directive 2009/104 (use of work equipment at work), which shall continue to prevail after the machinery has been put into service, having in mind that modifications are operations covered by the Directive 2009/104/CE. In addition, it will be beneficial to the competitiveness of the European industry and to the circular economy. Indeed, this proposal will allow users to improve their machinery and its lifespan, while maintaining a high level of safety, without disproportionate requirements and costs.

**Amendment 177**

David Cormand
on behalf of the Greens/EFA Group

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 16**

*Text proposed by the Commission*

(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;

*Amendment*

(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, **maintenance and repair operations by third parties are not substantial modifications**;
Amendment 178
Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation
Article 3 – paragraph 1 – point 16

Text proposed by the Commission

(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;

Amendment

(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 which has the effect of modifying its specific application and may therefore affect the compliance of the machinery product with the relevant essential health and safety requirements;

Or. en

Amendment 179
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 16

Text proposed by the Commission

(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;

Amendment

(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 a risk assessment the compliance of the machinery product with the relevant essential health and safety requirements is affected, excluding repair and maintenance works;

Or. en
Proposal for a regulation
Article 3 – paragraph 1 – point 17

Text proposed by the Commission

(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;

Amendment

(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 uses machinery products for his or her own purposes;

Amendment 181
Carlo Fidanza

Proposal for a regulation
Article 3 – paragraph 1 – point 18

Text proposed by the Commission

(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;

Amendment

(18) ‘instructions for use’ means the information provided by the manufacturer when the machinery product, except partly completed machinery, 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 and how to keep it operating safely and fit for purpose for its whole lifecycle;
Amendment 182
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Article 3 – paragraph 1 – point 18

Text proposed by the Commission

(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;

Amendment

(18) ‘instructions for use’ means the information provided by the manufacturer when the machinery product, except for partly completed machinery, 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;

Or. en

Amendment 183
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 18

Text proposed by the Commission

(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;

Amendment

(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;

Or. en
Amendment 184
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 19

Text proposed by the Commission

(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;

Amendment

(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 with regard to the manufacturer’s obligations under the requirements of this Regulation;

Or. en

Amendment 185
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 25

Text proposed by the Commission

(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;

Amendment

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

Or. en

Amendment 186
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior
Proposal for a regulation
Article 3 – paragraph 1 – point 28

Text proposed by the Commission

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

Amendment

(28) ‘conformity assessment’ means the process demonstrating whether the essential health and safety requirements of this Regulation relating to machinery products, except for partly completed machinery, have been fulfilled;

Or. en

Amendment 187
Carlo Fidanza

Proposal for a regulation
Article 3 – paragraph 1 – point 29

Text proposed by the Commission

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

Amendment

(29) ‘conformity assessment body’ means a body, natural or legal person with technical expertise that performs conformity assessment activities, including calibration, testing, certification and inspection;

Or. it

Amendment 188
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 29

Text proposed by the Commission

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

Amendment

(29) ‘conformity assessment body’ means a body that performs conformity assessment tasks, including calibration, testing, certification and inspection;
Amendment 189
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 29 a (new)

Text proposed by the Commission

Amendment

(29a) ‘technical documentation’ means all the elements referred to in Annex IV for the machinery products under this Regulation;

Or. en

Amendment 190
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 3 – paragraph 1 – point 30

Text proposed by the Commission

Amendment

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

(30) ‘notified body’ means a conformity assessment body notified in accordance with Article 25 of this Regulation;

Or. en

Amendment 191
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 5 – title

Text proposed by the Commission

Amendment

High-risk machinery products

Machinery products referred to in Annex I
Amendment 192
Arba Kokalari

Proposal for a regulation
Article 5 – title

Text proposed by the Commission

Amendment

*High-risk* machinery products

*Annex I* Machinery Products

Amendment 193
Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission

Amendment

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).

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

Amendment 194
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission

Amendment

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).

1. Machinery products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Article 21(2).
Amendment 195
Arba Kokalari

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission

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).

Amendment

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

Amendment 196
Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation
Article 5 – paragraph 1 a (new)

Text proposed by the Commission

Ia. The Commission shall update Annex I before the date referred to Article 52 to ensure relevant machineries are subject to the specific conformity assessment procedure.

Amendment

Or. en

Amendment 197
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

2. The Commission is empowered to

Amendment

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.

2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I, after consulting the stakeholders concerned, 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.

Amendment 198
Arba Kokalari

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

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.

Or. en

Amendment 199
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

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 machinery products in Annex I a new machinery product or withdrawing an existing machinery product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.

Or. en
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.

Amendment 200
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 5 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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.

Amendment

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 and foreseeable use. 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.

Amendment 201
Kateřina Konečná

Proposal for a regulation
Article 5 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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

Amendment

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.

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.

**Amendment 202**
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 5 – paragraph 3 – subparagraph 1

**Text proposed by the Commission**
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.

**Amendment**
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 and foreseeable use. 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.

**Amendment 203**
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Article 5 – paragraph 3 – subparagraph 1

**Text proposed by the Commission**
A machinery product shall be included in

**Amendment**
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.

**Amendment 204**

Arba Kokalari

Proposal for a regulation
Article 5 – paragraph 3 – subparagraph 1

*Text proposed by the Commission*

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.

*Amendment*

A machinery product shall be included in the list of 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 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.

**Or. en**

**Amendment 205**

Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 5 – paragraph 4 – point d

A machinery product shall be included in the list of 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 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.

**Or. en**
Text proposed by the Commission

(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.

Amendment

(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), the Machinery Administrative Cooperation Group reporting and the European Injury Database (EU IDB).

Or. en

Amendment 206
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 5 – paragraph 4 – point d

Text proposed by the Commission

(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.

Amendment

(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 and the Pan-European Injury Database.

Or. en

Amendment 207
Kateřina Konečná

Proposal for a regulation
Article 5 – paragraph 5
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.

If at least three Member States request to list a new machinery product in Annex I, the Commission shall without delay analyse this request.

Or. en

Amendment 208
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 5a (new)

Text proposed by the Commission

Amendment

Article 5a

Pan-European Injury Database

1. A Pan-European Injury Database (IDB), which would cover all types of injuries involving consumer products shall be set up and coordinated by the European Commission.

2. The relevant market surveillance authorities and public authorities established by the Member States shall contribute to the establishment of the database and deliver injury data to the database, based on a common methodology, comprehensive and in accordance with European and national laws on data protection.

3. The Commission shall support the co-ordination of the collection of data from Member States and the operation of the database.
Amendment 209
Kateřina Konečná

Proposal for a regulation
Article 6 a (new)

Text proposed by the Commission

Amendment

Article 6a

Pan-European Injury Database

1. A Pan-European Injury Database (IDB), which would cover all types of injuries involving consumer products shall be set up and coordinated by the European Commission.

2. The relevant market surveillance authorities established by the Member States shall contribute to the establishment of the database and deliver injury data to the database, based on a common methodology, comprehensive and in accordance with European and national laws on data protection.

3. The Commission shall support the co-ordination of the collection of data from Member States and the operation of the database.

Amendment 210
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Article 8 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The health and safety requirements covered by the other more specific Union harmonisation legislation shall be
assessed according to the conformity assessment procedure set out in this Regulation.

Or. en

Justification

Situation is clear and specified in the legal text when it comes to the link between Low Voltage Directive (LVD) 2014/35/EU and Machinery Regulation (see Annex III, point 1.5): requirements of both legislations have to be applied (as appropriate), but the conformity assessment procedure has to be made just once, according the Machinery Regulation only. This approach should be extended also to other applicable legislations such as Pressure Equipment Directive (PED) 2014/68/EU. Interpretational issues were recently raised, as there is partial overlap in the aspects covered, but divergence in the conformity assessment procedures, for example, for pressure equipment above category 1 installed in machinery. Deviating from the modules set by the Machinery Regulation, mandating multiple and diverging conformity assessment modules on similar requirements, will generate diverging interpretations, additional administrative burdens and useless costs.

Amendment 211
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission

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.

Amendment

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 and only apply to artificial intelligence systems with self-determining, evolving behaviour or logic during normal operation, in order not to compromise the safety of the machinery product as a whole.

Or. en

Justification

Only AI systems with an unpredictable non-deterministic behaviour during the use of the
machine, i.e. AI systems capable of evolving autonomously during their lifecycle, should be considered as "high-risk" and included in Annex I. Deterministic software, applications with off-line updates and upgrades, or even statistical analysis in low-risk operations, should not be considered as ‘high-risk’ AI.

Amendment 212
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission
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.

Amendment
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 and only applies to artificial intelligence systems with self-determining, evolving behaviour or logic during normal operation, so as not to compromise the safety of the machinery product as a whole.

Amendment 213
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Article 9 – paragraph 1

Text proposed by the Commission
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

Amendment
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 and only applies to
the safety of the machinery product as a whole.

*artificial intelligence systems with self-determining, evolving behaviour or logic during normal operation*, so as not to compromise the safety of the machinery product as a whole.

**Amendment 214**

Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

**Proposal for a regulation**

**Article 10 – paragraph 1**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. When <em>placing</em> 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.</td>
<td>1. When a machinery product <em>is placed</em> 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.</td>
</tr>
</tbody>
</table>

**Amendment 215**

Carlo Fidanza

**Proposal for a regulation**

**Article 10 – paragraph 1 a (new)**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. <strong>Manufacturers shall draw up recycling instructions for the buyer or company using the machine. Responsibility for recycling shall, however, fall to the company and/or users.</strong></td>
<td></td>
</tr>
</tbody>
</table>
Amendment 216
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 10 – paragraph 2 – subparagraph 1

**Text proposed by the Commission**

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.

**Amendment**

Before a machinery product is placed 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.

Or. en

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Amendment 217
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 10 – paragraph 3

**Text proposed by the Commission**

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.

**Amendment**

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity electronically, 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.

Or. en
Amendment 218
Ivan Štefanec

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

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.

 Amendment

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 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.

Or. en

Amendment 219
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 10 – paragraph 6

Text proposed by the Commission

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

 Amendment

6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address, web address, email address and telephone number at which they can be contacted on the machinery product or 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
Proposal for a regulation
Article 10 – paragraph 7

Text proposed by the Commission
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.

Amendment
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 and accessible for persons with disabilities in accordance with requirements of Directive (EU) 2019/882 (European Accessibility Act), as determined by the Member State concerned. Such instructions and information shall be clear, understandable, intelligible and legible.

Proposal for a regulation
Article 10 – paragraph 10 a (new)

Text proposed by the Commission
10a. Manufacturers shall provide users with information on security-related updates and identified cyber risks in a timely and reliable manner.

Amendment
10a. Manufacturers shall provide users with information on security-related updates and identified cyber risks in a timely and reliable manner.
Amendment 222
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Article 10 – paragraph 10 b (new)

Text proposed by the Commission

Amendment

10b. Manufacturers shall ensure access to stable and ongoing technical support over the normal lifetime of a machinery product, if its safety depends on software.

Or. en

Amendment 223
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 11 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

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:

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The authorised representative shall have the appropriate financial and organisational means to perform the tasks specified in the mandate. The authorised representative shall provide a copy of the mandate to the competent authority, upon request, in a Union language determined by the competent authority. The mandate shall allow the authorised representative to do at least the following:

Or. en

Amendment 224
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

AM\1242038EN.docx 67/170 PE699.191v01-00
Proposal for a regulation
Article 11 – paragraph 2 – point a

Text proposed by the Commission
(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;

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

Or. en

Amendment 225
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 11 – paragraph 2 – point b

Text proposed by the Commission
(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;

Amendment
(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. It could be either in paper or electronic form;

Or. en

Amendment 226
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 12 – paragraph 2 – subparagraph 1

Text proposed by the Commission
Before placing a machinery product on the

Amendment
Before a machinery product is placed on

PE699.191v01-00
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).

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).

Amendment 227
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 12 – paragraph 3

Text proposed by the Commission

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

Amendment

3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address, web address, email address and the telephone number at which they can be contacted on the machinery product or 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.

Amendment 228
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 12 – paragraph 4
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.

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.
Amendment 230
Christel Schaldemose

Proposal for a regulation
Article 15 – paragraph 1

_text proposed by the Commission_

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.

Or. en

Amendment 231
Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation
Article 15 – paragraph 1

_text proposed by the Commission_

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 point 1, 3, 7, 8, 10 and fill in the declaration in Annex V for the part that has been changed.

 Amendment

A natural or legal person, other than the manufacturer, the importer or the distributor, that carries out a substantial modification of the machinery product in order to put it on the market shall be considered a manufacturer for the purposes of this Regulation and shall be subject to
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.

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.

Or. en

Amendment 232
Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation
Article 15 – paragraph 1 a (new)

Text proposed by the Commission

A natural or legal person, other than the manufacturer, the importer or the distributor, that carries out a substantial modification of the machinery product for its own use shall be considered a manufacturer for the purposes of this Regulation. They shall have the following obligations with regards to the affected part of the machinery product or for the entire machinery product where the substantial modification has an impact on the safety of the machinery product as a whole:

(a) to ensure that the modified part and the machinery product remain in conformity with the essential health and safety requirements set out in Annex III;

(b) to draw up the technical documentation referred to in Annex IV that relates to the modification carried out, indicating in particular the date of implementation of the modification and the results of the risk assessment carried out in accordance with the general principles and with section 1.1.2 of Annex III. This documentation must be available to the market surveillance authorities for a period of 10 years after the machinery
product has been put into service;
(c) to carry out the conformity assessment procedure referred to in Article 21 section 3;
(d) to ensure that the instructions provided for in Annex III, section 1.7.4 are updated in view of the substantial modification made to the machinery product.

Amendment 233
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Article 17 – paragraph 3

Text proposed by the Commission

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).
Amendment 234
Arba Kokalari

Proposal for a regulation
Article 17 – paragraph 3

Text proposed by the Commission

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).

Amendment 235
Christel Schaldemose

Proposal for a regulation
Article 17 – paragraph 3
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).
Amendment 237
Christel Schaldemose

Proposal for a regulation
Article 17 – paragraph 3 – point a

Text proposed by the Commission Amendment
(a) no reference to harmonised deleted 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;

Amendment 238
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 17 – paragraph 3 – point a

Text proposed by the Commission Amendment
(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; (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 and no candidate standard is expected to be published;

Amendment 239
Christel Schaldemose

Proposal for a regulation
Article 17 – paragraph 3 – point b
(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.

Or. en

Amendment 240
Arba Kokalari

Proposal for a regulation
Article 17 – paragraph 3 – point b

Text proposed by the Commission

(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.

Or. en

Amendment 241
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Article 17 – paragraph 3 – point b

Text proposed by the Commission

(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.
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.

organisations to draft a harmonised standard for the essential health and safety requirements and **the requested standard has not been developed within 5 years following** the standardisation request, **on the basis of the complexity and the international context of the proposed standard**, or the request has not been accepted by any of the European standardisation organisations.

**Or. en**

_Justification_

Standards development may face technical and/or procedural difficulties, for example it may be hard to reach an agreement on a specific technical requirement and/or the HAS (harmonised standards) Consultants appointed by the European Commission may take time to review the standard and agree on the content. So, a longer time between the mandate and the standard development is necessary, so that the procedure foreseen by Article 17 – paragraph 3 – point b applies only when really appropriate and necessary.

**Amendment 242**

Salvatore De Meo, Andrea Caroppo

Proposal for a regulation

Article 17 – paragraph 3 – point b

**Text proposed by the Commission**

(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.

**Amendment**

(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements and **the requested standard has not been developed within 5 years following** the standardisation request, or the request has not been accepted by any of the European standardisation organisations.

**Or. en**

_Justification_

If the word "developed" refers to the date the harmonised standard is published, the current text could generate problems. In fact, standards' development may face technical and/or procedural difficulties (e.g. delays in reaching an agreement on a specific technical...
requirement, and/or unforeseen time by the HAS consultants appointed by the Commission to review the standard and agree on the content). A longer time between the mandate and the standard's development is necessary, so that the procedure foreseen by this provision applies only when really appropriate and necessary.

Amendment 243
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Article 17 – paragraph 3 – point b

Text proposed by the Commission
(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.

Amendment
(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 cannot be accepted by any of the European standardisation organisations due to problems that cannot be solved.

Or. en

Amendment 244
Kateřina Konečná

Proposal for a regulation
Article 17 – paragraph 3 – point b

Text proposed by the Commission
(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.

Amendment
(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 delays for over a year in the standardisation procedure or the request has not been accepted by any of the European standardisation organisations.

Or. en
Amendment 245
Christel Schaldemose

Proposal for a regulation
Article 17 – paragraph 3 – subparagraph 2

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

Amendment
deleted

Or. en

Amendment 246
Arba Kokalari

Proposal for a regulation
Article 17 – paragraph 3 – subparagraph 2

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

Amendment
deleted

Or. en

Amendment 247
Kateřina Konečná

Proposal for a regulation
Article 17 – paragraph 3 – subparagraph 2

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

Amendment
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3). The Commission shall also consult relevant stakeholders, especially trade unions and consumer organizations.

Or. en
Amendment 248
Arba Kokalari

Proposal for a regulation
Article 17 – paragraph 4

Text proposed by the Commission

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.**

Amendment

Or. en

Amendment 249
Christel Schaldemose

Proposal for a regulation
Article 17 – paragraph 4

Text proposed by the Commission

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.**

Amendment

Or. en

Amendment 250
Christel Schaldemose

Proposal for a regulation
Article 17 – paragraph 5
5. Machinery products that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme adopted in accordance with Regulation (EU) 2019/881 and the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III, sections 1.1.9 and 1.2.1, as regards protection against corruption and safety and reliability of control systems in so far as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.

Amendment 251
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 18 – paragraph 2

2. The EU declaration of conformity must be able to be filled electronically and 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.

Or. en
Amendment 252  
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation  
Article 18 – paragraph 2

Text proposed by the Commission

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.

Or. en

Amendment

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. 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.

Or. en

Amendment 253  
Marco Campomenosi, Alessandra Basso

Proposal for a regulation  
Article 18 – paragraph 2

Text proposed by the Commission

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.

Or. en

Amendment

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. 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.

Or. en

Amendment 254  
David Cormand  
on behalf of the Greens/EFA Group
Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

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.

Amendment

1. The CE marking shall be affixed visibly, legibly and indelibly to the documents accompanying the machinery product.

Or. en

Amendment 255
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission

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.

Amendment

1. In order to determine 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.

Or. en

Amendment 256
Svenja Hahn, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 21 – paragraph 1
1. In order to **certify** the conformity of a machinery product with this Regulation, the manufacturer or its authorised representative and the person who has carried out a substantial modification to the machinery product, shall apply one of the procedures for assessment of conformity referred to in paragraphs 2 and 3.

1. In order to **assess** the conformity of a machinery product with this Regulation, the manufacturer 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.

**Amendment 257**
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

**Proposal for a regulation**
**Article 21 – paragraph 2 – introductory part**

Text proposed by the Commission

1. 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:

1. Where the machinery product is a machinery product listed in Annex I, the manufacturer and the person who has carried out a substantial modification to the machinery product shall apply one of the following procedures:

**Amendment 258**
David Cormand
on behalf of the Greens/EFA Group

**Proposal for a regulation**
**Article 21 – paragraph 2 – introductory part**

Text proposed by the Commission

2. Where the machinery product is a high-risk machinery product listed in Annex I, the manufacturer or the

2. 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 carried out a substantial modification to the machinery product shall apply one of the following procedures:

Amendment 259  
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation  
Article 21 – paragraph 2 – point -a (new)

Text proposed by the Commission  
Amendment

(-a) the internal production control procedure (module A) set out in Annex VI;

Amendment 260  
David Cormand  
on behalf of the Greens/EFA Group

Proposal for a regulation  
Article 21 – paragraph 2 – point a

Text proposed by the Commission  
Amendment

(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;

(a) the internal production control procedure (module A) set out in Annex VI;

Amendment 261  
David Cormand  
on behalf of the Greens/EFA Group
Proposal for a regulation
Article 21 – paragraph 2 – point b

*Text proposed by the Commission*

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

*Amendment*

(b) **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;

Or. en

Amendment 262
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 21 – paragraph 2 – point b a (new)

*Text proposed by the Commission*

(ba) Conformity based on full quality assurance (module H) set out in Annex IX;

*Amendment*

Or. en

Amendment 263
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 21 – paragraph 3

*Text proposed by the Commission*

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.

*Amendment*

3. Where the machinery product is not a machinery product listed in Annex I, the manufacturer 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.
Amendment 264
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Article 21 – paragraph 3 a (new)

Or. en

Amendment

Text proposed by the Commission

3a. Where, in assessing the compliance of machinery with the essential health and safety requirements set out in Annex III, the manufacturer has applied harmonised standards the references of which have been published in the Official Journal of the European Union, the manufacturer shall use any of the following procedures:

(a) the internal production control procedure (module A) set out in Annex VI;

(b) 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;

(c) Conformity based on full quality assurance (module H) set out in Annex IX;

Amendment 265
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Alex Agius Saliba

Proposal for a regulation
Article 21 – paragraph 4
Text proposed by the Commission

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.

Amendment

4a. In assessing the compliance of machinery with the health and safety requirements set out in Annex III, the manufacturer has not applied or has applied only in part harmonised standards the references of which have been published in the Official Journal of the European Union, or when harmonised standards do not exist, machinery shall be submitted with regard to those essential health and safety requirements, to either of the following procedures:

(a) the internal production control procedure (module A) set out in Annex VI;

(b) 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;

Or. en
Amendment 267  
Svenja Hahn, Vlad-Marius Botoş, Karen Melchior  
Proposal for a regulation  
Article 22 – title  

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conformity assessment</strong> procedures for partly completed machinery</td>
<td>Procedures for partly completed machinery</td>
</tr>
</tbody>
</table>

Or. en

Amendment 268  
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Sandro Gozi, Stéphanie Yon-Courtin, Karen Melchior  
Proposal for a regulation  
Article 22 – paragraph 1 – introductory part  

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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:</td>
<td>1. The manufacturer of partly completed machinery shall, before placing partly completed machinery on the market, ensure that the following documents are drawn up in paper or digital form:</td>
</tr>
</tbody>
</table>

Or. en

Amendment 269  
Ivan Štefaneč  
Proposal for a regulation  
Article 22 – paragraph 2  

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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</td>
<td>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 technical documentation referred to in</td>
</tr>
</tbody>
</table>
Amendment 270
Kateřina Konečná

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

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.

Amendment

Member States shall lay down requirements including specific trainings and sufficient resources to ensure that persons, including workers, are protected when installing and using machinery products in order to guarantee a high level of protection for EU workers and citizens.
Text proposed by the Commission

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body, which is not a governmental entity that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 26. In addition, that body shall have arrangements to cover liabilities arising out of its activities.

Amendment

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body, which is not a governmental entity that body shall be a legal entity and shall comply mutatis mutandis with the requirements laid down in Article 26. In addition, that body shall have arrangements to cover liabilities arising out of its tasks.

Or. en

Amendment 272
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 26 – paragraph 2

Text proposed by the Commission

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

Amendment

2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its tasks.

Or. en

Amendment 273
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 26 – paragraph 4

Text proposed by the Commission

4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy

Amendment

4. A notifying authority shall not offer or provide any tasks that conformity assessment bodies perform, or consultancy
services on a commercial or competitive basis.

services on a commercial or competitive basis.

Or. en

Amendment 274
Carlo Fidanza

Proposal for a regulation
Article 28 – paragraph 2

Text proposed by the Commission

2. A conformity assessment body shall be established under national law of a Member State and have legal personality.

Amendment

2. A conformity assessment body shall be established under national law of a Member State and have natural or legal personality and technical expertise.

Or. it

Amendment 275
Carlo Fidanza

Proposal for a regulation
Article 28 – paragraph 3 – subparagraph 2

Text proposed by the Commission

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacture, provision, assembly, use or maintenance of machinery products which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a conformity assessment body.

Amendment

A body belonging to a business association, a professional body or professional federation representing undertakings involved in the design, manufacture, provision, assembly, use or maintenance of machinery products which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a conformity assessment body.

Or. it
Amendment 276  
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba  
Proposal for a regulation  
Article 28 – paragraph 4 – subparagraph 1  

*Text proposed by the Commission*  
A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of a machinery product, that they assess, nor the representative of any of those parties. This shall not preclude the use of a machinery product that is necessary for the operations of the conformity assessment body or the use of a machinery product for personal purposes.

*Amendment*  
A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, *importer*, *distributor*, installer, purchaser, owner, user or maintainer of a machinery product, that they assess, nor the *authorised* representative of any of those parties. This shall not preclude the use of a machinery product that is necessary for the operations of the conformity assessment body or the use of a machinery product for personal purposes.

Amendment 277  
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba  
Proposal for a regulation  
Article 28 – paragraph 4 – subparagraph 2  

*Text proposed by the Commission*  
A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, installation, use or maintenance of machinery products, or represent the parties engaged in those *activities*. They shall not engage in any *activity* that may conflict with their independence of judgement or integrity in relation to conformity assessment *activities* for which

*Amendment*  
A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, *import*, *distribution*, manufacture, marketing, installation, use or maintenance of machinery products, or represent the parties engaged in those *tasks*. They shall not engage in any *task* that may conflict with their independence of judgement or integrity in relation to conformity
they are notified. This shall in particular apply to consultancy services. assessment tasks for which they are notified. This shall in particular apply to consultancy services.

Amendment 278
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 28 – paragraph 4 – subparagraph 3

Text proposed by the Commission
A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.

Amendment
A conformity assessment body shall ensure that the tasks of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment tasks.

Or. en

Amendment 279
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 28 – paragraph 4 – subparagraph 3 a (new)

Text proposed by the Commission
The conformity assessment body shall ensure rotation between the responsible personnel carrying out the conformity assessment tasks.

Amendment
The conformity assessment body shall ensure rotation between the responsible personnel carrying out the conformity assessment tasks.

Or. en

Amendment 280
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba
Proposal for a regulation
Article 28 – paragraph 5

5. A conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence its judgement or the results of its conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

Amendment 281
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 28 – paragraph 6 – subparagraph 1

5. A conformity assessment body and its personnel shall carry out the conformity assessment tasks with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence its judgement or the results of its conformity assessment tasks, especially as regards persons or groups of persons with an interest in the results of those tasks.

Amendment 282
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba
Proposal for a regulation
Article 28 – paragraph 6 – subparagraph 2 – point a

Text proposed by the Commission

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment activities;

Amendment

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

Or. en

Amendment 283
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 28 – paragraph 6 – subparagraph 2 – point c

Text proposed by the Commission

(c) appropriate policies and procedures to distinguish between activities that it carries out as a notified body and other activities;

Amendment

(c) appropriate policies and procedures to distinguish between tasks that it carries out as a notified body and other tasks;

Or. en

Amendment 284
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 28 – paragraph 6 – subparagraph 2 – point d

Text proposed by the Commission

(d) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the machinery technology in question and the mass or serial nature of the production process.

Amendment

(d) procedures for the performance of conformity assessment tasks which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the machinery technology in question and the mass or serial nature of the production process.
Amendment 285
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 28 – paragraph 6 – subparagraph 3

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.</td>
<td>A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment tasks in an appropriate manner and shall have access to all necessary equipment or facilities.</td>
</tr>
</tbody>
</table>

Amendment 286
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 28 – paragraph 7 – point a

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;</td>
<td>(a) sound technical and vocational training covering all the conformity assessment tasks in relation to which the conformity assessment body has been notified;</td>
</tr>
</tbody>
</table>

Amendment 287
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba
Proposal for a regulation
Article 28 – paragraph 8 – subparagraph 1

Text proposed by the Commission

The impartiality of a conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment activities shall be guaranteed.

Amendment

The impartiality of a conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

Or. en

Amendment 288
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 28 – paragraph 8 – subparagraph 2

Text proposed by the Commission

The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment activities shall not depend on the number of conformity assessments carried out or on the results of those assessments.

Amendment

The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not depend on the number of conformity assessments carried out or on the results of those assessments.

Or. en

Amendment 289
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 28 – paragraph 10

Text proposed by the Commission

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment activities in accordance with

Amendment

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment tasks in accordance with
Annexes VII, VIII and IX, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected.

Annexes VII, VIII and IX, except in relation to the competent authorities of the Member State in which its tasks are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected.

Amendment 290
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 28 – paragraph 11

Text proposed by the Commission
11. A conformity assessment body shall participate in, or ensure that its personnel responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 40 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Amendment
11. A conformity assessment body shall participate in, or ensure that its personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation tasks and the tasks of the notified body coordination group established under Article 40 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Amendment 291
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 30 – paragraph 3

Text proposed by the Commission
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

Amendment
3. Tasks may be subcontracted or carried out by a subsidiary only with the agreement of the client.
Amendment 292
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 31 – paragraph 2

Text proposed by the Commission

2. The application for notification shall be accompanied by a description of the conformity assessment activities, of the conformity assessment procedures set out in Annexes VII, VIII and IX and of the kind of machinery product for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 28.

Amendment

2. The application for notification shall be accompanied by a description of the conformity assessment tasks, of the conformity assessment procedures set out in Annexes VII, VIII and IX and of the kind of machinery product for which the conformity assessment body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 28.

Amendment 293
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 32 – paragraph 3 – point a

Text proposed by the Commission

(a) full details of the conformity assessment activities to be performed;

Amendment

(a) full details of the conformity assessment tasks to be performed;

Amendment 294
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba
Proposal for a regulation
Article 32 – paragraph 5 – subparagraph 1

Text proposed by the Commission
The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it includes documentary evidence referred to in Article 31(3).

Amendment
The conformity assessment body concerned may perform the tasks of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it includes documentary evidence referred to in Article 31(3).

Or. en

Amendment 295
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 33 – paragraph 2 – subparagraph 1

Text proposed by the Commission
The Commission shall make publicly available the list of notified bodies including the identification numbers that have been assigned to them and the conformity assessment activities for which they have been notified.

Amendment
The Commission shall make publicly available the list of notified bodies including the identification numbers that have been assigned to them and the conformity assessment tasks for which they have been notified.

Or. en

Amendment 296
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 36 – paragraph 2 – subparagraph 1
Text proposed by the Commission

A notified body shall perform its activities in a proportionate manner, avoiding unnecessary burdens for economic operators, and taking due account of the size of an undertaking, the sector in which the undertaking operates, the structure of the undertaking, the degree of complexity of the machinery technology in question and the mass or serial nature of the production process.

Amendment

A notified body shall perform its tasks in a proportionate manner, avoiding unnecessary burdens for economic operators, and taking due account of the size of an undertaking, the sector in which the undertaking operates, the structure of the undertaking, the degree of complexity of the machinery technology in question and the mass or serial nature of the production process.

Or. en

Amendment 297
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 38 – paragraph 1 – point c

Text proposed by the Commission

(c) any request for information which it has received from market surveillance authorities regarding its conformity assessment activities;

Amendment

(c) any request for information which it has received from market surveillance authorities regarding its conformity assessment tasks;

Or. en

Amendment 298
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 38 – paragraph 1 – point d

Text proposed by the Commission

(d) on request, any conformity assessment activities performed within the scope of its notification and any other activity performed, including cross-border

Amendment

(d) on request, any conformity assessment tasks performed within the scope of its notification and any other task performed, including cross-border tasks
activities and subcontracting.

Amendment 299
Adriana Maldonado López, Clara Aguilera, María Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Article 38 – paragraph 2

2. A notified body shall provide other notified bodies carrying out similar conformity assessment activities covering the same kinds of machinery product with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Amendment

2. A notified body shall provide other notified bodies carrying out similar conformity assessment tasks covering the same kinds of machinery product with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Amendment 300
Carlo Fidanza

Proposal for a regulation
Article 41 – paragraph 4 – subparagraph 1

Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, second subparagraph, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the machinery product being made available on their national market, to withdraw the machinery product from that market or to recall it.

Amendment

Where the relevant economic operator does not take corrective action referred to in paragraph 1, second subparagraph, within the specified period or where the non-compliance or the risk referred to in paragraph 1 persists, the market surveillance authorities shall ensure that the machinery product concerned is withdrawn or recalled, or that its being made available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly without delay.
**Amendment 301**
Kateřina Konečná

Proposal for a regulation
Article 48 – paragraph 1

*Text proposed by the Commission*

1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of this Regulation and shall take all measures necessary to ensure that they are enforced. The penalties provided for shall be effective, proportionate and dissuasive and may include criminal penalties for serious infringements.

*Amendment*

1. Member States shall lay down the rules on penalties *and fines* applicable to infringements by economic operators of this Regulation and shall take all measures necessary to ensure that they are enforced. The penalties *and fines* provided for shall be effective, proportionate and dissuasive and may include criminal penalties for serious infringements. *Fines shall amount to at least 3% of the economic operator’s worldwide turnover of the preceding fiscal year for serious breaches of this regulation.*

**Amendment 302**
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Article 49 – paragraph 2 – subparagraph 1

*Text proposed by the Commission*

Directive 2006/42/EC is repealed with effect from … [30 months after the date of entry into force of this Regulation].

*Amendment*

Directive 2006/42/EC is repealed with effect from … [48 months after the date of entry into force of this Regulation].

**Amendment 303**
Carlo Fidanza
Proposal for a regulation
Article 49 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Directive 2006/42/EC is repealed with effect from … [30 months after the date of entry into force of this Regulation].

Amendment

Directive 2006/42/EC is repealed with effect from … [36 months after the date of entry into force of this Regulation].

Or. en

Amendment 304
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Article 50 – paragraph 1

Text proposed by the Commission

1. Member States shall not until … [42 months after the date of entry into force of this Regulation] impede the making available on the market of machinery which was placed on the market in conformity with Directive 2006/42/EC before … [the date of entry into force of this Regulation]. However, Chapter VI of this Regulation shall apply mutatis mutandis to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC as from … [the date of entry into force of this Regulation].

Amendment

1. Member States shall not until … [60 months after the date of entry into force of this Regulation] impede the placing on the market of machinery which was placed on the market in conformity with Directive 2006/42/EC before the date of its repeal. However, Chapter VI of this Regulation shall apply mutatis mutandis to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC as from … [the date of entry into force of this Regulation].

Or. en

Justification

The article must be clear and give provisions not only until the date of the entry into force of this Regulation, but up to the repeal of Directive 2006/42/EC. A sharp deadline stopping all sales of machinery compliant with the Directive 2006/42/EC would be critical especially for dealers and the rest of the distribution network, as well as for the many SMEs involved in this sector. Moreover, in some sectors, sales are seasonal. A deadline not matching the season might be a serious issue for involved economic operators.
Amendment 305
Arba Kokalari

Proposal for a regulation
Article 50 – paragraph 1

*Text proposed by the Commission*

1. Member States shall not until … [42 months after the date of entry into force of this Regulation] impede the making available on the market of machinery which was placed on the market in conformity with Directive 2006/42/EC before … [the date of entry into force of this Regulation]. However, Chapter VI of this Regulation shall apply mutatis mutandis to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC as from … [the date of entry into force of this Regulation].

*Amendment*

1. Member States shall not until … [60 months after the date of entry into force of this Regulation] impede the making available on the market of machinery which was placed on the market in conformity with Directive 2006/42/EC before … [the date of entry into force of this Regulation]. However, Chapter VI of this Regulation shall apply mutatis mutandis to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC as from … [the date of entry into force of this Regulation].

Or. en

Amendment 306
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 50 – paragraph 1

*Text proposed by the Commission*

1. Member States shall not until … [42 months after the date of entry into force of this Regulation] impede the making available on the market of machinery which was placed on the market in conformity with Directive 2006/42/EC before … [the date of entry into force of this Regulation]. However, Chapter VI of this Regulation shall apply mutatis mutandis to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC as from … [the date of entry into force of this Regulation].

*Amendment*

1. Member States shall not until … [60 months after the date of entry into force of this Regulation] impede the making available on the market of machinery which was placed on the market in conformity with Directive 2006/42/EC before … [the date of entry into force of this Regulation]. However, Chapter VI of this Regulation shall apply mutatis mutandis to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC as from … [the date of entry into force of this Regulation].
Directive 2006/42/EC as from … [the date of entry into force of this Regulation].

Amendment 307
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Article 50 – paragraph 1

Text proposed by the Commission

1. Member States shall not until … [42 months after the date of entry into force of this Regulation] impede the making available on the market of machinery which was placed on the market in conformity with Directive 2006/42/EC before … [the date of entry into force of this Regulation]. However, Chapter VI of this Regulation shall apply mutatis mutandis to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC as from … [the date of entry into force of this Regulation].

Amendment

1. Member States shall not until … [60 months after the date of entry into force of this Regulation] impede the placing available on the market of machinery which was placed on the market in conformity with Directive 2006/42/EC before the date of its repeal. However, Chapter VI of this Regulation shall apply mutatis mutandis to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC as from … [the date of entry into force of this Regulation].

Justification

Extension of the transition period is aligned with the proposal by rapporteur Stefanec. Furthermore, the article must be clear and give provisions for machines legally manufactured according Directive 2006/42/EC not only up to the date of entry into force of the new Machinery Regulation, but up to the repeal of Directive 2006/42/EC. Also, it must be clear on the fact that it talks about new machines only. But, according to the Blue Guide and to Art 3 (11) of the new Machinery Regulation, the making available includes also machines which have already been used in the EU market. From our perspective, machines which were already used in the EU market shall not be included in this limitation. Thus the reference to ‘placing on the market’, which is the first ‘making available on the market’ and applies only to new products. A sharp deadline stopping all sales of machinery compliant with the Directive 2006/42/EC would be critical especially for dealers and the rest of the distribution network and for the many involved SMEs. It has to be recalled that for some sectors, like for ag machinery, sales are seasonal. A deadline not matching the season might be a serious issue for involved economic operators.
Amendment 308
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 50 – paragraph 2

Text proposed by the Commission

2. EC type-examination certificates and approval decisions issued in accordance with Article 14 of Directive 2006/42/EC shall remain valid until … [42 months after the date of entry into force of this Regulation], unless they expire before that date.

Amendment

2. EC type-examination certificates and approval decisions issued in accordance with Article 14 of Directive 2006/42/EC shall remain valid until … [60 months after the date of entry into force of this Regulation], unless they expire before that date.

Or. en

Amendment 309
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 51 – paragraph 1

Text proposed by the Commission

1. By … [54 months after the date of entry into force of this Regulation] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.

Amendment

1. By … [72 months after the date of entry into force of this Regulation] and every four years thereafter, the Commission shall submit a report on the evaluation and review of this Regulation to the European Parliament and to the Council. The reports shall be made public.

Or. en

Amendment 310
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Article 51 – paragraph 2 – subparagraph 1– point b
(b) the conformity assessment procedure applicable to high-risk machinery products listed in Annex I.

(b) the conformity assessment procedure applicable to machinery products listed in Annex I.

Amendment 311
Kateřina Konečná

Proposal for a regulation
Article 52 – paragraph 2

Text proposed by the Commission  

Amendment

It shall apply from … [30 months after the date of entry into force of this Regulation].

It shall apply from … [24 months after the date of entry into force of this Regulation].

Amendment 312
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Article 52 – paragraph 2

Text proposed by the Commission  

Amendment

It shall apply from … [30 months after the date of entry into force of this Regulation].

It shall apply from … [48 months after the date of entry into force of this Regulation].

Amendment 313
Sandro Gozi, Stéphanie Yon-Courtin

Proposal for a regulation
Article 52 – paragraph 2
Text proposed by the Commission
Amendment

It shall apply from … [30 months after the date of entry into force of this Regulation].
It shall apply from … [24 months after the date of entry into force of this Regulation].

Or. en

Amendment 314
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex I – subheading 1

Text proposed by the Commission
Amendment

HIGH-RISK MACHINERY PRODUCTS
Categories of machinery products to which one of the procedures referred to in Article 5 and 21 must be applied

Or. en

Amendment 315
Christel Schaldemose

Proposal for a regulation
Annex I – point 24

Text proposed by the Commission
Amendment

24. Software ensuring safety functions, including AI systems. deleted

Or. en

Amendment 316
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex I – point 24
Text proposed by the Commission

24. Software ensuring safety functions, including AI systems.

Amendment

24. The safety component of software of AI systems with self-determining, evolving behaviour or logic during normal operation and ensuring safety functions.

Or. en

Justification

The present drafting from the Commission could be interpreted as a full inspection and validation of all software dealing with safety functions. In recital 17 there is a clear reference only to software as safety component, that is ensuring a safety function and being placed independently on the market. This must be reflected in this point of Annex I, also to have a better connection with the indicative list of safety components provided in Annex II. Furthermore, as explained in amendments 1, 3 and 4, within this Regulation the categorisation as high-risk should only be limited to software of "real" AI systems, which means capable of evolving autonomously during their lifecycle.

Amendment 317
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex I – point 24

Text proposed by the Commission

24. Software ensuring safety functions, including AI systems.

Amendment

24. The safety component of software of AI systems with self-determining, evolving behaviour or logic during normal operation and ensuring safety functions.

Or. en

Justification

The present drafting could be interpreted as a full inspection and validation of all software dealing with safety functions, when placed independently on the market as safety components. Furthermore, the categorisation as "high-risk" should only be limited to software of AI systems capable of evolving autonomously during their lifecycle.
Amendment 318
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex I – point 24

Text proposed by the Commission

24. Software ensuring safety functions, including AI systems.

Amendment

24. The safety component software of AI systems ensuring safety functions.

Or. en

Amendment 319
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex I – point 24

Text proposed by the Commission

24. Software ensuring safety functions, including AI systems.

Amendment

24. Software, including AI systems, fulfilling safety functions.

Or. en

Amendment 320
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex I – point 25

Text proposed by the Commission

25. Machinery embedding AI systems ensuring safety functions.

Amendment

25. Machinery embedding AI systems ensuring safety functions. deleted

Or. en

Amendment 321
Christel Schaldemose
Proposal for a regulation
Annex I – point 25

Text proposed by the Commission

25. Machinery embedding AI systems ensuring safety functions.

Amendment

25. Machinery embedding AI systems ensuring safety functions, where the safety functions can evolve over time or exhibit non-deterministic behaviour and where the AI systems have not previously been subjected to a conformity assessment.

Or. en

Amendment 322
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex I – point 25

Text proposed by the Commission

25. Machinery embedding AI systems ensuring safety functions.

Amendment

25. AI systems with self-determining, evolving behaviour or logic during normal operation ensuring safety functions and embedded in machinery.

Or. en

Justification

The definition of Artificial Intelligence given in the AI draft Regulation is very broad and not fully applicable for machinery products, as it is originally intended to cover both high-risks and low-risks environments overall. Key issue of this Machinery regulation is that any system falling in the AI definition automatically becomes ‘high-risk’, even when this is not really the case. The intent of this amendment is to cover only AI systems with an unpredictable non-deterministic behaviour during the use of the machine, which means AI systems capable of evolving autonomously during their lifecycle. Deterministic software, applications with offline updates and upgrades, or even statistical analysis in low-risk operations, should not be considered as ‘high-risk’ AI to be then included in Annex I.

Amendment 323
Salvatore De Meo, Andrea Caroppo
Proposal for a regulation
Annex I – point 25

25. **Machinery embedding** AI systems ensuring safety functions.

Amendment

25. AI systems with self-determining, evolving behaviour or logic during normal operation ensuring safety functions and embedded in machinery.

Or. en

**Justification**

The categorisation as "high-risk" within this Regulation should only be limited to software of AI systems that are capable of evolving autonomously during their lifecycle.

Amendment 324
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex I – point 25

25. Machinery embedding AI systems ensuring safety functions.

Amendment

25. Machinery embedding AI systems ensuring safety functions, if these AI systems have not already been subjected to a conformity assessment.

Or. en

Amendment 325
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Annex I – point 25 a (new)

25a. Escalators and moving walks.

Or. en
Amendment 326
David Cormand
on behalf of the Greens/EFA Group
Proposal for a regulation
Annex I – point 25 a (new)

Text proposed by the Commission
Amendment

25a. Escalators

Amendment 327
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba
Proposal for a regulation
Annex I – point 25 b (new)

Text proposed by the Commission
Amendment

25b. Cranes with a load moment >150 kNm.

Amendment 328
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba
Proposal for a regulation
Annex I – point 25 c (new)

Text proposed by the Commission
Amendment

25c. Palletisers, depalletisers, pallet wrapping machines.

Or. en
Amendment 329
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex II – point 18

Text proposed by the Commission
18. Software ensuring safety functions, including AI systems.

Amendment
18. Software of AI systems with self-determining, evolving behaviour or logic during normal operation and ensuring safety functions.

Or. en

Justification
To ensure alignment and consistency between item 24 of Annex I and Annex II (list of safety components).

Amendment 330
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex II – point 18

Text proposed by the Commission
18. Software ensuring safety functions, including AI systems.

Amendment
18. Software of AI systems with self-determining, evolving behaviour or logic during normal operation ensuring safety functions.

Or. en

Justification
This proposed amendment is intended to ensure alignment and consistency between Annex I and Annex II.

Amendment 331
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex II – point 18
18. Software ensuring safety functions, including AI systems.

18. Software, including AI systems, fulfilling safety functions.

Amendment 332
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex II – point 18

18. Software ensuring safety functions, including AI systems.

18. Software of AI systems ensuring safety functions.

Amendment 333
Svenja Hahn, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – point 1 – paragraph 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.

The manufacturer of a machinery product 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 or minimise all relevant risks, taking into account the results of the risk assessment.

Or. en
Amendment 334
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – point 1 – paragraph 2 – introductory part

Text proposed by the Commission
By the iterative process of risk assessment and risk reduction referred to in the first subparagraph, the manufacturer or his or her authorised representative shall:

Amendment
By the iterative process of risk assessment and risk reduction referred to in the first subparagraph, the manufacturer shall:

Or. en

Amendment 335
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – point 2

Text proposed by the Commission
2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery product in question when it is used under the conditions foreseen by the manufacturer or his or her authorised representative or in foreseeable abnormal situations. However, the principles of safety integration established in section 1.1.2 and the obligations concerning marking of machinery products and instructions referred to in sections 1.7.3 and 1.7.4 apply in all cases.

Amendment
2. The obligations laid down by the essential health and safety requirements only apply when the corresponding hazard exists for the machinery product in question when it is used under the conditions foreseen by the manufacturer or in foreseeable abnormal situations. However, the principles of safety integration established in section 1.1.2 and the obligations concerning marking of machinery products and instructions referred to in sections 1.7.3 and 1.7.4 apply in all cases.

Or. en

Amendment 336
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba
Proposal for a regulation  
Annex III – Part 1 – point 1.1 – point 1.1.2 – point a

**Text proposed by the Commission**

(a) A machinery product shall be designed and constructed so that it is fit for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions *foreseen but also* taking into account any reasonably foreseeable misuse thereof. The aim of protective measures shall be to eliminate any risk throughout the foreseeable lifetime of the machinery product including the phases of transport, assembly, dismantling, disabling and scrapping.

**Amendment**

(a) A machinery product shall be designed and constructed so that it is fit for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the *reasonably foreseeable* conditions *of use* also taking into account any reasonably foreseeable misuse thereof. The aim of protective measures shall be to eliminate any risk throughout the foreseeable lifetime of the machinery product including the phases of transport, assembly, dismantling, disabling and scrapping.

Or. en

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**Amendment 337**

David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation  
Annex III – Part 1 – point 1.1 – point 1.1.2 – point a

**Text proposed by the Commission**

(a) A machinery product shall be designed and constructed so that it is fit for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under *the* conditions *foreseen* but also taking into account any reasonably foreseeable misuse thereof. The aim of protective measures shall be to eliminate any risk throughout the foreseeable lifetime of the machinery product including the phases of transport, assembly, dismantling, disabling and scrapping.

**Amendment**

(a) A machinery product shall be designed and constructed so that it is fit for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under *reasonably foreseeable* conditions *of use* but also taking into account any reasonably foreseeable misuse thereof. The aim of protective measures shall be to eliminate any risk throughout the foreseeable lifetime of the machinery product including the phases of transport, assembly, dismantling, disabling and scrapping.

Or. en
Amendment 338
Kateřina Konečná

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.2 – point a

Text proposed by the Commission

(a) A machinery product shall be designed and constructed so that it is fit for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof. The aim of protective measures shall be to eliminate any risk throughout the foreseeable lifetime of the machinery product including the phases of transport, assembly, dismantling, disabling and scrapping.

Amendment

(a) A machinery product shall be designed and constructed so that it is fit for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under reasonably foreseeable condition of use but also taking into account any reasonably foreseeable misuse thereof. The aim of protective measures shall be to eliminate any risk throughout the foreseeable lifetime of the machinery product including the phases of transport, assembly, dismantling, disabling and scrapping.

Or. en

Amendment 339
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.2 – point e

Text proposed by the Commission

(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.

Amendment

(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 where applicable. A machinery product must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.

Or. en
Amendment 340
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.2 – point e

Text proposed by the Commission

(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.

Amendment

(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 where applicable. The machinery product shall be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.

Or. en

Amendment 341
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.2 – point e

Text proposed by the Commission

(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.

Amendment

(e) A machinery product shall be designed and constructed in such a way that it is possible 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.

Or. en

Justification

It could be complicated to apply this requirement to all machines, as it depends on the design.

EN
of the safety functions and on the manufacturing and operational constraints. A physical test is not always possible by the user (and not always appropriate). Generally, only some safety functions are designed to be tested by the user (for example: cat.2 according EN13849-1), that is already in the scope of this kind of harmonized standards (EN 13849, ISO 25119, IEC 62061, etc.)

Amendment 342
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.2 – point e

Text proposed by the Commission
(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.

Amendment
(e) A machinery product shall be designed and constructed in such a way that it is possible 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.

Or. en

Justification
It could be really complicated to apply this requirement on all machines. It really depends on the design of the safety functions and on the manufacturing and operational constraints. A physical test is not always possible by the user (and not always appropriate). Generally, only some safety functions are designed to be tested by the user (for example: cat.2 according EN13849-1), what is already in the scope of this kind of harmonized standards (EN 13849, ISO 25119, IEC 62061, etc.) However, we agree on the fact that the safety functions have to be testable by an appropriate and trained person with access to the safety program for example.

Amendment 343
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.2 – point e a (new)
The manufacturer shall inform the user about vulnerabilities that might arise and provide remedial measures.

Amendment 344
Kateřina Konečná
Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.6 – introductory part

Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator shall be reduced to the minimum possible, taking into account ergonomic principles such as:

Under the intended conditions of use, the discomfort, fatigue and physical and cognitive workload faced by the operator shall be eliminated to the minimum possible, taking into account ergonomic principles such as:

Amendment 345
Kateřina Konečná
Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.6 – point c

(c) avoiding a machine-determined work rate;

(c) avoiding a machine-determined work rate by allowing its adaptivity;

Amendment 346
Kateřina Konečná
Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.6 – point e

Text proposed by the Commission

(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;

Amendment

(e) adapting the human-machinery product interface, as well as the security systems and the emergency stop systems, 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;

Or. en

Amendment 347
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.6 point f

Text proposed by the Commission

(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.

Amendment

(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).

Or. en

Amendment 348
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.6 point f
Text proposed by the Commission

(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.

Amendment

(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).

Amendment 349
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.6 point f

Text proposed by the Commission

(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.

Amendment

(f) adapting a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy and to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner if the outcome of the planned action has a safety impact.

Justification

Though it relates only to guiding ergonomics principles, it should be drafted more as a generic essential requirement, with a clear guidance, where the details are defined in standards. In particular: • The above text is too restrictive in possibilities to communicate. • The need to communicate should be linked to possible hazards for operators/bystanders in close proximity. • Feedback to the surrounding should be limited to those situations in which it really matters, so to have a maximum impact to the addressee.
Amendment 350  
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation  
Annex III – Part 1 – point 1.1 – point 1.1.6 point f

**Text proposed by the Commission**

(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.

**Amendment**

(f) adapting a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy and to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner if the outcome of the planned action has a safety impact.

**Or. en**

**Justification**

The above text is too restrictive in relation to communication possibilities. The need to communicate should be linked to possible hazards for operators/bystanders in close proximity. Moreover, a feedback to the surrounding should be limited to those situations in which it really matters, so to have a maximum impact to the addressee.

Amendment 351  
Christel Schaldemose

Proposal for a regulation  
Annex III – Part 1 – point 1.1 – point 1.1.9 – paragraph 1

**Text proposed by the Commission**

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.

**Amendment**

deleted
Amendment 352
Kateřina Konečná

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.9 – paragraph 1

Text proposed by the Commission
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.

Amendment
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 other unintended (and potentially hazardous) functions.

Justification
By design, machinery should only work as intended.

Amendment 353
Christel Schaldemose

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.9 – paragraph 2

Text proposed by the Commission
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.

Amendment
deleted
Amendment 354
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.9 – paragraph 2

**Text proposed by the Commission**
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.

**Amendment**
A hardware component **relevant** for connection or **access to software** 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 **aforementioned** hardware component, when relevant for connection or access to software that is critical for the compliance of the machinery product.

Or. en

Amendment 355
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.9 – paragraph 2

**Text proposed by the Commission**
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.**

**Amendment**
A hardware component **relevant** for connection or **access to software** 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.

Or. en
Justification

The new cybersecurity principles (protection, traceability, etc.) should be applicable only to hardware associated with machinery connectivity and/or access to machinery software which is critical from a safety standpoint. The last sentence is already covered by Annex III, 1.2.1.

Amendment 356
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.9 – paragraph 2

<table>
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<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
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<td>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. <strong>The machinery product shall collect evidence of a legitimate or illegitimate intervention in the hardware component.</strong></td>
<td>A hardware component relevant for connection or access to software 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.</td>
</tr>
</tbody>
</table>
accidental or intentional corruption.

Amendment 358
Christel Schaldemose

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.9 – paragraph 4

Text proposed by the Commission

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.

Amendment

Amendment 359
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.9 – paragraph 5

Text proposed by the Commission

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.

Amendment

Amendment 360
Christel Schaldemose

Proposal for a regulation
Annex III – Part 1 – point 1.1 – point 1.1.9 – paragraph 5
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.

Amendment 361
Christel Schaldemose

Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 2 – point a

(a) they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including malicious attempts from third parties to create a hazardous situation;

Amendment 362
Kateřina Konečná

Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 2 – point a

(a) they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including malicious attempts from third parties to create other unintended (and potentially hazardous)
functions;

Justification

By design, machinery should only work as intended

Amendment 363
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 2 – point a

Text proposed by the Commission

(a) they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including malicious attempts from third parties to create a hazardous situation;

Amendment

(a) they can reasonably withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended external influences, including known malicious attempts from third parties to create a hazardous situation;

Amendment 364
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 2 – point a

Text proposed by the Commission

(a) they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including malicious attempts from third parties to create a hazardous situation;

Amendment

(a) they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended external influences, including malicious attempts from third parties to create a hazardous situation;
Amendment 365
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 2 – point d

Text proposed by the Commission

(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;

Amendment

(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 safety functions upgrades are part of the limits defined by the manufacturer;

Justification

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).

Amendment 366
Kateřina Konečná

Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 2 – point d

Text proposed by the Commission

(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;

risk assessment performed by the manufacturer, including any modifications to the settings or rules generated by the machinery product or by operators, covering also its development based on machine learning, which cannot go beyond the limits addressed in the risk assessment;

_or. en_

*Justification*

to focus only on the learning phase would be too narrow in our opinion here

**Amendment 367**

Carlo Fidanza, Evžen Tošenovský

**Proposal for a regulation**

Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 2 – point f

**Text proposed by the Commission**

(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;

**Amendment**

(f) the tracing log of the data generated in relation to an intervention to modify the versions of safety software ensuring safety functions 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;

_or. en_

*Justification*

This is a very broad requirement, which could lead to various interpretations. It should be made clear that this requirement is applicable only to software ensuring safety functions

**Amendment 368**

Salvatore De Meo, Andrea Caroppo
Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 2 – point f

Text proposed by the Commission

(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;

Amendment

(f) the tracing log of the data generated in relation to an intervention to modify the versions of software ensuring safety functions 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;

Or. en

Justification

This requirement is too broad and it could lead to various interpretations. It should be made clear that this requirement is applicable only to software ensuring safety functions.

Amendment 369
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 2 – point g

Text proposed by the Commission

(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.

Amendment

deleted

Or. en
Justification

This requirement is very broad and unclear; in particular the wording “safety related decision-making process” would need to be clearly specified. It raises additional questions on how and where to save such huge amounts of data (logs for example can easily be stored on the machine itself) and how to guarantee the privacy of the operator/owner of the Machinery Product. Additionally, for the purpose of demonstrating conformity, this request is already well covered in the requirements of Annex IV, dealing with the technical file.

Amendment 370
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 2 – point g

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(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.</td>
<td>deleted</td>
</tr>
</tbody>
</table>

Justification

This requirement is very broad and unclear. In particular, the wording “safety related decision-making process” would need to be clearly specified. It raises additional questions on how and where to save such huge amounts of data (logs for example can easily be stored on the machine itself) and how to guarantee the privacy of the operator/owner of the Machinery Product. Additionally, for the purpose of demonstrating conformity, this request is already well covered in the requirements of Annex IV.

Amendment 371
Kateřina Konečná

Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 4 – point c
(c) modifications to the settings or rules, generated by the machinery product or by operators covering also the learning phase, shall be prevented, where such modifications may lead to hazardous situations;

(c) modifications to the settings or rules, generated by the machinery product or by operators covering also the process of machine learning, shall be prevented, where such modifications may lead to hazardous situations;

Justification

alignment to comment above

Amendment 372
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 1 – point 1.2 – point 1.2.1 – paragraph 6

Text proposed by the Commission

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.

deleted

Amendment

Or. en

Amendment 373
Kateřina Konečná

Proposal for a regulation
Annex III – Part 1 – point 1.3 – point 1.3.7 – introductory part

Text proposed by the Commission

1.3.7. Risks related to moving parts and psychological stress

Amendment

1.3.7. Risks related to moving parts and cognitive workload

Or. en
Amendment 374
Kateřina Konečná

Proposal for a regulation
Annex III – Part 1 – point 1.3 – point 1.3.7 – paragraph 4 – introductory part

Text proposed by the Commission
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:

Amendment
The prevention of risks of contact leading
to hazard situations and the cognitive workload that may be caused by the interaction with the machine shall be adapted to:

Or. en

Amendment 375
Arba Kokalari

Proposal for a regulation
Annex III – Part 1 – point 1.3 – point 1.3.7 – paragraph 4 – point b

Text proposed by the Commission
(b) human-machine interaction.

Amendment
deleted

Or. en

Amendment 376
Kateřina Konečná

Proposal for a regulation
Annex III – Part 1 – point 1.3 – point 1.3.7 – paragraph 4 – point b

Text proposed by the Commission
(b) human-machine interaction.

Amendment
(b) human-machine coexistence in a shared space with direct collaboration.

Or. en
Amendment 377
Arba Kokalari

Proposal for a regulation
Annex III – Part 1 – point 1.3 – point 1.3.7 – paragraph 5

Text proposed by the Commission

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.

Amendment

deleted

Or. en

Amendment 378
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 1 – point 1.3 – point 1.3.7 – paragraph 5

Text proposed by the Commission

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.

Amendment

deleted

Or. en

Justification

This portion of text is redundant because of the requirements already given in sub clause
1.1.6. Ergonomics.

Amendment 379
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 1 – point 1.3 – point 1.3.7 – paragraph 5

Text proposed by the Commission

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.

Amendment

deleted

Or. en

Justification

This portion of text is redundant because of the requirements already given in sub clause 1.1.6. Ergonomics.

Amendment 380
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex III – Part 1 – point 1.3 – point 1.3.7 – paragraph 5

Text proposed by the Commission

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

Amendment

deleted
planned actions (what it is going to do and why) to operators in a comprehensible manner.

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**Amendment 381**  
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

**Proposal for a regulation**  
Annex III – Part 1 – point 1.3 – point 1.3.7 – paragraph 5

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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 <strong>planned actions (what it is going to do and why)</strong> to operators in a comprehensible manner.</td>
<td>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 <strong>visual or audio signals</strong>, gestures, facial expressions or body movement).</td>
</tr>
</tbody>
</table>

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**Amendment 382**  
Salvatore De Meo, Andrea Caroppo

**Proposal for a regulation**  
Annex III – Part 1 – point 1.6 – point 1.6.2 – paragraph 2

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be <strong>dimensioned and adapted for the use of</strong> rescue equipment in such a way that a timely rescue of the persons is guaranteed.</td>
<td>In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be <strong>designed taking emergency rescue into consideration</strong>.</td>
</tr>
</tbody>
</table>
Justification

It’s not possible or feasible to design the machine in a way to guarantee a timely rescue; this depends on many external factors, including the emergency services in the local area where the machine is operating. Requirement should be limited to what is in the responsibility of the manufacturer.

Amendment 383
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex III – Part 1 – point 1.6 – point 1.6.2 – paragraph 2

Text proposed by the Commission
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.*

Amendment
In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be *designed taking emergency rescue into consideration.*

Or. en

Amendment 384
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 1 – point 1.6 – point 1.6.2 – paragraph 2

Text proposed by the Commission
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.*

Amendment
In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be *designed taking emergency rescue into consideration.*

Or. en
**Justification**

*It’s not possible or feasible to design the machine in a way to guarantee a timely rescue; this depends on many external factors, including the emergency services in the local area where the machine is operating. Requirement should be limited to what is in the responsibility of the manufacturer.*

**Amendment 385**  
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

**Proposal for a regulation**  
*Annex III – Part 1 – point 1.6 – point 1.6.2 – paragraph 2*

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be <em>dimensioned and adapted for the use of rescue equipment in such a way that a timely rescue of the persons is guaranteed.</em></td>
<td>In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be <em>designed in a way that takes emergency rescue into account.</em></td>
</tr>
</tbody>
</table>

**Amendment 386**  
Kateřina Konečná

**Proposal for a regulation**  
*Annex III – Part 1 – point 1.7 – point 1.7.4 – paragraph 2*

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
<td>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 speaks fluently and fully understands.</td>
</tr>
</tbody>
</table>
Amendment 387
Kateřina Konečná

Proposal for a regulation
Annex III – Part 1 – point 1.7 – point 1.7.4 – paragraph 3

Text proposed by the Commission

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.

Amendment

For up to five years after the time of the purchase of the machinery product, the instructions shall be provided in paper format free of charge upon request from the purchaser. If a purchaser gives her or his explicit consent to only receive a digital format of the instructions, at least a quick start must be delivered in a printed version free of charge.

Or. en

Justification

Digital formats of instructions should only be delivered if the purchaser agrees to. In any case, a quick start guide must always be provided in a printed version.

Amendment 388
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex III – Part 1 – point 1.7 – point 1.7.4 – paragraph 4 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 389
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 1 – point 1.7 – point 1.7.4 – paragraph 4 – point c
(c) be presented in a format that makes it 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

Amendment 390
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Annex III – Part 1 – point 1.7 – point 1.7.4 – paragraph 4 – point c

(c) be presented in a format that makes it possible for the end user to download the instructions throughout the expected lifetime of the machinery product 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

Amendment 391
Carlo Fidanza, Evžen Tošenovský
Proposal for a regulation
Annex III – Part 1 – point 1.7 – point 1.7.4 – paragraph 4 – point c

Text proposed by the Commission

(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

Amendment

(c) provide in a format over the whole lifecycle of the machinery product and in all the different versions 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.

Or. en

Justification

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. However, 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.

Amendment 392
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 1 – point 1.7 – point 1.7.4 – point 1.7.4.2 – point 1 – point c

Text proposed by the Commission

(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.

Amendment

(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 over the whole lifecycle of the machinery product;
Justification

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.

Amendment 393
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 1 – point 1.7 – point 1.7.4 – point 1.7.4.2 – point 1 – point w

Text proposed by the Commission

(w) where the machinery product

deleted
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.

Justification

This information requirement should only be applicable to machinery intended to generate hazardous substances from the materials likely to be processed. The amount of material processed is highly dependent on the type of material, size of cutting device used, the speed of the cutting device, the speed of the feed rate of the material or machine and the state of wear of the cutting device. The external capturing, filtration or discharge devices has no influence over these factors, it can provide only a flow of air through a collection duct.

Amendment 394
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 2 – point 2.2 – point 2.2.1 – paragraph 1 – point e

Text proposed by the Commission

(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.

Amendment

(e) Where the use of external devices is not feasible, information on the use of appropriate personal protective equipment (PPE) should be provided in the instructions.

Justification

This Amendment shall be considered together with Amendment 16. The Regulation should clarify what the hazardous materials and substances are that are referred to in 2.2.1 and 1.7.4.2 and what flow rate is required to be declared in section 1.7.4.2. Adding the required additional substance capturing device will create new/additional risks, and will limit the intended use of machinery.
### Amendment 395
Salvatore De Meo, Andrea Caroppo

**Proposal for a regulation**
Annex III – Part 2 – point 2.2 – point 2.2.1 – point 2.2.1.1 – paragraph 1 – introductory part

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>The instructions <strong>shall</strong> give the following information concerning vibrations, <em>expressed as acceleration (m/s²)</em>, and transmitted by portable handheld and hand-guided machinery:</td>
<td>The instructions <strong>must</strong> give the following information concerning vibrations transmitted by portable handheld and hand-guided machinery:</td>
</tr>
</tbody>
</table>

---

### Amendment 396
Salvatore De Meo, Andrea Caroppo

**Proposal for a regulation**
Annex III – Part 2 – point 2.2 – point 2.2.1 – point 2.2.1.1 – paragraph 1 – point a

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) the vibration total value <strong>from continuous vibrations</strong> to which the hand-arm system is subjected;</td>
<td>(a) the vibration total value to which the hand-arm system is subjected, <em>if it exceeds 2,5 m/s²</em>. Where this value does not exceed 2,5 m/s², this must be mentioned;</td>
</tr>
</tbody>
</table>

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### Amendment 397
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

**Proposal for a regulation**
Annex III – Part 2 – point 2.2 – point 2.2.1 – point 2.2.1.1 – paragraph 1 – point b

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b) <strong>the mean value of the peak amplitude of the acceleration from repeated shock vibrations</strong>, to which the hand-arm system is subjected; deleted</td>
<td></td>
</tr>
</tbody>
</table>

---
Amendment 398
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 2 – point 2.2 – point 2.2.1 – point 2.2.1.1 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment
deleted

Or. en

Amendment 399
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 2 – point 2.2 – point 2.2.1 – point 2.2.1.1 – paragraph 1 – point c

Text proposed by the Commission

(c) the uncertainty of both measurements.

Amendment
(c) the uncertainty of measurement.

Justification

These declared values would be of no use for workplace risk assessments of hand/arm vibrations.

Amendment 400
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex III – Part 3 – point 3.1 – point 3.1.1 – point b
(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.

Amendment 401
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex III – Part 3 – point 3.1 – point 3.1.1 – point b a (new)

Text proposed by the Commission

Amendment

(ba) 'Driver' means an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.

Amendment 402
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.2 – paragraph 1

Text proposed by the Commission

Amendment

Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the surroundings should the machinery

Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the surroundings should the machinery
roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, 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, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems or provision shall not be fitted if they increase the risk.

Amendment 403
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.2 – paragraph 1

Text proposed by the Commission
Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the surroundings should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, 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, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems or provision shall not be fitted if they increase the risk.

Amendment
Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the surroundings should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, 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, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems shall be designed according to ergonomic principles. Such restraint systems or provision shall not be fitted if
they increase the risk.

Amendment 404
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.2 – paragraph 1

Text proposed by the Commission
Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the surroundings should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, 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, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems or provision shall not be fitted if they increase the risk.

Amendment
Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the surroundings should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, 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, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems or provision shall have an ergonomic design and shall not be fitted if they increase the risk.

Or. en

Amendment 405
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.2 – paragraph 2

Text proposed by the Commission
A visual or audible signal shall be provided at the driving position alerting the driver

Amendment
Where there is a considerable risk of rolling or tipping over, the machine shall not be able to move when the restraint
when the restraint system is not active.

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

Or. en

Amendment 406
David Cormand
on behalf of the Greens/EFA Group

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.2 – paragraph 2

Text proposed by the Commission

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

Amendment

The machine shall not be able to move when the restraint system is not active in case there is a significant risk of tipping or rolling over. A visual and audible signal shall be provided at the driving position alerting the driver when the restraint system is not active.

Or. en

Amendment 407
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoş, Karen Melchior

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.2 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 408
Marco Campomenosi, Alessandra Basso
Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.2 – paragraph 2

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

Amendment
A visual or audible signal shall be provided at the driving position to warn the driver when he is in the driving position and not using the restraint system.

Or. en

Amendment 409
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.2 – paragraph 2

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

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

Or. en

Justification
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. Indeed, a visual signal alone is not sufficient for the driver to be alerted.

Amendment 410
David Cormand

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.2 – paragraph 2

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

Amendment
The machine shall not be able to move when the restraint system is not active in case there is a significant risk of tipping
A visual and audible signal shall be provided at the driving position alerting the driver when the restraint system is not active.

Amendment 411
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.4 – paragraph 1

Text proposed by the Commission

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.

Amendment
When a supervisory control function is needed as a protective measure on autonomous mobile machinery products, that function shall be specific to its autonomous operation. Where the supervisory control function allows a remote action from the operator, the function shall be designed in such a way that that action does not increase any risk.

Amendment 412
Kateřina Konečná

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.4 – paragraph 1

Text proposed by the Commission

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

Amendment

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.

shall only allow actions to stop and to start remotely the machine and must include a function which would allow the operator to bring the machinery into a secure state. 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.

Or. en

Justification

Important security function for remote actions

Amendment 413
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.4 – paragraph 2

Text proposed by the Commission

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.

Amendment

deleted

Or. en

Amendment 414
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.4 – paragraph 3

Text proposed by the Commission

This information shall alert the driver of the occurrence of unforeseen or dangerous situations present or

Amendment

deleted

Or. en
impending, which require driver’s intervention.

Amendment 415
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 3 – point 3.2 – point 3.2.4 – paragraph 4

Text proposed by the Commission Amendment

If the supervisory control function is not active, the machinery shall not be able to operate.

Amendment 416
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 3 – point 3.3 – point 3.3.3 – paragraph 6 – introductory part

Text proposed by the Commission Amendment

Autonomous mobile machinery products shall comply with any of the following conditions:

Autonomous mobile machinery products shall comply with one or both of the following conditions:

Amendment 417
Christel Schaldemose

Proposal for a regulation
Annex III – Part 3 – point 3.3 – point 3.3.3 – paragraph 6 – point a

Text proposed by the Commission Amendment

(a) it shall move and operate in an enclosed zone fitted with a peripheral

(a) it shall move and operate in an enclosed zone fitted with a peripheral
protection system comprising guards or protective devices; protection system comprising guards or protective devices or where access is restricted by administrative means.

Amendment 418
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 3 – point 3.5 – point 3.5.4 – paragraph 1

Text proposed by the Commission

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.

Amendment

Mobile machinery product shall, where relevant during normal operation, be designed, constructed and equipped, so as to minimize 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.

Justification

The text should be more generic and clearer in its scope; details are to be discussed and drafted within standardisation. It must be clarified that it makes reference to machinery during normal operation with the aim of minimising risks. So, two distinctive essential requirements are to be identified: • If there is a risk of contact during normal operation, it must be minimised by design; • If the risk of contact remains high during a significant time of normal operation, it must be assessed how to minimise the risk of harm when contact with energized power lines occurs.

Amendment 419
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 3 – point 3.5 – point 3.5.4 – paragraph 1

Text proposed by the Commission

Depending on the height of the machinery

Amendment

Mobile machinery product shall, where relevant during normal operation, be designed, constructed and equipped, so as to minimize 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.

Justification

The text should be more generic and clearer in its scope; details are to be discussed and drafted within standardisation. It must be clarified that it makes reference to machinery during normal operation with the aim of minimising risks. So, two distinctive essential requirements are to be identified: • If there is a risk of contact during normal operation, it must be minimised by design; • If the risk of contact remains high during a significant time of normal operation, it must be assessed how to minimise the risk of harm when contact with energized power lines occurs.
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. Relevant during normal operation, be designed, constructed and equipped, so as to minimize 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.

**Justification**

The text should be more generic and clearer in its scope; details are to be discussed and drafted within standardisation. It must be clarified that it makes reference to machinery during normal operation with the aim of minimising risks.

**Amendment 420**
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex III – Part 3 – point 3.5 – point 3.5.4 – paragraph 2

Text proposed by the Commission

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.

Amendment

Deleted

**Amendment 421**
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 3 – point 3.5 – point 3.5.4 – paragraph 2
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.

When the risk of contact or electric arc with an energised overhead power line is relevant during normal operations in terms of exposure to the risks, mobile machinery products shall be designed, constructed and equipped in such a way that the risk of harm is minimized in the event of contact or electrical arc with an energized power line.

Justification

Two distinctive essential requirements are to be identified. First, if there is a risk of contact during normal operation, it must be minimised by design. Second, if the risk of contact remains high during a significant time of normal operation, it must be assessed how to minimise the risk of harm when contact with energized power lines occurs.

Amendment 422
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex III – Part 3 – point 3.5 – point 3.5.4 – paragraph 2

Justification

The text should be more generic and clearer in its scope; details are to be discussed and drafted within standardisation. It must be clarified that it makes reference to machinery during normal operation with the aim of minimising risks. So, two distinctive essential
requirements are to be identified: • If there is a risk of contact during normal operation, it must be minimised by design; • If the risk of contact remains high during a significant time of normal operation, it must be assessed how to minimise the risk of harm when contact with energized power lines occurs.

Amendment 423
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 3 – point 3.6 – point 3.6.3 – point 3.6.3.1 – paragraph 1 – introductory part

Text proposed by the Commission
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:

Amendment
The instructions must give the following information concerning vibrations transmitted by the machinery to the hand-arm system or to the whole body:

Or. en

Amendment 424
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 3 – point 3.6 – point 3.6.3 – point 3.6.3.1 – paragraph 1 – point a

Text proposed by the Commission
(a) the vibration total value from continuous vibrations to which the hand-arm system is subjected;

Amendment
(a) the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s². Where this value does not exceed 2,5 m/s², this must be mentioned;

Or. en

Justification
The requirements on vibrations in this section would create confusion with the Directive on workers protection from physical agents (vibrations), Directive 2002/44/EC, since the changes proposed would result in these two directives not being aligned anymore. The physical agents (vibration) Directive 2002/44/EC has no requirements for exposure values below 2.5 m/s², as for vibration values measured below 2.5 m/s² the uncertainty in many
cases will be higher than the declared/measured value, which does not make any sense for the user.

Amendment 425
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex III – Part 3 – point 3.6 – point 3.6.3 – point 3.6.3.1 – paragraph 1 – point b

Text proposed by the Commission Amendment

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

Or. en

Amendment 426
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 3 – point 3.6 – point 3.6.3 – point 3.6.3.1 – paragraph 1 – point b

Text proposed by the Commission Amendment

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

Or. en

Amendment 427
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 4 – point 4.1 – point 4.1.3 – paragraph 1

Text proposed by the Commission Amendment

When lifting machinery or lifting accessories are placed on the market or are

When lifting machinery or lifting accessories are placed on the market or are
first put into service, the manufacturer or his or her authorised representative shall ensure, by taking appropriate measures or having them taken, that the machinery or the lifting accessories which are ready for use — whether manually or power-operated — can fulfil their specified functions safely.

Amendment 428
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex III – Part 4 – point 4.3 – point 4.3.1 – paragraph 1

Text proposed by the Commission
Each length of lifting chain, rope or webbing not forming part of an assembly shall bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his or her authorised representative and the identifying reference of the relevant certificate.

Amendment
Each length of lifting chain, rope or webbing not forming part of an assembly shall bear a mark or, where this is not possible, a plate or irremovable ring bearing the name and address of the manufacturer or his or her authorised representative and the identifying reference of the relevant declaration of conformity.

Amendment 429
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Annex III – Part 6 – point 6.2 – paragraph 3

Text proposed by the Commission
The control devices for the movements referred to in the first paragraph shall be of the hold-to-run type except where the carrier is completely enclosed. If there is no risk of persons or objects on the carrier colliding or falling and no other risks due

Amendment
The control devices for the movements referred to in the first paragraph shall be of the hold-to-run type except where the carrier is completely enclosed. 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

to the upward and downward movements of the carrier, including in case of power failure and rescue, control devices authorising automatic stops at preselected positions may be used instead of hold-to-run type control devices

Amendment 430
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex IV – Part A – paragraph 2 – point a

Text proposed by the Commission

(a) a complete description of the machinery product and of its intended use;

Amendment

(a) a complete description of the machinery product;

Amendment 431
Marco Campomenosi, Alessandra Basso

Proposal for a regulation
Annex IV – Part A – paragraph 2 – point n

Text proposed by the Commission

(n) the source code or programmed logic of the safety related software to demonstrate the conformity of the machinery product with this Regulation further to a reasoned request from a competent national authority provided that 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;

deleted

Amendment

Or. en
Amendment 432
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex V – point 3

Text proposed by the Commission

3. The address where the *machine* product is permanently installed only for *lifting* machinery *product* installed in a building or a structure:

Amendment

3. The address where the *machinery* product is permanently installed only for machinery *products for lifting persons from one level of a building to another level* installed in a building or a structure:

Or. en

Amendment 433
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex V – point 6

Text proposed by the Commission

6. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:

Amendment

6. The object of the declaration described in point 5 is in conformity with the relevant Union harmonisation legislation:

Or. en

Amendment 434
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex VII – point 2

Text proposed by the Commission

2. EU type-examination shall be carried out by assessment of the adequacy of the technical design of the machinery product through examination of the technical documentation, plus examination of a specimen of the machinery product

Amendment

2. EU type-examination shall be carried out by assessment of the adequacy of the technical design of the machinery product through examination of the technical documentation, plus examination of a *physical or digital* specimen of the
that is representative of the production envisaged (production type).

Amendment 435
Adriana Maldonado López, Clara Aguilera, Maria Grapini, Maria-Manuel Leitão-Marques, Christel Schaldemose, Alex Agius Saliba

Proposal for a regulation
Annex VII – point 5 – paragraph 1

Text proposed by the Commission
The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, as mentioned in Article 32, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

Amendment
The notified body shall draw up an evaluation report that records the tasks undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, as mentioned in Article 32, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

Or. en

Amendment 436
Salvatore De Meo, Andrea Caroppo

Proposal for a regulation
Annex X – paragraph 1

Text proposed by the Commission
The assembly instructions for partly completed machinery shall contain a description of the conditions, which are to be met to ensure that the partly completed machinery is correctly incorporated in the final machinery product, and that the final machinery product does not compromise health and safety of persons and, where appropriate, domestic animals and property.

Amendment
The assembly instructions for partly completed machinery shall contain a description of the conditions, which are to be met to ensure that the partly completed machinery is correctly incorporated in the final machinery product, and a statement that the final machinery product shall not compromise health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the
and, where applicable, the environment.

Or. en

Justification

The manufacturer of the PCM (partly completed machinery) cannot describe the conditions to be met to ensure that the final machinery does not compromise health and safety. This is under the responsibility of the PCM integrator by applying machinery legislation to the whole machinery.

Amendment 437
Carlo Fidanza, Evžen Tošenovský

Proposal for a regulation
Annex X – paragraph 1

Text proposed by the Commission

The assembly instructions for partly completed machinery shall contain a description of the conditions, which are to be met to ensure that the partly completed machinery is correctly incorporated in the final machinery product, and that the final machinery product does not compromise health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.

Amendment

The assembly instructions for partly completed machinery shall contain a description of the conditions, which are to be met to ensure that the partly completed machinery is correctly incorporated in the final machinery product, and a statement that the final machinery product shall not compromise health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.

Or. en

Justification

The manufacturer of the PCM (partly completed machinery) cannot describe the conditions to be met to ensure that the final machinery does not compromise health and safety. This is under the responsibility of the PCM integrator by applying machinery legislation to the whole machinery.

Amendment 438
Svenja Hahn, Dita Charanzová, Vlad-Marius Botoș, Karen Melchior

Proposal for a regulation
Annex X – paragraph 2 a (new)
Text proposed by the Commission

Amendment

The assembly instructions are provided by the manufacturer in digital form.

Or. en