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*Plenary sitting*

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**A9-0141/2022**

5.5.2022

**\*\*\*I**  
**REPORT**

on the proposal for a regulation of the European Parliament and of the Council  
on Machinery products  
(COM(2021)0202 – C9-0145/2021 – 2021/0105(COD))

Committee on the Internal Market and Consumer Protection

Rapporteur: Ivan Štefanec

### ***Symbols for procedures***

- \* Consultation procedure
- \*\*\* Consent procedure
- \*\*\*I Ordinary legislative procedure (first reading)
- \*\*\*II Ordinary legislative procedure (second reading)
- \*\*\*III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

### ***Amendments to a draft act***

#### **Amendments by Parliament set out in two columns**

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

#### **Amendments by Parliament in the form of a consolidated text**

New text is highlighted in ***bold italics***. Deletions are indicated using either the **■** symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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## DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the proposal for a regulation of the European Parliament and of the Council on machinery products  
(COM(2021)0202 – C9-0145/2021 – 2021/0105(COD))**

**(Ordinary legislative procedure: first reading)**

*The European Parliament,*

- having regard to the Commission proposal to Parliament and the Council (COM(2021)0202),
  - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0145/2021),
  - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
  - having regard to the opinion of the European Economic and Social Committee of 22 September 2021<sup>1</sup>,
  - having regard to Rule 59 of its Rules of Procedure,
  - having regard to the opinion of the Committee on Employment and Social Affairs,
  - having regard to the report of the Committee on the Internal Market and Consumer Protection (A9-0141/2022),
1. Adopts its position at first reading hereinafter set out;
  2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
  3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

### **Amendment 1**

**Proposal for a regulation  
Recital 7 a (new)**

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<sup>1</sup> OJ C 517, 22.12.2021, p. 67

*Text proposed by the Commission*

*Amendment*

***(7a) Article 4 of Regulation (EU) No 2019/1020 lays down the tasks of economic operators regarding products subject to certain Union harmonisation legislation. It also provides that such products are to be placed on the market only if there is an economic operator established in the Union who is responsible for those tasks. That Union harmonisation legislation includes Directive 2006/42/EC. As a result, machinery products covered by this Regulation are to be placed on the market only if there is an economic operator established in the Union who is responsible for the tasks set out in Article 4 of Regulation (EU) No 2019/1020 in their respect.***

## **Amendment 2**

### **Proposal for a regulation Recital 10**

*Text proposed by the Commission*

*Amendment*

(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.

(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 should consider the safety implications, accordingly.*** The same applies where a machinery product is normally used to provide a service to a consumer.

## **Amendment 3**

**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<sup>19</sup> and Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>20</sup> respectively, they should be excluded from the scope of this Regulation.

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<sup>19</sup> Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).

<sup>20</sup> Regulation (EU) No 168/2013 of the

*Amendment*

(15) Since the purpose of this Regulation is to address the risks stemming from machinery function and not the transport of goods, persons **or animals**, it should not apply to vehicles **the** only objective **of which** is the mere transport of **animals by road, air, on water or on rail networks, or transport of goods or persons by air, water or rail**, 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. **Furthermore, non-type-approved, off-road vehicles, as well as e-bikes, cargo e-bikes, e-scooters and similar means of transport should also be covered by this Regulation as regards their machinery function, with the exception of road circulation risks, until such time as those means of transport become the subject of specific Union legislation.** 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<sup>19</sup> and Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>20</sup> respectively, they should be excluded from the scope of this Regulation.

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<sup>19</sup> Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1).

<sup>20</sup> 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).

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 4**

#### **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<sup>21</sup> 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<sup>22</sup> as radio equipment. Those products should also be excluded from the scope of this Regulation.

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<sup>21</sup> Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 35).

<sup>22</sup> Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L

##### *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 Council<sup>21</sup> 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<sup>22</sup> as radio equipment. Those products should also be excluded from the scope of this Regulation.

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<sup>21</sup> Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 35).

<sup>22</sup> Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L



## Amendment 5

### 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 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***

##### *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 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.

*whole.*

## Amendment 6

### 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. ***With a view to*** properly reflecting all machinery products ***and the hazards thereof***, criteria should be established for the assessment by the Commission of which machinery products should be ***added to*** the list of machinery products ***that should be subject to a specific conformity assessment procedure.***

## Amendment 7

### Proposal for a regulation

#### Recital 23

*Text proposed by the Commission*

(23) In order to ensure that machinery products, when placed on the market or put into service, do not entail health and safety risks for persons or domestic animals and do not cause harm to property and, where applicable, the environment, essential health and safety requirements should be set out which have to be met in order for the machinery products to be allowed on the market. Machinery products should comply with the essential health and safety requirements when placed on the market or put into service. Where such machinery products are subsequently modified, by physical or digital means, in a way that is not foreseen by the manufacturer and that may imply that it no longer meets the relevant essential health and safety

*Amendment*

(23) In order to ensure that machinery products, when placed on the market or put into service, do not entail health and safety risks for persons or domestic animals and do not cause harm to property and, where applicable, the environment, essential health and safety requirements should be set out which have to be met in order for the machinery products to be allowed on the market. Machinery products should comply with the essential health and safety requirements when placed on the market or put into service. Where such machinery products are subsequently modified, by physical or digital means, in a way that is not foreseen by the manufacturer and that may imply that it no longer meets the relevant essential health and safety

requirements, the modification should be considered as substantial. For example, users may upload software in a machinery product that is not foreseen by the manufacturer and that may generate new risks. In order to ensure the compliance of such a machinery product with the relevant essential health and safety requirements, the person that carries out the substantial modification should be required to perform a new conformity assessment before placing the modified machinery product on the market or putting it into service. That requirement should only apply with respect to the modified part of the machinery product, provided that the modification does not affect the machinery product as a whole. In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to aspects of the machinery product that are not impacted by the modification. It should be up to the person who carries out the substantial modification to demonstrate that the modification does not have an impact on the machinery product as a whole.

requirements, the modification should be considered as substantial. ***However, repair and maintenance operations which do not affect the machinery product's compliance with the relevant essential health and safety requirements should not be considered to be substantial modifications.*** For example, users may upload software in a machinery product that is not foreseen by the manufacturer and that may generate new risks. ***A change to the hardware or software in a machinery product might change its intended functions, type or performance, which might change the nature of the hazard or increase the level of risk.*** In order to ensure the compliance of such a machinery product with the relevant essential health and safety requirements, the person that carries out the substantial modification should be required to perform a new conformity assessment before placing the modified machinery product on the market or putting it into service. That requirement should only apply with respect to the modified part of the machinery product, provided that the modification does not affect the machinery product as a whole. In order to avoid an unnecessary and disproportionate burden, the person carrying out the substantial modification should not be required to repeat tests and produce new documentation in relation to aspects of the machinery product that are not impacted by the modification. It should be up to the person who carries out the substantial modification to demonstrate that the modification does not have an impact on the machinery product as a whole.

## **Amendment 8**

### **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 **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**.

*Amendment*

(24) In the machinery sector, around 98 % of the companies are small or medium sized enterprises (SMEs). In order to **avoid unnecessary burdens** on SMEs, notified bodies should **simplify and facilitate procedures**.

## **Amendment 9**

### **Proposal for a regulation Recital 25**

*Text proposed by the Commission*

(25) Economic operators should be responsible for the compliance of machinery products with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment, as well as the fair competition on the Union market.

*Amendment*

(25) Economic operators should be responsible for the compliance of machinery products with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as the health and safety of persons, **in particular consumers and professional operators**, where appropriate, domestic animals and property and, where applicable, the environment, as well as the fair competition on the Union market.

## **Amendment 10**

### **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

*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

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<sup>23</sup>.*

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<sup>23</sup> + *OJ: Please insert in the text the number of the Regulation contained in document ...*

## Amendment 11

### 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

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. *The risk assessment should also address future updates or developments of software installed in the machinery product which were foreseen when the machinery product was placed on the market or put into service.* 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.

#### *Amendment*

(31) It is essential that, before drawing up the EU declaration of conformity, the manufacturer prepares a technical *documentation* 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 *documentation* file where knowledge of such plans is essential for assessing conformity with the essential health and safety requirements set out in

assessing conformity with the essential health and safety requirements set out in this Regulation.

this Regulation.

## **Amendment 12**

### **Proposal for a regulation**

#### **Recital 32**

##### *Text proposed by the Commission*

(32) It is necessary to ensure that machinery products from third countries entering the Union market comply with the requirements of this Regulation and do not pose a risk to the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment, and in particular, that appropriate conformity assessment procedures have been carried out by manufacturers with regard to such machinery products. Provision should therefore be made for importers to ensure that machinery products that they place on the market comply with the requirements of this Regulation and do not pose a risk to the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment. For the same reason, provision should also be made for importers to ensure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the competent national authorities.

##### *Amendment*

(32) It is necessary to ensure that machinery products from third countries entering the Union market comply with the requirements of this Regulation and do not pose a risk to the health and safety of persons, ***in particular consumers and professional operators***, where appropriate, domestic animals and property and, where applicable, the environment, and in particular, that appropriate conformity assessment procedures have been carried out by manufacturers with regard to such machinery products. Provision should therefore be made for importers to ensure that machinery products that they place on the market comply with the requirements of this Regulation and do not pose a risk to the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment. For the same reason, provision should also be made for importers to ensure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the competent national authorities.

## **Amendment 13**

### **Proposal for a regulation**

#### **Recital 34**

*Text proposed by the Commission*

(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.

**Amendment 14**

**Proposal for a regulation**  
**Recital 35**

*Text proposed by the Commission*

(35) In view of ensuring the health and safety of the users of the machinery product, economic operators should ensure that all relevant documentation, such as the user's instructions, whilst containing precise and comprehensible information, is easily understandable, takes into account technological developments and changes to end-user behaviour, and is as up to date as possible. When machinery products are made available on the market in packages containing multiple units, the instructions and information should accompany the smallest commercially available unit.

**Amendment 15**

*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, ***the e-mail address*** 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.

*Amendment*

(35) In view of ensuring the health and safety of the users of the machinery product, economic operators should ensure that all relevant documentation, such as the user's instructions, whilst containing precise and comprehensible information, is easily understandable ***and available in a language which can be easily understood by end-users, as determined by the Member State concerned***, takes into account technological developments and changes to end-user behaviour, and is as up to date as possible. When machinery products are made available on the market in packages containing multiple units, the instructions and information should accompany the smallest commercially available unit.

**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 ***on an exceptional basis*** to establish technical specifications for the essential health and safety requirements ***provided that in doing so it duly respects the standardisation organisations' role and functions***. 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 16**

**Proposal for a regulation**  
**Recital 45**

*Text proposed by the Commission*

(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

*Amendment*

(45) The list of machinery in Annex ***IV*** 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 ***potentially*** 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 17**

### **Proposal for a regulation Recital 45 a (new)**

*Text proposed by the Commission*

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.

*Amendment*

***(45a) Nevertheless, provisions related to the conformity assessment of software ensuring safety functions set out in this Regulation should only apply to AI systems with a self-determining and evolving behaviour during normal operation that are developed through any machine learning techniques and approaches. On the contrary, those provisions should not apply to conventional software incapable of learning or evolving, and programmed only to execute certain automated functions of machinery products.***

## **Amendment 18**

### **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***

## Amendment 19

### Proposal for a regulation Recital 50

#### *Text proposed by the Commission*

(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***.

#### *Amendment*

(50) Manufacturers should be responsible for ***ensuring that a*** conformity ***assessment is carried out in respect*** of their machinery products ***in accordance*** with this Regulation. Nevertheless, for certain types of machinery products that have a higher risk factor, a stricter ***conformity assessment*** procedure requiring ***the*** participation of a notified body ***could be applied***.

## Amendment 20

### Proposal for a regulation Recital 60

#### *Text proposed by the Commission*

(60) Member States should take all appropriate measures to ensure that machinery products covered by this Regulation may be placed on the market only if, when properly installed and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment. Machinery products covered by this Regulation should be considered as non-compliant with the essential health and safety requirements

#### *Amendment*

(60) Member States should take all appropriate measures to ensure that machinery products covered by this Regulation may be placed on the market only if, when properly installed and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons, ***in particular consumers and professional operators***, and, where appropriate, domestic animals and property and, where applicable, the environment. Machinery products covered by this Regulation should be considered as non-

laid down in this Regulation only under conditions of use, which could result from lawful and readily predictable human behaviour.

compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use, which could result from lawful and readily predictable human behaviour.

## Amendment 21

### Proposal for a regulation

#### Recital 65

##### *Text proposed by the Commission*

(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.

##### *Amendment*

(65) In order to take into account technical progress and knowledge or new scientific evidence **and to ensure a sufficient level of data availability**, 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 machinery products **in Annex I** and the indicative list of safety components **in Annex II, and of supplementing the obligations of Member States to communicate information on the categories of machinery products which are subject to a specific conformity assessment procedure. Where a new machinery product is added to the list in Annex I, the Commission should ensure that economic operators are provided with sufficient time to comply with their obligations under this Regulation**. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including **with experts and stakeholders**. 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.

## Amendment 22

## Proposal for a regulation

### Recital 66

#### *Text proposed by the Commission*

(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission establishing technical specifications for the **essential** health and safety requirements, requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet the requirements for its notification and establishing whether a national measure in respect of compliant machinery which a Member State finds to pose a risk to health and safety of persons is justified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>26</sup>.

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<sup>26</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

## Amendment 23

### Proposal for a regulation

#### Article 1 – subparagraph 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

#### *Amendment*

(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission establishing technical specifications for the health and safety requirements, requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet the requirements for its notification and establishing whether a national measure in respect of compliant machinery which a Member State finds to pose a risk to health and safety of persons, **in particular consumers and professional operators**, is justified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>26</sup>.

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<sup>26</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

#### *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.

machinery products in the Union, *ensuring a high level of protection for Union consumers and professional operators.*

#### **Amendment 24**

##### **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, persons *or animals* by air, water or rail except for machinery mounted on those vehicles;

#### **Amendment 25**

##### **Proposal for a regulation**

##### **Article 2 – paragraph 2 – point e a (new)**

*Text proposed by the Commission*

*Amendment*

*(ea) motor vehicles and their trailers, as well as systems, components and separate technical units, parts and equipment designed and constructed for such vehicles, which fall within the scope of application of Regulation (EU) 2018/858, except for machinery mounted on those vehicles;*

#### **Amendment 26**

##### **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

*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 fall within the scope of application of Regulation (EU) No

168/2013;

168/2013, *except for machinery mounted on those vehicles*;

### **Amendment 27**

#### **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 **tractors**, that fall within the scope of application of Regulation (EU) No 167/2013, *except for machinery mounted on them*;

### **Amendment 28**

#### **Proposal for a regulation**

#### **Article 2 – paragraph 2 – point g a (new)**

*Text proposed by the Commission*

*Amendment*

**(ga) motor vehicles exclusively intended for competition**;

### **Amendment 29**

#### **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;

### **Amendment 30**

**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 (a), (b), (c), (d) and (e) missing only the upload of a software intended for *its* specific application.

*Amendment*

(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.***

**Amendment 31**

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

*Text proposed by the Commission*

*Amendment*

***(1a) ‘machinery product’ means ‘machinery’, ‘interchangeable equipment’, a ‘safety component’, a ‘lifting accessory’, ‘chains’, ‘ropes’, ‘slings’, ‘webbing’, a ‘removable mechanical transmission device’ and ‘partly completed machinery’;***

**Amendment 32**

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

*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 machinery, is assembled with that machinery 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;

**Amendment 33**

**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 34**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 3 a (new)**

*Text proposed by the Commission*

**Amendment 35**

**Proposal for a regulation**

**Article 3 – paragraph 1 – point 10**

*Text proposed by the Commission*

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

**Amendment 36**

*Amendment*

(3) ‘safety component’ means a physical or digital component, including software, of *a machinery product with the exception of 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;

*Amendment*

*(3a) ‘safety function’ means a protective measure, designed to eliminate, or, if that is not possible, to reduce, a risk;*

*Amendment*

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



**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, ***with the exception of partly completed machinery***;

**Amendment 37**

**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<sup>28</sup>

*Amendment*

***deleted***

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<sup>28</sup> + ***OJ: Please insert in the text the number of the Regulation contained in document ... and insert the number, date, title and OJ reference of that Regulation in the footnote.***

**Amendment 38**

**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

*Amendment*

(16) ‘substantial modification’ means a modification of a machinery product, ***with the exception of 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 not addressed in the initial risk assessment***, and as a result of which the compliance of the machinery

*may be* affected;

product with the relevant essential health and safety requirements *is* affected;

## Amendment 39

### 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 **(i)** markets those machinery products under his or her name or trademark or **(ii) uses** machinery products for his or her own ***purposes in the course of his or her business***;

## Amendment 40

### 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, ***with the exception of partly completed machinery,*** is placed on the market or put into service to inform the user of the machinery product of the intended ***and*** 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 on how to keep that machinery product safe and ensure that it remains “fit for purpose” during its entire lifetime;***

## Amendment 41

**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, ***with the exception of partly completed machinery***, is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

**Amendment 42**

**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, ***with the exception of partly completed machinery***, have been fulfilled;

**Amendment 43**

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

*Text proposed by the Commission*

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

*Amendment*

(30) ‘notified body’ means a conformity assessment body notified in accordance with Article 24 of this Regulation;

**Amendment 44**

**Proposal for a regulation**  
**Article 3 – paragraph 1 – point 33 a (new)**

*Text proposed by the Commission*

*Amendment*

***(33a) ‘lifetime’ means the period from the moment that a machinery product is placed on the market or put into service until the moment that it is discarded, including the effective time when the machinery product is capable of being used and the phases of transport, assembly, dismantling, disabling, scrapping or other physical or digital modifications foreseen by the manufacturer;***

#### **Amendment 45**

**Proposal for a regulation  
Article 3 – paragraph 1 – point 33 b (new)**

*Text proposed by the Commission*

*Amendment*

***(33b) ‘professional operator’ means a natural person who uses or operates a machinery product in the course of his or her professional activity or work.***

#### **Amendment 46**

**Proposal for a regulation  
Article 5 – title**

*Text proposed by the Commission*

*Amendment*

***High-risk*** machinery products

***Categories of*** machinery products ***subject to specific conformity assessment procedure***

#### **Amendment 47**

**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 **that fall within the categories** listed in Annex I shall be subject to **the** specific conformity assessment procedures, referred to in Article 21(2) **and (2a)**.

**Amendment 48**

**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.

*Amendment*

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 **adding to** the list of **categories 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.

**Amendment 49**

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

*Text proposed by the Commission*

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

*Amendment*

3. A machinery product shall be **added to** the list of **categories of** machinery products in Annex I if it poses a risk to human health taking into account its design, intended purpose **and any foreseeable use**. A machinery product shall be withdrawn from the list of **categories 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 severity of that harm.

the probability of occurrence of harm and the severity of that harm.

## **Amendment 50**

### **Proposal for a regulation**

#### **Article 5 – paragraph 4 – introductory part**

##### *Text proposed by the Commission*

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

##### *Amendment*

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

## **Amendment 51**

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

## **Amendment 52**

### **Proposal for a regulation**

#### **Article 5 – paragraph 4 – subparagraph 1 (new)**

*Text proposed by the Commission*

*Amendment*

***By ... [the date of application of this Regulation referred to in Article 52], and every three years thereafter, Member States shall provide the information referred to in the first subparagraph.***

## **Amendment 53**

### **Proposal for a regulation Article 5 – paragraph 4 a (new)**

*Text proposed by the Commission*

*Amendment*

***4a. The Commission is empowered to adopt delegated acts in accordance with Article 45 to supplement paragraph 4 of this Article by specifying Member States' obligations to communicate information through the establishment of a common methodology on the assessment, analysis and statistics referred to in points (a) to (d), in order to ensure that a sufficient level of data availability for the Commission's assessment referred to in paragraph 4 is carried out.***

## **Amendment 54**

### **Proposal for a regulation Article 5 – paragraph 4 b (new)**

*Text proposed by the Commission*

*Amendment*

***4b. A machinery product that is established as posing a risk to human health according to paragraph 3 shall be included in the list of categories of machinery products in Annex I, Part A, if at least one of the following conditions is fulfilled:***

***(a) no harmonised standards or technical specifications covering all the relevant essential health and safety requirements***

*exist for the category of the machinery product in question;*

*(b) residual risks due to shortcomings of protective measures exist and information communicated to the Commission in accordance with paragraph 4 demonstrates a recurrence of serious or fatal accidents or damage to health in relation with these residual risks;*

*(c) statistics on accidents referred to in paragraph 4 demonstrate either shortcomings in the relevant harmonised standards or technical specifications or a recurring incorrect application of the relevant harmonised standards or technical specifications;*

*(d) the degree of uncertainty of the potential risk related to new types of machinery or technologies.*

*A machinery product that is established as posing a risk to human health in accordance with paragraph 3 and which does not fulfil any of the conditions set out in the first subparagraph shall be included in the list of categories of machinery products in Annex I, Part B, without prejudice to Article 11 of Regulation (EU) No 1025/2012 on formal objections to harmonised standards.*

*The Commission, when establishing whether a machinery product poses a risk to human health in accordance with paragraph 3 shall inter alia take into account the information communicated to it pursuant to paragraph 4.*

## **Amendment 55**

### **Proposal for a regulation Article 7 – paragraph 1 a (new)**

*Text proposed by the Commission*

*Amendment*

*Partly completed machinery shall only be made available on the market if it satisfies*



*the applicable essential health and safety requirements set out in Annex III and the manufacturer has declared this to be the case in the EU declaration of incorporation.*

## Amendment 56

### Proposal for a regulation Article 9

*Text proposed by the Commission*

*Amendment*

#### *Article 9*

*Regulation (EU) .../... of the European Parliament and of the Council<sup>+</sup>*

*deleted*

*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.*

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<sup>29</sup> + *OJ: Please insert in the text the number of the Regulation contained in document ... .*

## Amendment 57

### Proposal for a regulation Article 10 – paragraph 1

*Text proposed by the Commission*

*Amendment*

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

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

## Amendment 58

### Proposal for a regulation

#### Article 10 – paragraph 2 – subparagraph 1

*Text proposed by the Commission*

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

*Amendment*

2. Before placing a machinery product on the market **or putting it into service**, 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 59

### 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 **in paper or electronic form**, 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 60

### Proposal for a regulation

#### Article 10 – paragraph 5

*Text proposed by the Commission*

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

*Amendment*

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

**Amendment 61**

**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 details shall be in a language easily understood by end-users and market surveillance authorities.

*Amendment*

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

**Amendment 62**

**Proposal for a regulation  
Article 10 – paragraph 9**

*Text proposed by the Commission*

9. Manufacturers who consider or have reason to believe that a machinery product, which they have placed on the market or put into service is not in

*Amendment*

9. Manufacturers who consider or have reason to believe that a machinery product, which they have placed on the market or put into service is not in

conformity with the essential health and safety requirements set out in Annex III shall immediately take the corrective measures necessary to bring that machinery product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the machinery product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the machinery product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

conformity with the essential health and safety requirements set out in Annex III shall immediately take the corrective measures necessary to bring that machinery product into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the machinery product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the machinery product available on the market *or put into service* to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

### **Amendment 63**

#### **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;

### **Amendment 64**

#### **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;*

## Amendment 65

### 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 and the **website or** 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 66

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

*Text proposed by the Commission*

(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;

*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 **and no such reference is expected to be published within a reasonable period; and**

## Amendment 67

### 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

*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 has not been accepted by any of the European standardisation organisations.

requirements and *the requested standard has not been developed within three years following* the standardisation *request*, or the request has not been accepted by any of the European standardisation organisations.

## Amendment 68

### Proposal for a regulation

#### Article 17 – paragraph 3 – subparagraph 1 a (new)

*Text proposed by the Commission*

*Amendment*

***The Commission shall duly consult all relevant stakeholders.***

## Amendment 69

### Proposal for a regulation

#### Article 17 – paragraph 4 a (new)

*Text proposed by the Commission*

*Amendment*

***4 a. If harmonised standards covering the essential health and safety requirements set out in Annex III are developed and the references to them are published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, the relevant technical specifications shall no longer apply.***

## Amendment 70

### Proposal for a regulation

#### Article 18 – paragraph 2

*Text proposed by the Commission*

*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 ***and shall be***

2. The EU declaration of conformity ***shall be able to be completed electronically and*** shall have the model structure set out in Annex V, shall contain the elements specified in the relevant

*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.

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.

## Amendment 71

### 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 certify 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, **2a** and 3.

## Amendment 72

### 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 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*

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

## Amendment 73

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

**2 a.** *Where the machinery product is a machinery product listed in Annex I, part B, and has been manufactured in accordance with harmonised standards or technical specifications covering all the relevant essential health and safety requirements, the manufacturer and the person who has carried out a substantial modification to the machinery product shall apply one of the following procedures:*

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

*(b) the 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 74**

##### **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 75**



**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*

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.

**Amendment 76**

**Proposal for a regulation**  
**Article 22 – title**

*Text proposed by the Commission*

**Conformity assessment** procedures for partly completed machinery

*Amendment*

Procedures for partly completed machinery

**Amendment 77**

**Proposal for a regulation**  
**Article 22 – paragraph 1 – introductory part**

*Text proposed by the Commission*

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:

*Amendment*

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 electronic form**:

**Amendment 78**

**Proposal for a regulation**  
**Article 22 – paragraph 2**

*Text proposed by the Commission*

2. Where relevant, the manufacturer of partly completed machinery **or the**

*Amendment*

2. Where relevant, the manufacturer of partly completed machinery shall make

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

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

## **Amendment 79**

### **Proposal for a regulation**

#### **Article 28 – paragraph 4 – subparagraph 1**

##### *Text proposed by the Commission*

4. 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*

4. 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 80**

### **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 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 they are notified. This shall in particular apply to consultancy services.

*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 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 they are notified. This shall in particular apply to consultancy services.

**Amendment 81**

**Proposal for a regulation**

**Article 28 – paragraph 6 – subparagraph 1**

*Text proposed by the Commission*

6. A conformity assessment body shall be capable of carrying out all the conformity assessment ***activities*** mentioned in Annexes VII, VIII and IX and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

*Amendment*

6. A conformity assessment body shall be capable of carrying out all the conformity assessment ***tasks*** mentioned in Annexes VII, VIII and IX and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

**Amendment 82**

**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***;

## Amendment 83

### 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 activities;

## Amendment 84

### Proposal for a regulation

#### Article 41 – paragraph 1 – subparagraph 1

*Text proposed by the Commission*

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a machinery product covered by this Regulation presents a risk to the health or safety of persons, and, where appropriate, domestic animals or to property and, where applicable, the environment, they shall carry out an evaluation in relation to the machinery product concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

*Amendment*

1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a machinery product covered by this Regulation **does not comply with the requirements laid down in this Regulation** or presents a risk to the health or safety of persons, and, where appropriate, domestic animals or to property and, where applicable, the environment, they shall carry out an evaluation in relation to the machinery product concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

## Amendment 85

### Proposal for a regulation

#### Article 41 – paragraph 1 – subparagraph 2

*Text proposed by the Commission*

Where, in the course of the evaluation

*Amendment*

Where, in the course of the evaluation

referred to in the first subparagraph, the market surveillance authorities find that the machinery product does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take *all* appropriate corrective action to bring the *machinery product into compliance with those requirements, to withdraw the machinery product from the market*, or to *recall it* within a reasonable period which is commensurate with the nature of the risk referred to in the first subparagraph.

## Amendment 86

### Proposal for a regulation Article 41 – paragraph 3

*Text proposed by the Commission*

3. The economic operator shall ensure that *all* appropriate corrective action is taken in respect of all the machinery products concerned that the economic operator has made available on the market throughout the Union.

## Amendment 87

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

*Text proposed by the Commission*

4. 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*.

referred to in the first subparagraph, the market surveillance authorities find that the machinery product does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take appropriate *and proportionate* corrective action, *as provided for in Article 16(3) of Regulation (EU) 2019/1020*, to bring the *non-compliance to an end* or to *eliminate the risk they specify* within a reasonable period which is commensurate with the nature of the risk referred to in the first subparagraph.

*Amendment*

3. The economic operator shall ensure that appropriate corrective action is taken in respect of all the machinery products concerned that the economic operator has made available on the market throughout the Union.

*Amendment*

4. 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, first subparagraph, persists*, the market surveillance authorities shall *ensure that* the machinery product *concerned is withdrawn or recalled, or that making*

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 88

### Proposal for a regulation Article 41 – paragraph 4 – subparagraph 2

*Text proposed by the Commission*

*The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.*

*Amendment*

*deleted*

## Amendment 89

### Proposal for a regulation Article 41 – paragraph 5 – subparagraph 1

*Text proposed by the Commission*

5. The information referred to in paragraph 4, *second subparagraph*, shall include all available details, in particular the data necessary for the identification of the non-compliant machinery product, the origin of that machinery product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:

*Amendment*

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant machinery product, the origin of that machinery product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to any of the following:

## Amendment 90

### Proposal for a regulation Article 41 – paragraph 7

*Text proposed by the Commission*

7. Where, within three months of receipt of the information referred to in paragraph 4, **second subparagraph**, no objection has been raised by either a Member State or the Commission in respect of a **provisional** measure taken by a Member State, that measure shall be deemed justified.

*Amendment*

7. Where, within three months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a measure taken by a Member State, that measure shall be deemed justified.

**Amendment 91**

**Proposal for a regulation**  
**Article 45 – paragraph 2**

*Text proposed by the Commission*

2. The power to adopt delegated acts referred to in Articles 5(2) and 6(2) shall be conferred on the Commission for a period of five years from ... [the date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

*Amendment*

2. The power to adopt delegated acts referred to in Articles 5(2), **5(4a)** and 6(2) shall be conferred on the Commission for a period of five years from ... [the date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

**Amendment 92**

**Proposal for a regulation**  
**Article 45 – paragraph 4**

*Text proposed by the Commission*

4. The delegation of powers referred to in Articles 5(2) and 6(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power

*Amendment*

4. The delegation of powers referred to in Articles 5(2), **5(4a)** and 6(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of

specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

## **Amendment 93**

### **Proposal for a regulation Article 45 – paragraph 6**

#### *Text proposed by the Commission*

6. A delegated act adopted pursuant to Articles 5(2) and 6(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

#### *Amendment*

6. A delegated act adopted pursuant to Articles 5(2), **5(4a)** and 6(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

## **Amendment 94**

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

#### *Text proposed by the Commission*

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

#### *Amendment*

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

## **Amendment 95**

### **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 96**

**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 97**

**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

*Amendment*

1. Member States shall not 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 ***application*** 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 ***application*** of this Regulation].

*Amendment*

2. EC type-examination certificates and approval decisions issued in accordance with Article 14 of Directive 2006/42/EC shall remain valid until they expire.

*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.

the European Parliament and to the Council. The reports shall be made public.

#### **Amendment 98**

##### **Proposal for a regulation Article 51 – paragraph 2 – point b**

*Text proposed by the Commission*

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

*Amendment*

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

#### **Amendment 99**

##### **Proposal for a regulation Article 52 – paragraph 2**

*Text proposed by the Commission*

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

*Amendment*

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

#### **Amendment 100**

##### **Proposal for a regulation Annex I – subheading 1**

*Text proposed by the Commission*

**HIGH-RISK MACHINERY PRODUCTS**

*Amendment*

**Categories of machinery products subject to a specific conformity assessment procedure**

**Part A**

#### **Amendment 101**

##### **Proposal for a regulation Annex I – point 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

**1. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:** *deleted*

#### **Amendment 102**

##### **Proposal for a regulation Annex I – point 1 – point 1.1**

*Text proposed by the Commission*

*Amendment*

**1.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;** *deleted*

#### **Amendment 103**

##### **Proposal for a regulation Annex I – point 1 – point 1.2**

*Text proposed by the Commission*

*Amendment*

**1.2. sawing machinery with fixed blade(s) during cutting, having a manually operated reciprocating saw-bench or carriage;** *deleted*

#### **Amendment 104**

##### **Proposal for a regulation Annex I – point 1 – point 1.3**

*Text proposed by the Commission*

*Amendment*

**1.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the** *deleted*

*workpieces, with manual loading and/or unloading;*

#### **Amendment 105**

##### **Proposal for a regulation Annex I – point 1 – point 1.4**

*Text proposed by the Commission*

*Amendment*

**1.4. *sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.*** *deleted*

#### **Amendment 106**

##### **Proposal for a regulation Annex I – point 2**

*Text proposed by the Commission*

*Amendment*

**2. *Hand-fed surface planing machinery for woodworking.*** *deleted*

#### **Amendment 107**

##### **Proposal for a regulation Annex I – point 3**

*Text proposed by the Commission*

*Amendment*

**3. *Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.*** *deleted*

#### **Amendment 108**

##### **Proposal for a regulation Annex I – point 4 – introductory part**

*Text proposed by the Commission*

*Amendment*

**4. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:** *deleted*

#### **Amendment 109**

##### **Proposal for a regulation Annex I – point 4 – point 4.1**

*Text proposed by the Commission*

*Amendment*

**4.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;** *deleted*

#### **Amendment 110**

##### **Proposal for a regulation Annex I – point 4 – point 4.2**

*Text proposed by the Commission*

*Amendment*

**4.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.** *deleted*

#### **Amendment 111**

##### **Proposal for a regulation Annex I – point 5**

*Text proposed by the Commission*

*Amendment*

**5. Combined machinery of the types referred to in points 1 to 4 and in point 7 for working with wood and material with similar physical characteristics.** *deleted*

## **Amendment 112**

### **Proposal for a regulation Annex I – point 6**

*Text proposed by the Commission*

*Amendment*

**6. Hand-fed tenoning machinery with several tool holders for woodworking.** *deleted*

## **Amendment 113**

### **Proposal for a regulation Annex I – point 7**

*Text proposed by the Commission*

*Amendment*

**7. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.** *deleted*

## **Amendment 114**

### **Proposal for a regulation Annex I – point 10**

*Text proposed by the Commission*

*Amendment*

**10. Injection or compression plastics-moulding machinery with manual loading or unloading.** *deleted*

## **Amendment 115**

### **Proposal for a regulation Annex I – point 11**

*Text proposed by the Commission*

*Amendment*

**11. Injection or compression rubber-moulding machinery with manual loading or unloading.** *deleted*

## **Amendment 116**

### **Proposal for a regulation Annex I – point 12 – introductory part**

*Text proposed by the Commission*

*Amendment*

**12. Machinery for underground working of the following types:** *deleted*

## **Amendment 117**

### **Proposal for a regulation Annex I – point 12 – point 12.1**

*Text proposed by the Commission*

*Amendment*

**12.1. locomotives and brake-vans;** *deleted*

## **Amendment 118**

### **Proposal for a regulation Annex I – point 12 – point 12.2**

*Text proposed by the Commission*

*Amendment*

**12.2. hydraulic-powered roof supports.** *deleted*

## **Amendment 119**

### **Proposal for a regulation Annex I – point 19**

*Text proposed by the Commission*

*Amendment*

**19. Protective devices designed to detect the presence of persons.** *deleted*

## **Amendment 120**

### **Proposal for a regulation Annex I – point 20**

*Text proposed by the Commission*

*Amendment*

**20. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 10 and 11.** *deleted*

#### **Amendment 121**

##### **Proposal for a regulation Annex I – point 21**

*Text proposed by the Commission*

*Amendment*

**21. Logic units to ensure safety functions.** *deleted*

#### **Amendment 122**

##### **Proposal for a regulation Annex I – point 22**

*Text proposed by the Commission*

*Amendment*

**22. Roll-over protective structures (ROPS).** *deleted*

#### **Amendment 123**

##### **Proposal for a regulation Annex I – point 23**

*Text proposed by the Commission*

*Amendment*

**23. Falling-object protective structures (FOPS).** *deleted*

#### **Amendment 124**

##### **Proposal for a regulation Annex I – point 24**



*Text proposed by the Commission*

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

*Amendment*

24. AI systems ***with self-determining and evolving behaviour that are a safety component and are developed through any machine-learning techniques and approaches.***

## **Amendment 125**

### **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 ***with self-determining and evolving behaviour as a safety component that has not been placed independently on the market and are developed through any machine-learning techniques and approaches.***

## **Amendment 126**

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

*Text proposed by the Commission*

*Amendment*

#### ***Part B***

***25a. Circular saws (single- or multi-blade) for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:***

***25a.1. sawing machinery with fixed blade(s) during cutting, having a fixed bed or support with manual feed of the workpiece or with a demountable power feed;***

***25a.2. sawing machinery with fixed blade(s) during cutting, having a***

*manually operated reciprocating saw-bench or carriage;*

*25a.3. sawing machinery with fixed blade(s) during cutting, having a built-in mechanical feed device for the workpieces, with manual loading and/or unloading;*

*25a.4. sawing machinery with movable blade(s) during cutting, having mechanical movement of the blade, with manual loading and/or unloading.*

*25b. Hand-fed surface planing machinery for woodworking.*

*25c. Thicknessers for one-side dressing having a built-in mechanical feed device, with manual loading and/or unloading for woodworking.*

*25d. Band-saws with manual loading and/or unloading for working with wood and material with similar physical characteristics or for working with meat and material with similar physical characteristics, of the following types:*

*25d.1. sawing machinery with fixed blade(s) during cutting, having a fixed or reciprocating-movement bed or support for the workpiece;*

*25d.2. sawing machinery with blade(s) assembled on a carriage with reciprocating motion.*

*25e. Combined machinery of the types referred to in points 25a to 25d and in point 25g for working with wood and material with similar physical characteristics.*

*25f. Hand-fed tenoning machinery with several tool holders for woodworking.*

*25g. Hand-fed vertical spindle moulding machinery for working with wood and material with similar physical characteristics.*

*25h. Injection or compression plastics-moulding machinery with manual loading*

*or unloading.*

**25i. Injection or compression rubber-moulding machinery with manual loading or unloading.**

**25j. Machinery for underground working of the following types:**

**25j.1. locomotives and brake-vans;**

**25j.2. hydraulic-powered roof supports.**

**25k. Protective devices designed to detect the presence of persons.**

**25l. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in points 9, 25h and 25i.**

**25m. Logic units to ensure safety functions.**

**25n. Roll-over protective structures (ROPS).**

**25o. Falling-object protective structures (FOPS).**

## **Amendment 127**

### **Proposal for a regulation Annex II – point 18**

*Text proposed by the Commission*

18. **Software ensuring safety functions, including** AI systems.

*Amendment*

18. AI systems **with self-determining and evolving behaviour that are a safety component and are developed through any machine-learning techniques and approaches.**

## **Amendment 128**

### **Proposal for a regulation Annex III – point 1 – introductory part**

*Text proposed by the Commission*

1. The manufacturer of a machinery

*Amendment*

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.

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 and minimise all relevant risks, taking into account the results of the risk assessment.

## Amendment 129

### Proposal for a regulation

#### Annex III – point 1 – subparagraph 1 – 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:

## Amendment 130

### Proposal for a regulation

#### Annex III – point 1 – subparagraph 1 – point c

##### *Text proposed by the Commission*

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

##### *Amendment*

(c) identify the hazards that may be generated by the machinery product and the associated hazardous situations, including hazards that may be generated during the lifecycle of the machinery product that are foreseeable at the time of placing of the machinery product on the market as an intended evolution of its fully or partially evolving behaviour or logic as a result of the machinery product designed to operate with varying levels of autonomy;

*system that has been carried out pursuant to the Regulation ... of the European Parliament and of the Council+ on a European approach for Artificial Intelligence+<sup>30</sup> ;.*

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*<sup>30</sup> + OJ: Please insert in the text the number of the Regulation contained in document ... and insert the number, date, title and OJ reference of that Regulation in the footnote*

## **Amendment 131**

### **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.

## **Amendment 132**

### **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

#### *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 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.

risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable **use or** 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 133**

#### **Proposal for a regulation**

##### **Annex III – Part 1 – point 1.1 – point 1.1.2 – point b – introductory part**

###### *Text proposed by the Commission*

(b) In selecting the most appropriate methods, the manufacturer **or his or her authorised representative** shall apply the following principles, in the order given:

###### *Amendment*

(b) In selecting the most appropriate methods, the manufacturer shall apply the following principles, in the order given:

### **Amendment 134**

#### **Proposal for a regulation**

##### **Annex III – Part 1 – point 1.1 – point 1.1.2 – point c**

###### *Text proposed by the Commission*

(c) When designing and constructing a machinery product and when drafting the instructions, the manufacturer **or his or her authorised representative** shall envisage not only the intended use of the machinery product but also any reasonably foreseeable misuse thereof. The machinery product shall be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions shall draw the user's attention to ways — which experience has shown might occur — in which the machinery product should not be used.

###### *Amendment*

(c) When designing and constructing a machinery product and when drafting the instructions, the manufacturer shall envisage not only the intended use of the machinery product but also any reasonably foreseeable misuse thereof. The machinery product shall be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. Where appropriate, the instructions shall draw the user's attention to ways — which experience has shown might occur — in which the machinery product should not be used.

## Amendment 135

### 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. 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 136

### Proposal for a regulation

#### Annex III – Part 1 – point 1.1 – point 1.1.5 – subparagraph 2

##### *Text proposed by the Commission*

During the transportation of the machinery product **and/or** its component parts, there shall be no possibility of sudden movements or of hazards due to instability as long as the machinery product **and/or** its component parts are handled in accordance with the instructions.

##### *Amendment*

During the transportation of the machinery product **or** its component parts, there shall be no possibility of sudden movements or of hazards due to instability as long as the machinery product **or** its component parts are handled in accordance with the instructions.

## Amendment 137

### Proposal for a regulation

#### Annex III – Part 1 – point 1.1 – point 1.1.6 – subparagraph 1 – introductory part

##### *Text proposed by the Commission*

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:

##### *Amendment*

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

## Amendment 138

### Proposal for a regulation

#### Annex III – Part 1 – point 1.1 – point 1.1.6 – subparagraph 1 – point c

##### *Text proposed by the Commission*

(c) avoiding a machine-determined work rate;

##### *Amendment*

(c) avoiding a machine-determined work rate **by allowing adaptations**;

## Amendment 139

### Proposal for a regulation

#### Annex III – Part 1 – point 1.1 – point 1.1.6 – subparagraph 1 – 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 (**such as** verbally through words and non-verbally through gestures, facial expressions or body movement) and to communicate its planned actions (**such as** what it is going to do and why) to operators in a comprehensible manner.

## Amendment 140

### Proposal for a regulation

#### Annex III – Part 1 – point 1.1 – point 1.1.7 – subparagraph 1

##### *Text proposed by the Commission*

The operating position shall be designed and constructed in such a way as to avoid any risk due to exhaust gases **and/or** lack of oxygen.

##### *Amendment*

The operating position shall be designed and constructed in such a way as to avoid any risk due to exhaust gases **or** lack of oxygen.

## Amendment 141



## Proposal for a regulation

### Annex III – Part 1 – point 1.1 – point 1.1.7 – subparagraph 3

#### *Text proposed by the Commission*

Where appropriate, the operating position shall be fitted with an adequate cabin designed, constructed **and/or** equipped to fulfil the above requirements. The exit shall allow rapid evacuation. Moreover, when applicable, an emergency exit shall be provided in a direction which is different from the usual exit.

#### *Amendment*

Where appropriate, the operating position shall be fitted with an adequate cabin designed, constructed **or** equipped to fulfil the above requirements. The exit shall allow rapid evacuation. Moreover, when applicable, an emergency exit shall be provided in a direction which is different from the usual exit.

## Amendment 142

## Proposal for a regulation

### Annex III – Part 1 – point 1.1 – point 1.1.9 – subparagraph 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 **to, 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 **that** hardware component.

## Amendment 143

## Proposal for a regulation

### Annex III – Part 1 – point 1.2 – point 1.2.1 – subparagraph 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 and unintended external influences, including **predictable misuse** from third parties **creating a potentially** hazardous situation **or function**;

## Amendment 144

### Proposal for a regulation

#### Annex III – Part 1 – point 1.2 – point 1.2.1 – subparagraph 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 *or upgraded* 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 *its development based on machine* learning, which cannot go beyond the limits addressed in the risk assessment;

## Amendment 145

### Proposal for a regulation

#### Annex III – Part 1 – point 1.2 – point 1.2.1 – subparagraph 4 – point c

##### *Text proposed by the Commission*

(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;

##### *Amendment*

(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;

## Amendment 146

### Proposal for a regulation

#### Annex III – Part 1 – point 1.3 – point 1.3.2 – subparagraph 4

##### *Text proposed by the Commission*

Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned shall be mounted,

##### *Amendment*

Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned shall be mounted,

positioned **and/or** guarded in such a way that any fragments will be contained, preventing hazardous situations.

positioned **or** guarded in such a way that any fragments will be contained, preventing hazardous situations.

#### Amendment 147

##### Proposal for a regulation

##### Annex III – Part 1 – point 1.3 – point 1.3.7 – introductory part

*Text proposed by the Commission*

*Amendment*

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

1.3.7. Risks related to moving parts and **cognitive workload**

#### Amendment 148

##### Proposal for a regulation

##### Annex III – Part 1 – point 1.3 – point 1.3.7 – subparagraph 4 – introductory part

*Text proposed by the Commission*

*Amendment*

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:

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:

#### Amendment 149

##### Proposal for a regulation

##### Annex III – Part 1 – point 1.3 – point 1.3.7 – paragraph 5

*Text proposed by the Commission*

*Amendment*

***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.***

***deleted***

## Amendment 150

### Proposal for a regulation

#### Annex III – Part 1 – point 1.5 – point 1.5.1 – subparagraph 2

##### *Text proposed by the Commission*

The safety objectives set out in Directive 2014/35/EU shall apply to a machinery product. However, the obligations concerning conformity assessment and the placing on the market **and/or** putting into service of a machinery product with regard to electrical risks are governed solely by this Regulation.

##### *Amendment*

The safety objectives set out in Directive 2014/35/EU shall apply to a machinery product. However, the obligations concerning conformity assessment and the placing on the market **or** putting into service of a machinery product with regard to electrical risks are governed solely by this Regulation.

## Amendment 151

### Proposal for a regulation

#### Annex III – Part 1 – point 1.5 – point 1.5.4 – subparagraph 1

##### *Text proposed by the Commission*

Errors likely to be made when fitting or refitting certain parts, which could be a source of risk, shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves **and/or** their housings. The same information shall be given on moving parts **and/or** their housings where the direction of movement needs to be known in order to avoid a risk.

##### *Amendment*

Errors likely to be made when fitting or refitting certain parts, which could be a source of risk, shall be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves **or** their housings. The same information shall be given on moving parts **or** their housings where the direction of movement needs to be known in order to avoid a risk.

## Amendment 152

### Proposal for a regulation

#### Annex III – Part 1 – point 1.6 – point 1.6.2 – subparagraph 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**

##### *Amendment*

In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be **designed in a**

*and adapted for the use of rescue equipment in such a way that a timely rescue of the persons is guaranteed.*

way that *guarantees* a timely *emergency* rescue of the persons.

### **Amendment 153**

#### **Proposal for a regulation**

#### **Annex III – Part 1 – point 1.7 – point 1.7.4 – subparagraph 2**

##### *Text proposed by the Commission*

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.

##### *Amendment*

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

### **Amendment 154**

#### **Proposal for a regulation**

#### **Annex III – Part 1 – point 1.7 – point 1.7.4 – subparagraph 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) be presented in a format that makes it possible for the end user to download the instructions *over the 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.

### **Amendment 155**

#### **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 lifetime of the machinery product;***

**Amendment 156**

**Proposal for a regulation**

**Annex III – Part 2 – point 2.2 – introductory part**

*Text proposed by the Commission*

2.2. PORTABLE HAND-HELD  
**AND/OR** HAND-GUIDED MACHINERY

*Amendment*

2.2. PORTABLE HAND-HELD **OR**  
HAND-GUIDED MACHINERY

**Amendment 157**

**Proposal for a regulation**

**Annex III – Part 2 – point 2.2 – point 2.2.1 – subparagraph 1 – introductory part**

*Text proposed by the Commission*

Portable hand-held **and/or** hand-guided machinery shall:

*Amendment*

Portable hand-held **or** hand-guided machinery shall:

**Amendment 158**

**Proposal for a regulation**

**Annex III – Part 2 – point 2.2 – point 2.2.1 – subparagraph 1 – point c**

*Text proposed by the Commission*

(c) present no risks of accidental starting **and/or** continued operation after the operator has released the handles. Equivalent steps shall be taken if this requirement is not technically feasible;

*Amendment*

(c) present no risks of accidental starting **or** continued operation after the operator has released the handles. Equivalent steps shall be taken if this requirement is not technically feasible;

## Amendment 159

### Proposal for a regulation

#### Annex III – Part 2 – point 2.2 – point 2.2.1 – subparagraph 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) 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. ***Where the use of external devices is not feasible, information on the use of appropriate personal protective equipment (PPE) shall be provided in the instructions.***

## Amendment 160

### Proposal for a regulation

#### Annex III – Part 2 – point 2.2 – point 2.2.1 – subparagraph 1 a (new)

##### *Text proposed by the Commission*

##### *Amendment*

***The handles of portable machinery shall be designed and constructed in such a way as to make starting and stopping that machinery straightforward.***

## Amendment 161

### Proposal for a regulation

#### Annex III – Part 3 – point 3.2 – point 3.2.2 – subparagraph 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.

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 **take ergonomic principles into account and shall** not be fitted if they increase the risk.

## Amendment 162

### Proposal for a regulation

#### Annex III – Part 3 – point 3.2 – point 3.2.2 – subparagraph 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 **driver is in the driving position and not using the** restraint system.

## Amendment 163

### Proposal for a regulation

#### Annex III – Part 3 – point 3.2 – point 3.2.4 – subparagraph 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**

##### *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 the machine **remotely and shall include a function which would allow the operator to bring the machinery into a secure state.**



*are operational.*

#### **Amendment 164**

##### **Proposal for a regulation**

##### **Annex III – Part 3 – point 3.3 – point 3.3.3 – subparagraph 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 **at least one** of the following **two** conditions:

#### **Amendment 165**

##### **Proposal for a regulation**

##### **Annex III – Part 4 – point 4.1 – point 4.1.3 – subparagraph 1**

*Text proposed by the Commission*

*Amendment*

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.

When lifting machinery or lifting accessories are placed on the market or are first put into service, the manufacturer 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 166**

##### **Proposal for a regulation**

##### **Annex III – Part 4 – point 4.3 – point 4.3.1 – subparagraph 1**

*Text proposed by the Commission*

*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

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*.

of the relevant *declaration of conformity*.

## Amendment 167

### Proposal for a regulation

#### Annex IV – Part A – subparagraph 2 – point o

##### *Text proposed by the Commission*

(o) for sensor-fed, remotely-driven, or autonomous machinery product, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used, ***without prejudice to the requirements for artificial intelligence (AI) systems set out in the Regulation (EU) .../... of the European Parliament and of the Council<sup>33</sup> if the safety related software includes an AI system;***

##### *Amendment*

(o) for sensor-fed, remotely-driven, or autonomous machinery product, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used;

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<sup>33</sup> + ***OJ: Please insert in the text the number of the Regulation contained in document ... and insert the number, date, title and OJ reference of that Regulation in the footnote.***

## Amendment 168

### Proposal for a regulation

#### Annex IV – Part B – subparagraph 2 – point a

##### *Text proposed by the Commission*

(a) a complete description of the partly completed machinery and of its intended ***use;***

##### *Amendment*

(a) a complete description of the partly completed machinery and of its intended ***function when incorporated into or assembled with machinery or other partly completed machinery or equipment;***

## Amendment 169

**Proposal for a regulation**  
**Annex IV – Part B – subparagraph 2 – point j**

*Text proposed by the Commission*

(j) *a copy of the assembly instructions for the* partly completed machinery set out in *section 1.7.4 of Annex III*;

*Amendment*

(j) *the EU declaration of incorporation for* partly completed machinery set out in *Annex V and the relevant assembly instructions for such machinery set out in Annex X*;

**Amendment 170**

**Proposal for a regulation**  
**Annex IV – Part B – subparagraph 2 – point k**

*Text proposed by the Commission*

(k) for partly completed machinery *products* produced in series, the internal measures that will be implemented to ensure that the partly completed machinery *product* remains in conformity with the essential health and safety requirements applied;

*Amendment*

(k) for partly completed machinery produced in series, the internal measures that will be implemented to ensure that the partly completed machinery remains in conformity with the essential health and safety requirements applied;

**Amendment 171**

**Proposal for a regulation**  
**Annex IV – Part B – subparagraph 2 – point m**

*Text proposed by the Commission*

(m) for sensor-fed, remotely-driven, or autonomous partly completed machinery, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used, *without prejudice to the requirements for artificial intelligence (AI) systems set out in the Regulation (EU) .../... of the European Parliament and of the Council<sup>34</sup> if the safety related software includes a AI system*;

*Amendment*

(m) for sensor-fed, remotely-driven, or autonomous partly completed machinery, if the safety related operations are controlled by sensor data, a description, where appropriate, of the general characteristics, capabilities and limitations of the system, data, development, testing and validation processes used;

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<sup>34</sup> + *OJ*: Please insert in the text the number of the Regulation contained in document ... and insert the number, date, title and OJ reference of that Regulation in the footnote.

#### **Amendment 172**

##### **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 lifting machinery product installed in a building or a structure:

#### **Amendment 173**

##### **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:

#### **Amendment 174**

##### **Proposal for a regulation Annex IX – point 3 – point 3.3 – subparagraph 3**

*Text proposed by the Commission*

The manufacturer *or his or her authorised representative* shall be notified of the decision.

*Amendment*

The manufacturer shall be notified of the decision.

#### **Amendment 175**

**Proposal for a regulation**  
**Annex IX – point 5 – introductory part**

*Text proposed by the Commission*

5. **Conformity** marking and declaration of conformity

*Amendment*

5. **CE** marking and **EU** declaration of conformity

**Amendment 176**

**Proposal for a regulation**  
**Annex IX – point 5 – point 5.1**

*Text proposed by the Commission*

5.1. The manufacturer shall affix the **required conformity** marking **set out in this Regulation**, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the applicable requirements of this Regulation.

*Amendment*

5.1. The manufacturer shall affix the **CE** marking, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual **machinery** product that satisfies the applicable requirements of this Regulation.

**Amendment 177**

**Proposal for a regulation**  
**Annex IX – point 5 – point 5.2**

*Text proposed by the Commission*

5.2. The manufacturer shall draw up a written declaration of conformity for each machinery product model and keep it at the disposal of the national authorities for ten years after the machinery product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

*Amendment*

5.2. The manufacturer shall draw up a written **EU** declaration of conformity for each machinery product model and keep it at the disposal of the national authorities for ten years after the machinery product has been placed on the market. The **EU** declaration of conformity shall identify the product model for which it has been drawn up.

**Amendment 178**

**Proposal for a regulation**  
**Annex IX – point 5 – subparagraph 1**

*Text proposed by the Commission*

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

*Amendment*

A copy of the **EU** declaration of conformity shall be made available to the relevant authorities upon request.

**Amendment 179**

**Proposal for a regulation**  
**Annex X – subparagraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***The assembly instructions may be provided by the manufacturer in electronic form.***

## EXPLANATORY STATEMENT

The Machinery Directive 2006/42/EC establishes a regulatory framework for placing machinery on the Single Market, ensuring its free movement and a high level of protection for users and other persons exposed to machinery products.

On 21 April 2021, the Commission put forward a proposal to revise the Machinery Directive. The proposed revision came 15 years after the adoption of the Machinery Directive, currently in force, reflecting the Commission Work Programme 2020 under the priority ‘A Europe fit for the Digital Age’. In parallel, the Commission proposed a new Artificial Intelligence Act, with the main goal to reflect the change of the digital transition and the impact of new technologies on the Union product safety legislation.

As the machinery sector is an essential part of the engineering industry and one of the industrial pillars of the EU economy, the Rapporteur finds it very important to consider changes to its legislative framework with due care in order to secure sustainable recovery from the COVID-19 crisis while enabling innovation and new design development, and to keep European producers and designers competitive at the global level playing field.

The Rapporteur welcomes the Commission proposal for a Regulation on machinery products and fully supports its alignment with the **New Legislative Framework (NLF)** as it brings coherence with the other legislative acts on products safety and horizontal transparency. The Rapporteur also supports the **conversion of the Directive into a Regulation** as it facilitates uniform application across all EU Member States and therefore the free movement of goods.

While preparing the draft report, the Rapporteur carried out a broad consultation with stakeholders, listening to views and needs of the manufacturers, notified bodies and consumers, and, in addition discussing the proposal with the Commission.

On that basis, the Rapporteur proposes the following main changes to the Commission proposal.

### 1. Scope and definitions

The Rapporteur proposes clarifying the scope, in particular with regard to the exclusion of motor vehicles from the Regulation. In addition, the Rapporteur proposes clarifications of several definitions, such as ‘safety component’ ‘substantial modification’ and ‘manufacturer’, and suggests new definitions on ‘machinery product’, ‘safety function’, ‘technical documentation’ and ‘lifecycle’ in order to contribute to the clearer understanding of the enacting provisions.

Since the Regulation applies to ‘machinery products’ which, according to the Commission proposal, cover also ‘partly completed machinery’, the Rapporteur considers it important to make a clearer distinction between the definitions applying to ‘partly completed machinery’ and those applying to other categories of machinery products.

This distinction should also be made in respect of the requirements for machinery products in general and those for ‘partly completed machinery’, and in respect of the obligations, including

(conformity) assessment procedures, of economic operators.

## **2. High-risk machinery products**

The Rapporteur proposes that the term ‘high-risk machinery products’ be replaced by ‘potentially high-risk machinery products’ throughout the text as he considers that machinery products placed nowadays on the market do not present a high risk by default but only in certain situations.

In addition, in respect of the Commission empowerment to adopt delegated acts to amend Annex I listing potentially high-risk machinery products, the Rapporteur proposes that such delegated acts should not apply earlier than 36 months after their entry into force, so that manufacturers have enough time to adapt their design and production.

The Rapporteur emphasised in the report that machinery products should comply with the **essential health and safety requirements** when placed on the market or put into service.

Finally, in Annex III the rapporteur specified that the remote control for supervisory control function for autonomous operations should be implemented only as an option, ensuring that the remote actions do not increase the level of risk.

## **3. Conformity assessment of potentially high-risk machinery products**

The Rapporteur proposes to keep the possibility for the manufacturers to use also the internal production control procedure (module A) set out in Annex VI for potentially high-risk machinery products, as he is not convinced that there are enough arguments for removing this option, while keeping in mind both the safety of machinery products and the machinery sector competitiveness and flexibility for innovation. In addition, keeping the possibility of using the internal production control procedure is of particular importance for SMEs.

Moreover, the Rapporteur believes that manufacturer’s authorised representative should not have a mandate for ensuring conformity assessment for machinery products or to be responsible for preparing technical documentation. The manufacturer should be the only responsible for these tasks, in line with the provisions of NLF.

## **4. Commission empowerment to adopt technical specifications**

In respect of the Commission proposal to be able to exceptionally adopt implementing acts establishing technical specifications for the essential health and safety requirements in case of absence of harmonised standards, the Rapporteur proposes that such technical specifications do not apply should harmonised standards be developed in the future. Also, the Rapporteur believes that technical specifications could be drafted by the Commission only if European standardisations organisations have not delivered harmonised standards 3 years after the standardisation request.

## **5. Documentation**



All relevant technical documentation, assembly instructions and declarations should be provided in digital or paper form and, if provided digitally, should be accessible during the whole lifecycle of the machinery product.

## **6. Market surveillance**

The Rapporteur clarifies the rights of Member states' market surveillance authorities and duties of economic operators in case where a machinery product does not comply with the requirements in this Regulation or poses a risk. While doing that, he strives to align the provisions on market surveillance with the Market Surveillance Regulation (EU) 2019/1020.

## **7. Deadlines and transitional provisions**

The Rapporteur proposes extending the deadline for the repeal of Directive 2006/42/EC from 30 to 48 months after the date of entry into force of the new Regulation. In line with that, the transitional period has been extended from 42 to 60 month, as well, and the deadline for the Commission to present its first report on the evaluation of the Regulation from 54 to 72 months. Finally, the date of application of the Regulation was postponed from 30 to 48 months after its entry into force.

8.3.2022

## OPINION OF THE COMMITTEE ON EMPLOYMENT AND SOCIAL AFFAIRS

for the Committee on the Internal Market and Consumer Protection

on the proposal for a regulation of the European Parliament and of the Council on machinery products

(COM(2021)0202 – C9-0145/2021 – 2021/0105(COD))

Rapporteur for opinion: Marianne Vind

### AMENDMENTS

The Committee on Employment and Social Affairs calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to take into account the following amendments:

#### Amendment 1

##### Proposal for a regulation

##### Recital 2

*Text proposed by the Commission*

(2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Union economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance.

*Amendment*

(2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Union economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance. ***Against this background and in view of the forthcoming implementation of the new EU strategic framework on health and safety at work 2021-2027 and its ‘vision zero’ approach to work-related deaths, one of the objectives of this Regulation is to set out ambitious occupational health and safety requirements for machinery products.***

## Amendment 2

### Proposal for a regulation Recital 5 a (new)

*Text proposed by the Commission*

*Amendment*

***(5a) A high-level of occupational health and safety (OHS) requirements is essential to ensure good working conditions and safe workplaces. Participation of workers and their representatives is crucial to protect workers' health and safety, including when installing and operating machinery products. Employers, trade unions and workers' representatives play an important role in implementing and monitoring OHS requirements at the workplace. They should be closely involved in all relevant phases when it comes to risk assessments and occupational health and safety policies.***

## Amendment 3

### Proposal for a regulation Recital 24

*Text proposed by the Commission*

*Amendment*

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

(24) In the machinery sector, around 98 % of the companies are small or medium sized enterprises (SMEs). In order to 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. ***The health and safety requirements set out in this regulation should apply equally to all undertakings.***

## Amendment 4

### Proposal for a regulation Recital 25

*Text proposed by the Commission*

(25) Economic operators should be responsible for the compliance of machinery products with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment, as well as the fair competition on the Union market.

*Amendment*

(25) Economic operators should be responsible for the compliance of machinery products with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as the health and safety of persons, ***in particular workers and users***, where appropriate, domestic animals and property and, where applicable, the environment, as well as the fair competition on the Union market.

**Amendment 5**

**Proposal for a regulation**

**Recital 32**

*Text proposed by the Commission*

(32) It is necessary to ensure that machinery products from third countries entering the Union market comply with the requirements of this Regulation and do not pose a risk to the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment, and in particular, that appropriate conformity assessment procedures have been carried out by manufacturers with regard to such machinery products. Provision should therefore be made for importers to ensure that machinery products that they place on the market comply with the requirements of this Regulation and do not pose a risk to the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment. For the same reason, provision should also be made for importers to ensure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection

*Amendment*

(32) It is necessary to ensure that machinery products from third countries entering the Union market comply with the requirements of this Regulation and do not pose a risk to the health and safety of persons, ***in particular workers and users***, where appropriate, domestic animals and property and, where applicable, the environment, and in particular, that appropriate conformity assessment procedures have been carried out by manufacturers with regard to such machinery products. Provision should therefore be made for importers to ensure that machinery products that they place on the market comply with the requirements of this Regulation and do not pose a risk to the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment. For the same reason, provision should also be made for importers to ensure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection

by the competent national authorities.

by the competent national authorities.

## Amendment 6

### Proposal for a regulation

#### Recital 35

##### *Text proposed by the Commission*

(35) In view of ensuring the health and safety of the users of the machinery product, economic operators should ensure that all relevant documentation, such as the user's instructions, whilst containing precise and comprehensible information, is easily understandable, takes into account technological developments and changes to end-user behaviour, and is as up to date as possible. When machinery products are made available on the market in packages containing multiple units, the instructions and information should accompany the smallest commercially available unit.

##### *Amendment*

(35) In view of ensuring the health and safety of the users of the machinery product, economic operators should ensure that all relevant documentation, such as the user's instructions, whilst containing precise and comprehensible information, is easily understandable **and available in all relevant languages**, takes into account technological developments and changes to end-user behaviour, and is as up to date as possible. When machinery products are made available on the market in packages containing multiple units, the instructions and information should accompany the smallest commercially available unit.

## Amendment 7

### Proposal for a regulation

#### Recital 39

##### *Text proposed by the Commission*

(39) This Regulation should **be limited to setting out the essential** health and safety requirements, supplemented by a number of more specific requirements for certain categories of machinery products. In order to facilitate the assessment of conformity with those health and safety requirements it is necessary to provide for a presumption of conformity for machinery which is in conformity with harmonised standards that are developed and which references are published in the Official Journal of the European Union in accordance with Regulation (EU) No

##### *Amendment*

(39) This Regulation should **set out** health and safety requirements, supplemented by a number of more specific requirements for certain categories of machinery products. In order to facilitate the assessment of conformity with those health and safety requirements it is necessary to provide for a presumption of conformity for machinery which is in conformity with harmonised standards that are developed and which references are published in the Official Journal of the European Union in accordance with Regulation(EU) No 1025/2012 of the

1025/2012 of the European Parliament and of the Council<sup>12</sup> for the purpose of expressing detailed technical specifications of those requirements.

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<sup>12</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52), 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

European Parliament and of the Council<sup>12</sup> for the purpose of expressing detailed technical specifications of those requirements.

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<sup>12</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52), 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

## Amendment 8

### Proposal for a regulation Recital 39 a (new)

*Text proposed by the Commission*

*Amendment*

***(39a) The Commission in cooperation with the European Agency for Safety and Health at work (EU-OSHA) should establish an alert mechanism in the existing institutional structure to identify OSH related shortcomings of this Regulation at an early stage in the future, especially in the context of digitalisation and Artificial Intelligence. Moreover, the Commission should upgrade and extend the injury database (IDB)<sup>1</sup>, covering all types of injuries linked to the use of machinery products, to monitor risks. The involvement of social partners is essential in both cases.***

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<sup>[1]</sup>[https://ec.europa.eu/health/system/files/2020-12/idb\\_flyer\\_en\\_0.pdf](https://ec.europa.eu/health/system/files/2020-12/idb_flyer_en_0.pdf)

## Amendment 9

### 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 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 10

### Proposal for a regulation Recital 41

*Text proposed by the Commission*

(41) Compliance with harmonised standards and with technical specifications established by the Commission should be voluntary. Alternative technical solutions should therefore be acceptable where compliance of the machinery with ***the relevant essential*** health and safety requirements is demonstrated in the technical file.

*Amendment*

(41) Compliance with harmonised standards and with technical specifications established by the Commission should be voluntary ***but should be considered as guidance***. Alternative technical solutions should therefore be acceptable where compliance of the machinery with health and safety requirements is demonstrated in the technical file.

## Amendment 11

### Proposal for a regulation Recital 42

*Text proposed by the Commission*

(42) **The essential** health and safety requirements should be satisfied in order to ensure that the machinery product is safe. Those requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.

*Amendment*

(42) Health and safety requirements should be satisfied in order to ensure that the machinery product is safe. Those requirements should be applied with discernment to take account of the state of the art **and the foreseeable risks** at the time of construction and of technical and economic requirements.

**Amendment 12**

**Proposal for a regulation**

**Recital 43**

*Text proposed by the Commission*

(43) In view of addressing the risks stemming from malicious third party actions that have an impact on the safety of machinery products, this Regulation should include **essential** health and safety requirements for which a presumption of conformity may be given to the appropriate extent by a certificate or statement of conformity issued under a relevant cybersecurity scheme adopted pursuant to and in accordance with Article 54(3) of Regulation (EU) 2019/881 of the European Parliament and of the Council<sup>13</sup>.

*Amendment*

(43) In view of addressing the risks stemming from malicious third party actions that have an impact on the safety of machinery products, this Regulation should include health and safety requirements for which a presumption of conformity may be given to the appropriate extent by a certificate or statement of conformity issued under a relevant cybersecurity scheme adopted pursuant to and in accordance with Article 54(3) of Regulation (EU) 2019/881 of the European Parliament and of the Council<sup>13</sup>.

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<sup>13</sup> Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).

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<sup>13</sup> Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act) (OJ L 151, 7.6.2019, p. 15).

**Amendment 13**



**Proposal for a regulation**  
**Recital 45**

*Text proposed by the Commission*

(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 14**

**Proposal for a regulation**  
**Recital 60**

*Text proposed by the Commission*

(60) Member States should take all appropriate measures to ensure that machinery products covered by this Regulation may be placed on the market only if, when properly installed and used for its intended purpose, or under

*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 ***and machine learning*** should be carried out by a third party.

*Amendment*

(60) Member States should take all appropriate measures to ensure that machinery products covered by this Regulation may be placed on the market only if, when properly installed and used for its intended purpose, or under

conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment. Machinery products covered by this Regulation should be considered as non-compliant with *the essential* health and safety requirements laid down in this Regulation only under conditions of use, which could result from lawful and readily predictable human behaviour.

conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons, *in particular workers and users*, and, where appropriate, domestic animals and property and, where applicable, the environment. Machinery products covered by this Regulation should be considered as non-compliant with health and safety requirements laid down in this Regulation only under conditions of use, which could result from lawful and readily predictable human behaviour.

*Nevertheless, reasonable anticipation of potentially hazardous development and use should be foreseen to assess compliance with health and safety requirements.*

## Amendment 15

### Proposal for a regulation Recital 65

#### *Text proposed by the Commission*

(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.

#### *Amendment*

(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 *social partners and other experts*. 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.

## Amendment 16

**Proposal for a regulation**  
**Recital 66**

*Text proposed by the Commission*

(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission establishing technical specifications for the **essential** health and safety requirements, requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet the requirements for its notification and establishing whether a national measure in respect of compliant machinery which a Member State finds to pose a risk to health and safety of persons is justified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>14</sup>.

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<sup>14</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

**Amendment 17**

**Proposal for a regulation**  
**Recital 76**

*Text proposed by the Commission*

(76) It is necessary to provide **for** sufficient **time** for economic operators to comply with their obligations under this Regulation, and for Member States to set up the administrative infrastructure necessary for its application. **The application of this Regulation should**

*Amendment*

(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission establishing technical specifications for the health and safety requirements, requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet the requirements for its notification and establishing whether a national measure in respect of compliant machinery which a Member State finds to pose a risk to health and safety of persons, **in particular workers and users**, is justified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>14</sup>.

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<sup>14</sup> Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

*Amendment*

(76) It is necessary to provide **a** sufficient **and reasonable time frame** for economic operators to comply with their obligations under this Regulation, and for Member States to set up the administrative infrastructure necessary for its application.

*therefore be deferred,*

## **Amendment 18**

### **Proposal for a regulation**

#### **Recital 76 a (new)**

*Text proposed by the Commission*

*Amendment*

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

## **Amendment 19**

### **Proposal for a regulation**

#### **Article 1 – paragraph 1**

*Text proposed by the Commission*

*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.

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 protection for all workers and other users.***

## **Amendment 20**

### **Proposal for a regulation**

#### **Article 3 – paragraph 1 – point 1 a (new)**

*Text proposed by the Commission*

*Amendment*

***(1a) When machinery contains embedded software, preinstalled or installed subsequently, the latter shall be considered as an integrated part of the machinery;***

## Amendment 21

### Proposal for a regulation Article 4a – (new)

*Text proposed by the Commission*

*Amendment*

#### *Article 4a (new)*

##### *European Injury Database*

- 1. The Commission shall upgrade and extend the European Injury Database (IDB), to collect information on all type of injuries linked to machinery products covered by this regulation.*
- 2. The competent national authorities of Member States shall provide the Commission with the relevant data, in compliance with Union and national rules on data protection.*
- 3. The Commission shall establish a common methodology for the collection of the data.*

## Amendment 22

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

*Text proposed by the Commission*

*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 **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 23

**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), the Machinery Administrative Cooperation Group reporting **and the European Injury Database**.

**Amendment 24**

**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, including social partners in this context.**

**Amendment 25**

**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 may lay down requirements, **including those concerning the availability of training sessions, sufficient resources and equipment**, 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 26

### Proposal for a regulation Annex I – point 24 a (new)

*Text proposed by the Commission*

*Amendment*

**24a. Safety component with fully or partially evolving behaviour or logic.**

## Amendment 27

### Proposal for a regulation Annex I – point 25

*Text proposed by the Commission*

*Amendment*

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

25. Machinery embedding **a component** ensuring safety functions **with fully or partially evolving behaviour or logic**.

## Amendment 28

### Proposal for a regulation Annex III – point 1 – paragraph 2 – point c

*Text proposed by the Commission*

*Amendment*

(c) identify the hazards that may be generated by the machinery product and the associated hazardous situations, including hazards that may be generated during the lifecycle of the machinery product that are foreseeable at the time of placing of the machinery product on the market as an intended evolution of its fully or partially evolving behaviour or logic as a result of the machinery product designed to operate with varying levels of autonomy. In this respect, where the machinery product integrates an artificial intelligence system, the machinery risk assessment shall consider the risk assessment for that

(c) identify the hazards that may be generated by the machinery product and the associated hazardous situations, including hazards that may be generated during the lifecycle of the machinery product that are foreseeable at the time of placing of the machinery product on the market as an intended evolution of its fully or partially evolving behaviour or logic as a result of the machinery product designed to operate **based on machine learning technologies, potentially** with varying levels of autonomy. In this respect, where the machinery product integrates an artificial intelligence system, the

artificial intelligence system that has been carried out pursuant to the Regulation ... of the European Parliament and of the Council+ on a European approach for Artificial Intelligence+<sup>30</sup> ; .

machinery risk assessment shall consider the risk assessment for that artificial intelligence system that has been carried out pursuant to the Regulation ... of the European Parliament and of the Council+ on a European approach for Artificial Intelligence+<sup>30</sup> ; .

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<sup>30</sup> + OJ: Please insert in the text the number of the Regulation contained in document ... and insert the number, date, title and OJ reference of that Regulation in the footnote

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<sup>30</sup> + OJ: Please insert in the text the number of the Regulation contained in document ... and insert the number, date, title and OJ reference of that Regulation in the footnote

## Amendment 29

### Proposal for a regulation Annex III – point 1 – paragraph 2 – point d

*Text proposed by the Commission*

(d) estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence;

*Amendment*

(d) estimate the risks, taking into account the severity of the possible injury or damage to health, ***including mental health***, and the probability of its occurrence;

## Amendment 30

### Proposal for a regulation Annex III – point 1 – paragraph 2 – point f

*Text proposed by the Commission*

(f) eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).

*Amendment*

(f) eliminate the hazards or ***sufficiently*** reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).

## Amendment 31

### Proposal for a regulation Annex III – Part 1 – point 1.1. – point 1.1.1. – paragraph 1 – point a



*Text proposed by the Commission*

*Amendment*

(a) ‘hazard’ means a potential source of injury or damage to health;

(a) ‘hazard’ means a potential source of injury or damage to health, ***including mental health***;

**Amendment 32**

**Proposal for a regulation**

**Annex III – Part 1 – point 1.1. – point 1.1.2. – point a**

*Text proposed by the Commission*

*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 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.

(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*** but also taking into account any reasonably foreseeable misuse thereof. The aim of protective measures shall be to eliminate any risk throughout the foreseeable ***lifecycle*** of the machinery product including the phases of transport, assembly, dismantling, disabling and scrapping.

**Amendment 33**

**Proposal for a regulation**

**Annex III – Part 1 – point 1.1. – point 1.1.2. – point e a (new)**

*Text proposed by the Commission*

*Amendment*

***(ea) The provisions set out in this Annex must be implemented and interpreted with the concurrence of the European Agency for Safety and Health at work (EU-OSHA) in a way that fully secures the health and safety of workers or machinery products operators. Manufacturers and suppliers of the machinery products must always aim to provide the highest possible OHS standards in order to ensure accident prevention and safe use of machinery***

***products. Machinery product operators must be provided with adequate protective equipment to ensure safe use and maintenance.***

#### **Amendment 34**

##### **Proposal for a regulation**

##### **Annex III – Part 1 – point 1.1. – point 1.1.6. – paragraph 1 – introductory part**

*Text proposed by the Commission*

*Amendment*

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 or*** reduced to the minimum possible, taking into account ergonomic principles such as:

#### **Amendment 35**

##### **Proposal for a regulation**

##### **Annex III – Part 1 – point 1.1. – point 1.1.6. – paragraph 1 – point c**

*Text proposed by the Commission*

*Amendment*

(c) ***avoiding*** a machine-determined work rate;

(c) ***preventing*** a machine-determined work rate ***by allowing adaptations***;

#### **Amendment 36**

##### **Proposal for a regulation**

##### **Annex III – Part 1 – point 1.1. – point 1.1.6. – paragraph 1 – point d**

*Text proposed by the Commission*

*Amendment*

(d) ***avoiding*** monitoring that requires lengthy concentration;

(d) ***preventing*** monitoring that requires lengthy concentration;

#### **Amendment 37**

##### **Proposal for a regulation**

##### **Annex III – Part 1 – point 1.1. – point 1.1.6. – paragraph 1 – 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, ***including 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;

**Amendment 38**

**Proposal for a regulation**

**Annex III – Part 1 – point 1.1. – point 1.1.6. – paragraph 1 – 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 ***based on machine learning technologies, potentially*** 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 39**

**Proposal for a regulation**

**Annex III – Part 1 – point 1.1. – point 1.1.6. – paragraph 1 – point f a (new)**

*Text proposed by the Commission*

*Amendment*

***(fa) communicating a machinery product's planned actions (what it is going to do and why) to operators in a comprehensible manner.***

**Amendment 40**

## 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 *potentially* hazardous *situations*.

## Amendment 41

### 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 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.

## Amendment 42

### 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 and unintended external influences, including *predictable misuse* from third parties to create a *potentially* hazardous situation *or function*;

## Amendment 43

### 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 *its development based on machine learning*, which cannot go beyond the limits addressed in the risk assessment;

## Amendment 44

### 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*

(g) recording of data on the safety related *machine-learning* 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 45

### Proposal for a regulation

#### Annex III – Part 1 – point 1.2. – point 1.2.1. – paragraph 4 – point c

*Text proposed by the Commission*

*Amendment*

(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;

#### **Amendment 46**

##### **Proposal for a regulation**

##### **Annex III – Part 1 – point 1.3. – point 1.3.7. – title**

*Text proposed by the Commission*

*Amendment*

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

1.3.7. Risks related to moving parts, psychological stress ***and cognitive workload***

#### **Amendment 47**

##### **Proposal for a regulation**

##### **Annex III – Part 1 – point 1.3. – point 1.3.7. – paragraph 4 – introductory part**

*Text proposed by the Commission*

*Amendment*

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:

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

#### **Amendment 48**

##### **Proposal for a regulation**

##### **Annex III – Part 1 – point 1.3. – point 1.3.7. – paragraph 4 – point b**

*Text proposed by the Commission*

*Amendment*

(b) human-machine ***interaction***.

(b) ***direct*** human-machine ***collaboration in a shared space***.

## Amendment 49

### Proposal for a regulation

#### Annex III – Part 1 – point 1.5. – point 1.5.13. – paragraph 2

##### *Text proposed by the Commission*

Where a risk cannot be eliminated, the machinery product shall be so equipped that hazardous materials and substances can be contained, captured, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.

##### *Amendment*

Where a risk cannot be eliminated, the machinery product shall be so equipped that hazardous materials and substances can be contained, captured, evacuated, precipitated by water spraying, filtered or treated by another equally effective method. ***In cases where the use of external devices is not feasible, information on the use of appropriate personal protective equipment (PPE) shall be provided in the operating instructions.***

## Amendment 50

### 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*

The instructions ***shall*** be provided in a digital format ***over the entire lifecycle*** of the machinery product. ***However, under the purchaser's request***, the instructions shall be provided in paper format free of charge ***up to two years after the purchase of the machinery product.***

## Amendment 51

### 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

##### *Amendment*

(c) be presented in a format that makes it possible for the end user to download the instructions ***over the entire lifecycle of the machinery product*** and save them on an electronic device so that he or she can

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

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 52

### 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 entire lifecycle of the machinery product;***

## Amendment 53

### 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) 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. ***Machinery may only be equipped with a connection for an***



*exhaust system if it is intended for this kind of operation. In situations where the use of external devices is not feasible, information on the use of appropriate personal protective equipment (PPE) shall be provided in the operating instructions.*

## Amendment 54

### Proposal for a regulation Annex III – Part 3 – paragraph 1

*Text proposed by the Commission*

*Machinery presenting risks due to its mobility shall meet all the essential health and safety requirements described in this chapter (see General Principles, point 4).*

*Amendment*

The essential health and safety requirements *laid down* in this *Annex are mandatory. Machinery product shall be designed and constructed with the purpose of approaching those objectives.*

## Amendment 55

### 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.

## Amendment 56

### 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 machinery 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.

## Amendment 57

### Proposal for a regulation

#### Annex III – Part 3 – point 3.3. – point 3.3.3. – paragraph 6 – introductory part

*Text proposed by the Commission*

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

*Amendment*

Autonomous mobile machinery products shall comply with ***at least one*** of the ***two*** following conditions:

## PROCEDURE – COMMITTEE ASKED FOR OPINION

<b>Title</b>	Machinery products
<b>References</b>	COM(2021)0202 – C9-0145/2021 – 2021/0105(COD)
<b>Committee responsible</b> Date announced in plenary	IMCO 7.6.2021
<b>Opinion by</b> Date announced in plenary	EMPL 16.12.2021
<b>Rapporteur for the opinion</b> Date appointed	Marianne Vind 1.12.2021
<b>Discussed in committee</b>	13.1.2022
<b>Date adopted</b>	3.3.2022
<b>Result of final vote</b>	+: 51 –: 0 0: 2
<b>Members present for the final vote</b>	Atidzhe Alieva-Veli, Dominique Bilde, Gabriele Bischoff, Vilija Blinkevičiūtė, Milan Brglez, Sylvie Brunet, Jordi Cañas, David Casa, Leila Chaibi, Ilan De Basso, Margarita de la Pisa Carrión, Özlem Demirel, Jarosław Duda, Estrella Durá Ferrandis, Lucia Ďuriš Nicholsonová, Rosa Estaràs Ferragut, Nicolaus Fest, Loucas Fourlas, Cindy Franssen, Helmut Geuking, Elisabetta Gualmini, Alicia Homs Ginel, France Jamet, Agnes Jongerius, Radan Kanev, Ádám Kósa, Stelios Kympouropoulos, Katrin Langensiepen, Miriam Lexmann, Elena Lizzi, Giuseppe Milazzo, Kira Marie Peter-Hansen, Dragos Pişlaru, Manuel Pizarro, Dennis Radtke, Elżbieta Rafalska, Guido Reil, Daniela Rondinelli, Mounir Satouri, Monica Semedo, Michal Šimečka, Beata Szydło, Eugen Tomac, Romana Tomc, Marie-Pierre Vedrenne, Nikolaj Villumsen, Marianne Vind, Maria Walsh, Stefania Zambelli, Tatjana Ždanoka
<b>Substitutes present for the final vote</b>	Evelyn Regner, Eugenia Rodríguez Palop, Sara Skyttedal

## FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

51	+
ECR	Giuseppe Milazzo, Margarita de la Pisa Carrión, Elżbieta Rafalska, Beata Szydło
ID	Dominique Bilde, France Jamet, Elena Lizzi, Stefania Zambelli
NI	Ádám Kósa, Daniela Rondinelli
PPE	David Casa, Jarosław Duda, Rosa Estaràs Ferragut, Loucas Furlas, Cindy Franssen, Helmut Geuking, Radan Kanev, Stelios Kypourouopoulos, Miriam Lexmann, Dennis Radtke, Sara Skytvedal, Eugen Tomac, Romana Tomc, Maria Walsh
Renew	Atidzhe Alieva-Veli, Sylvie Brunet, Jordi Cañas, Lucia Ďuriš Nicholsonová, Dragoş Pîslaru, Monica Semedo, Michal Šimečka, Marie-Pierre Vedrenne
S&D	Gabriele Bischoff, Vilija Blinkevičiūtė, Milan Brglez, Ilan De Basso, Estrella Durá Ferrandis, Elisabetta Gualmini, Alicia Homs Giné, Agnes Jongerius, Manuel Pizarro, Evelyn Regner, Marianne Vind
The Left	Leila Chaibi, Özlem Demirel, Eugenia Rodríguez Palop, Nikolaj Villumsen
Verts/ALE	Katrin Langensiepen, Kira Marie Peter-Hansen, Mounir Satouri, Tatjana Ždanoka

0	-

2	0
ID	Nicolaus Fest, Guido Reil

Key to symbols:

+ : in favour

- : against

0 : abstention

## PROCEDURE – COMMITTEE RESPONSIBLE

<b>Title</b>	Machinery products			
<b>References</b>	COM(2021)0202 – C9-0145/2021 – 2021/0105(COD)			
<b>Date submitted to Parliament</b>	22.4.2021			
<b>Committee responsible</b> Date announced in plenary	IMCO 7.6.2021			
<b>Committees asked for opinions</b> Date announced in plenary	EMPL 16.12.2021			
<b>Rapporteurs</b> Date appointed	Ivan Štefanec 27.5.2021			
<b>Discussed in committee</b>	27.5.2021	28.10.2021	1.12.2021	28.2.2022
<b>Date adopted</b>	3.5.2022			
<b>Result of final vote</b>	+: –: 0:	38 7 0		
<b>Members present for the final vote</b>	Alex Agius Saliba, Andrus Ansip, Pablo Arias Echeverría, Brando Benifei, Adam Bielan, Hynek Blaško, Biljana Borzan, Markus Buchheit, Andrea Caroppo, Anna Cavazzini, Dita Charanzová, Deirdre Clune, David Cormand, Alexandra Geese, Sandro Gozi, Maria Grapini, Svenja Hahn, Krzysztof Hetman, Virginie Joron, Eugen Jurzyca, Kateřina Konečná, Andrey Kovatchev, Jean-Lin Lacapelle, Maria-Manuel Leitão-Marques, Morten Løkkegaard, Adriana Maldonado López, Antonius Manders, Leszek Miller, Anne-Sophie Pelletier, Miroslav Radačovský, René Repasi, Christel Schaldemose, Andreas Schwab, Tomislav Sokol, Ivan Štefanec, Róza Thun und Hohenstein, Kim Van Sparrentak, Marion Walsmann, Marco Zullo			
<b>Substitutes present for the final vote</b>	Anna-Michelle Asimakopoulou, Marco Campomenosi, Maria da Graça Carvalho, Carlo Fidanza, Francisco Guerreiro, Kosma Złotowski			
<b>Date tabled</b>	5.5.2022			

## FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

38	+
ECR	Adam Bielan, Carlo Fidanza, Eugen Jurzyca, Kosma Złotowski
ID	Hynek Blaško, Markus Buchheit, Marco Campomenosi, Virginie Joron, Jean-Lin Lacapelle
NI	Miroslav Radačovský
PPE	Pablo Arias Echeverría, Anna-Michelle Asimakopoulou, Andrea Caroppo, Maria da Graça Carvalho, Deirdre Clune, Krzysztof Hetman, Andrey Kovatchev, Antonius Manders, Andreas Schwab, Tomislav Sokol, Ivan Štefanec, Marion Walsmann
Renew	Sandro Gozi, Róza Thun und Hohenstein
S&D	Alex Agius Saliba, Brando Benifei, Biljana Borzan, Maria Grapini, Maria-Manuel Leitão-Marques, Adriana Maldonado López, Leszek Miller, René Repasi, Christel Schaldemose
Verts/ALE	Anna Cavazzini, David Cormand, Alexandra Geese, Francisco Guerreiro, Kim Van Sparrentak

  

7	-
Renew	Andrus Ansip, Dita Charanzová, Svenja Hahn, Morten Løkkegaard, Marco Zullo
The Left	Kateřina Konečná, Anne-Sophie Pelletier

  

0	0

Key to symbols:

+ : in favour

- : against

0 : abstention