



**2021/0105(COD)**

20.10.2021

**\*\*\*I**

## **DRAFT 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 Rule 59 of its Rules of Procedure,
  - having regard to the report of the Committee on the Internal Market and Consumer Protection (A9-0000/2021),
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)**

*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. Directive 2006/42/EC is listed**

*among the Union harmonisation legislation to which Article 4 applies. Therefore, machinery products covered by this Regulation may 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(3) of Regulation (EU) No 2019/1020 in respect of that product.*

Or. en

## Amendment 2

### 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.

##### *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 *of which the* only objective is the mere transport of goods, persons *or animals* on road, by air, on water or on rail networks, regardless of the speed limits. However, machinery mounted on such vehicles or mobile machinery intended for facilitating works such as in construction sites or warehouses e.g. dumpers and forklifts, have a machinery function and should therefore be covered by this Regulation. ***Equally, non-type-approved, off-road and competition vehicles, as well as e-bikes, e-scooters and similar means of transport should be covered by this Regulation.*** Since agricultural and forestry vehicles and two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment designed and constructed for such vehicles, fall within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council<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).

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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).

Or. en

### Amendment 3

#### 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

*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 153, 22.5.2014, p. 62).

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 153, 22.5.2014, p. 62).

Or. en

#### Amendment 4

##### 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

###### *Amendment*

(19) Where machinery products pose risks that are addressed by the essential health and safety requirements set out in this Regulation but are also wholly or partly covered by other more specific Union legislation, this Regulation should not apply to the extent that those risks are covered by that other Union legislation. In other cases, machinery products may pose risks that are not covered by the essential health and safety requirements set out in this Regulation. For example, machinery products incorporating a Wi-Fi function or an artificial intelligence system may pose risks not addressed by the essential health and safety requirements set out in this Regulation, as this Regulation does not deal with risks specific to such systems. For artificial intelligence systems, the specific Union legislation on artificial intelligence should apply, since it contains specific safety requirements for **potentially** high-risk artificial intelligence systems. In order to avoid incoherence with regard to



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

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

Or. en

## Amendment 5

### 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 ***potentially*** high-risk machinery products. ***With a view to*** properly reflecting all ***potentially*** 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 ***potentially*** high risk machinery products.

Or. en

## Amendment 6

### Proposal for a regulation Recital 23

#### *Text proposed by the Commission*

(23) In order to ensure that machinery

#### *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.

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. ***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.

Or. en

## Amendment 7

### Proposal for a regulation

#### Recital 29

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

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

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

Or. en

## Amendment 8

### Proposal for a regulation Recital 31

*Text proposed by the Commission*

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

*Amendment*

(31) It is essential that, before drawing up the EU declaration of conformity, the manufacturer prepares a technical *documentation* 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 this Regulation.

Or. en

## Amendment 9

### 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

*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

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.

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.

Or. en

## Amendment 10

### 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 required.

Or. en

## Amendment 11

### 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 ***potentially*** high-risk machinery products and the indicative list of safety components. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

Or. en

**Amendment 12**

**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) ***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,*** which have as their only objective the transport of goods, persons *or animals* by road, air, water or rail.

Or. en

## Amendment 13

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 1 – point d

*Text proposed by the Commission*

(d) assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point (7) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;

*Amendment*

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

Or. en

## Amendment 14

### Proposal for a regulation

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

*Text proposed by the Commission*

*Amendment*

***(1 a) ‘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’, as defined in this Regulation;***

Or. en

## Amendment 15

### 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

*Amendment*

(2) ‘interchangeable equipment’ means a device which, after the putting into service of machinery, is assembled with that machinery by the operator himself in



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;

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

Or. en

## Amendment 16

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

#### *Text proposed by the Commission*

(3) ‘safety component’ means a physical or digital component, including software, **of** machinery which **serves** to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endangers the safety of persons but which is not necessary in order for the machinery to function or may be substituted by normal components in order for the machinery to function;

#### *Amendment*

(3) ‘safety component’ means a physical or digital component, including software, **a** machinery **product** which **is designed or intended** to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endangers the safety of persons but which is not necessary in order for the machinery to function or may be substituted by normal components in order for the machinery to function;

Or. en

## Amendment 17

### 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*

(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;

Or. en



## Amendment 18

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 19

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

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 20

### 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

*Amendment*

(17) ‘manufacturer’ means any natural or legal person who manufactures

machinery products or who has machinery products designed or manufactured, and markets those machinery products under his or her name or trademark or who designs **and** constructs machinery products for his or her own use;

machinery products **or puts machinery products into service**, or who has machinery products designed or manufactured, and markets those machinery products under his or her name or trademark or who designs, constructs **and uses** machinery products for his or her own use;

Or. en

## Amendment 21

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 18

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

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

##### *Amendment*

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

Or. en

## Amendment 22

### Proposal for a regulation

#### Article 3 – paragraph 1 – point 28

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

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

##### *Amendment*

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

*machinery*, have been fulfilled;

Or. en

### **Amendment 23**

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

#### **Article 3 – paragraph 1 – point 33 a (new)**

*Text proposed by the Commission*

*Amendment*

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

Or. en

### **Amendment 24**

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

#### **Article 3 – paragraph 1 – point 33 b (new)**

*Text proposed by the Commission*

*Amendment*

***(33 b) ‘technical documentation’ means documentation that makes it possible to assess whether the machinery is in conformity with the relevant requirements, including documentation containing an analysis and assessment of risks;***

Or. en

### **Amendment 25**

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

#### **Article 3 – paragraph 1 – point 33 c (new)**

*Text proposed by the Commission*

*Amendment*

***(33 c) ‘lifecycle’ means the entire period during which a machinery product is***

*capable of being used, including after it has been physically or digitally modified.*

Or. en

## **Amendment 26**

### **Proposal for a regulation**

#### **Article 5 – title**

*Text proposed by the Commission*

High-risk machinery products

*Amendment*

**Potentially** high-risk machinery products

Or. en

## **Amendment 27**

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

Or. en

## **Amendment 28**

### **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

*Amendment*

2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I in view of technical progress and knowledge or new scientific evidence by including in the list of **potentially** high-risk machinery products

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

a new machinery product or withdrawing an existing machinery product from that list, pursuant to the criteria laid down in paragraphs 3 and 4. ***The delegated acts including a new machinery product in the list shall not apply earlier than 36 months after their entry into force.***

Or. en

## Amendment 29

### 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 the severity of that harm.

*Amendment*

3. A machinery product shall be included in the list of ***potentially*** high-risk machinery products in Annex I if it poses a ***high*** risk to human health taking into account its design, intended purpose ***and foreseeable use***. A machinery product shall be withdrawn from the list of ***potentially*** 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.

Or. en

## Amendment 30

### 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

*Amendment*

(d) statistics on accidents caused by the machinery product for the preceding four years based, in particular information obtained from the Information and Communication System for Market

Surveillance (ICSMS) information, safeguard clauses, Rapid Alert System (RAPEX) and the Machinery Administrative Cooperation Group reporting.

Surveillance (ICSMS) information, safeguard clauses, Rapid Alert System (RAPEX), **European Injury Database (EU-IDB)** and the Machinery Administrative Cooperation Group reporting.

Or. en

## Amendment 31

### 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 essential health and safety requirements set out in Annex III with which the manufacturer has declared, in the EU declaration of incorporation, that the partly completed machinery conforms.***

Or. en

## Amendment 32

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

*Text proposed by the Commission*

*Amendment*

***The health and safety requirements covered by the other more specific Union harmonisation legislation shall be checked as part of the conformity assessment procedure set out in this Regulation.***

Or. en

## Amendment 33

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

*Text proposed by the Commission*

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.

*Amendment*

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.

Or. en

## Amendment 34

### 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.

Or. en

## Amendment 35

### 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

*Amendment*

3. Manufacturers shall keep the technical documentation and the EU declaration of conformity ***in paper or electronic form***, where relevant, at the

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.

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

Or. en

## **Amendment 36**

### **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*** 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.

Or. en

## **Amendment 37**

### **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

#### *Amendment*

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.

*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.

Or. en

## Amendment 38

### 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 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.

#### *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 *or put into service* to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

Or. en

## Amendment 39

### 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**

Or. en

## Amendment 40

### Proposal for a regulation

#### Article 17 – paragraph 3 – point b

*Text proposed by the Commission*

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

*Amendment*

(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements and ***the requested standard has not been developed within 3 years following the standardisation request***, or the request has not been accepted by any of the European standardisation organisations

Or. en

## Amendment 41

### 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 in the future, the relevant technical specifications shall no longer apply.*

Or. en

## Amendment 42

### 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 *establish* the conformity of a machinery product with this Regulation, the manufacturer and the person who has carried out a substantial modification to the machinery product, shall apply one of the procedures for assessment of conformity referred to in paragraphs 2 and 3.

Or. en

## Amendment 43

### 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 *potentially* high-risk machinery product listed in Annex I, the manufacturer and the person who has carried out a substantial modification to the machinery product shall apply one of the following procedures:

Or. en

## Amendment 44

### Proposal for a regulation

#### Article 21 – paragraph 2 – point -a (new)

*Text proposed by the Commission*

*Amendment*

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

Or. en

## Amendment 45

### Proposal for a regulation

#### Article 21 – paragraph 3

*Text proposed by the Commission*

*Amendment*

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.

3. Where the machinery product is not a ***potentially*** high-risk 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.

Or. en

## Amendment 46

### Proposal for a regulation

#### Article 21 – paragraph 4

*Text proposed by the Commission*

*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 ***and reduce those fees proportionately to***

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.

*their specific interests and needs.*

Or. en

#### **Amendment 47**

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

*Text proposed by the Commission*

*Amendment*

**Conformity assessment** procedures for partly completed machinery

Procedures for partly completed machinery

Or. en

#### **Amendment 48**

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

*Text proposed by the Commission*

*Amendment*

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:

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 digital or paper form**:

Or. en

#### **Amendment 49**

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

*Text proposed by the Commission*

*Amendment*

2. Where relevant, the manufacturer of partly completed machinery **or the manufacturer's authorised representative** shall make available to the competent

2. Where relevant, the manufacturer of partly completed machinery shall make available to the competent national authority upon its request the source code

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.

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.

Or. en

## Amendment 50

### 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.

Or. en

## Amendment 51

### Proposal for a regulation

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

*Text proposed by the Commission*

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*

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 appropriate ***and proportionate*** corrective action, ***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.

Or. en

## Amendment 52

### 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*

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.

Or. en

## Amendment 53

### 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.**

*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 persists,** the market surveillance authorities shall **ensure that** the machinery product **concerned is withdrawn or recalled, or that its** being made available on **the** market **is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly.**

Or. en

**Amendment 54**

**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**

Or. en

**Amendment 55**

**Proposal for a regulation**

**Article 41 – paragraph 5 – introductory part**

*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

*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



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:

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:

Or. en

## **Amendment 56**

### **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.

Or. en

## **Amendment 57**

### **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].

Or. en

## Amendment 58

### Proposal for a regulation Article 50 – paragraph 1

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 59

### Proposal for a regulation Article 50 – paragraph 2

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 60

### Proposal for a regulation Article 51 – paragraph 1

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 61

### 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 **potentially** high-risk machinery products listed in Annex I.

Or. en

## Amendment 62

### 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].

Or. en

## Amendment 63

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

*Text proposed by the Commission*

HIGH-RISK MACHINERY PRODUCTS

*Amendment*

**POTENTIALLY** HIGH-RISK  
MACHINERY PRODUCTS

Or. en

## Amendment 64

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

*Text proposed by the Commission*

24. Software ensuring safety functions, including AI systems.

*Amendment*

24. **The safety component of** software ensuring safety functions, including **of** AI systems.

Or. en

## Amendment 65

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

*Text proposed by the Commission*

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

*Amendment*

25. AI systems ensuring safety functions **and embedded in machinery**.

Or. en

## Amendment 66

### Proposal for a regulation Annex III – point 1 – subparagraph 1

*Text proposed by the Commission*

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.

*Amendment*

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

Or. en

**Amendment 67**

**Proposal for a regulation  
Annex III – point 1 –subparagraph 2**

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

**Amendment 68**

**Proposal for a regulation  
Annex III – point 1 – subparagraph 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 reduce ***sufficiently*** the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b).

Or. en

## Amendment 69

### Proposal for a regulation Annex III – point 2

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 70

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

*Text proposed by the Commission*

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

*Amendment*

(a) A machinery product shall be designed and constructed so that it is fit for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions **and the use** 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 **lifecycle** of the machinery product including the phases of transport, assembly, dismantling, disabling and scrapping.

## Amendment 71

### 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 72

### 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 73

### Proposal for a regulation

#### Annex III – Part 1 – point 1.1 – point 1.1.5 – paragraph 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.

Or. en

## Amendment 74

### Proposal for a regulation

#### Annex III – Part 1 – point 1.1 – point 1.1.7 – paragraph 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.

Or. en

## Amendment 75

### Proposal for a regulation

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

##### *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



different from the usual exit.

from the usual exit.

Or. en

## **Amendment 76**

### **Proposal for a regulation**

#### **Annex III – Part 1 – point 1.3 – point 1.3.2 – paragraph 4**

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

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.

##### *Amendment*

Where a risk of rupture or disintegration remains despite the measures taken, the parts concerned shall be mounted, positioned *or* guarded in such a way that any fragments will be contained, preventing hazardous situations.

Or. en

## **Amendment 77**

### **Proposal for a regulation**

#### **Annex III – Part 1 – point 1.5 – point 1.5.1 – paragraph 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.

Or. en

## **Amendment 78**

### **Proposal for a regulation**

#### **Annex III – Part 1 – point 1.5 – point 1.5.4 – paragraph 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.

Or. en

**Amendment 79**

**Proposal for a regulation**

**Annex III – Part 1 – point 1.7 – point 1.7.4 – paragraph 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.

Or. en

**Amendment 80**

**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.

Or. en

## **Amendment 81**

### **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;***

Or. en

## **Amendment 82**

### **Proposal for a regulation**

#### **Annex III – Part 2 – point 2.2 – title**

##### *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

Or. en

## Amendment 83

### Proposal for a regulation

#### Annex III – Part 2 – point 2.2 – point 2.2.1 – paragraph 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:

Or. en

## Amendment 84

### Proposal for a regulation

#### Annex III – Part 2 – point 2.2 – point 2.2.1 – paragraph 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;

Or. en

## Amendment 85

### 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***

*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.

*designed and constructed in such a way as to make starting and stopping straightforward.*

Or. en

## Amendment 86

### Proposal for a regulation

#### Annex III – Part 2 – point 2.2 – point 2.2.1 – paragraph 1 – point f (new)

*Text proposed by the Commission*

*Amendment*

**(f) *The handles of portable machinery shall be designed and constructed in such a way as to make starting and stopping that machinery straight forward.***

Or. en

## Amendment 87

### Proposal for a regulation

#### Annex III – Part 3 – point 3.2 – point 3.2.4 – paragraph 1

*Text proposed by the Commission*

*Amendment*

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

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

Or. en

## Amendment 88

### Proposal for a regulation

#### Annex III – Part 3 – point 3.2 – point 3.2.4 – paragraph 2

*Text proposed by the Commission*

*Amendment*

*The information the driver receives from the machine when the supervisory control function is active shall enable the driver to have a complete and accurate view of the operation, movement and safe positioning of the machine in its travel and working area.* *deleted*

Or. en

## Amendment 89

### Proposal for a regulation

#### Annex III – Part 3 – point 3.2 – point 3.2.4 – paragraph 3

*Text proposed by the Commission*

*Amendment*

*This information shall alert the driver of the occurrence of unforeseen or dangerous situations present or impending, which require driver's intervention.* *deleted*

Or. en

## Amendment 90

### Proposal for a regulation

#### Annex III – Part 3 – point 3.2 – point 3.2.4 – paragraph 4

*Text proposed by the Commission*

*Amendment*

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

Or. en

## Amendment 91

### Proposal for a regulation

#### Annex III – Part 4 – point 4.1 – point 4.1.2 – point 4.1.2.3 – paragraph 1

*Text proposed by the Commission*

Machinery, lifting accessories and their components shall be capable of withstanding the stresses to which they are subjected during their **lifetime**, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement shall also be satisfied during transport, assembly and dismantling.

*Amendment*

Machinery, lifting accessories and their components shall be capable of withstanding the stresses to which they are subjected during their **lifecycle**, both in and, where applicable, out of use, under the installation and operating conditions provided for and in all relevant configurations, with due regard, where appropriate, to the effects of atmospheric factors and forces exerted by persons. This requirement shall also be satisfied during transport, assembly and dismantling.

Or. en

## Amendment 92

### Proposal for a regulation

#### Annex IV – Part A – paragraph 2 – point 1

*Text proposed by the Commission*

**(l) where appropriate, the declaration of incorporation for partly completed machinery set out in Annex V and the relevant assembly instructions for such machinery;**

*Amendment*

**deleted**

Or. en

## Amendment 93

### Proposal for a regulation

#### Annex IV – Part B – paragraph 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**;

Or. en

## **Amendment 94**

### **Proposal for a regulation**

#### **Annex IV – Part B – paragraph 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** section 1.7.4 **in Annex X**;

Or. en

## **Amendment 95**

### **Proposal for a regulation**

#### **Annex IV – Part B – paragraph 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;

Or. en



## Amendment 96

### Proposal for a regulation

#### Annex IX – point 3 – point 3.3 – paragraph 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.

Or. en

## Amendment 97

### Proposal for a regulation

#### Annex IX – point 5 – Title

*Text proposed by the Commission*

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

*Amendment*

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

Or. en

## Amendment 98

### 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 to each individual **machinery** product that **is in conformity with the type described in the EU type-examination certificate and that** satisfies the applicable requirements of this Regulation.

Or. en

## **Amendment 99**

### **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.

Or. en

## **Amendment 100**

### **Proposal for a regulation Annex IX – point 5 – paragraph 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.

Or. en

## 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.