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2021/0105 (COD)**

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**NOTE**

From:	General Secretariat of the Council
To:	Working Party on Technical Harmonisation (Machinery)
Subject:	Machinery Regulation - Consolidated comments from CZ, DK, ES, FI, IT, MT, SE, PT on the FR Presidency compromise of 25.02.2022

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
2021/0105 (COD)		
Proposal for a		
REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL		
on machinery products		
(Text with EEA relevance)		
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,		
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Having regard to the proposal from the European Commission,		
After transmission of the draft legislative act to the national parliaments,		
Having regard to the opinion of the European Economic and Social Committee <sup>1</sup> ,		
Acting in accordance with the ordinary legislative procedure,		
Whereas:		
(1) Directive 2006/42/EC <sup>2</sup> of the European Parliament and of the Council was adopted in		

<sup>1</sup> OJ C [...], [...], p. [...].

<sup>2</sup> Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
the context of establishing the internal market, in order to harmonise health and safety requirements for machinery in all Member States and to remove obstacles to trade in machinery between Member States.		
(2) The machinery sector is an important part of the engineering industry and is one of the industrial mainstays of the Union economy. The social cost of the large number of accidents caused directly by the use of machinery can be reduced by inherently safe design and construction of machinery and by proper installation and maintenance. <b><u>In particular, the proper installation of lifting machinery is essential to ensure the compliance with applicable essential health and safety requirements 4.1.3.</u></b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>(3) Experience with the application of Directive 2006/42/EC has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. It is therefore necessary to improve, simplify and adapt the provisions set out in that Directive to the needs of the market and provide clear rules in relation to the framework within which <del>machinery</del> products <b><u>subject to this Regulation</u></b> may be made available on the market. <b><u>In this respect, this Regulation makes a distinction between machinery, related products (interchangeable equipment; safety components, lifting accessories, chains, ropes and webbing; removable mechanical transmission devices) and partly completed</u></b></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>machinery which are all products subject to this Regulation.</u></b>		
(4) Since the rules setting out the requirements for <del>machinery</del> products <b><u>subject to this Regulation</u></b> , in particular the essential health and safety requirements and the conformity assessment procedures, need to be of uniform application for all operators across the Union, and not give room for divergent implementation by Member States, Directive 2006/42/EC should be replaced by a regulation.		
(5) Member States are responsible for protecting, on their territory, the health and safety of persons, in particular workers and		

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consumers, and,-where appropriate, domestic animals and property, notably in relation to the risks arising out of the <b><u>intended</u></b> use <b><u>or reasonably foreseeable misuse</u></b> of machinery <b><u>or related products, and, where applicable, the environment</u></b> . For the avoidance of doubt, domestic animals should be considered to include farm animals.		
(6) Regulation (EC) No 765/2008 of the European Parliament <sup>3</sup> lays down rules on the accreditation of conformity assessment bodies, <del>provides a framework for the market surveillance of products and for controls on products from third countries,</del> and lays down the general principles of the CE marking. That		

<sup>3</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

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Regulation should be applicable to <del>machinery</del> products <b><u>subject to</u></b> <del>covered by</del> this Regulation in order to ensure that those products, which are benefiting from the free movement of goods within the Union, fulfil requirements providing a high level of protection of public interests such as the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.		
(7) Regulation (EU) No 2019/1020 of the European Parliament and of the Council <sup>4</sup> sets out rules on market surveillance and control of products entering the Union market. <b><u>As Directive 2006/42/EC is listed in Annex I of</u></b>		

<sup>4</sup> Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L169, 25.6.2019, p. 1.)



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><b><u>Regulation (EU) No 2019/1020</u></b>, that Regulation already applies to <del>machinery</del> <b><u>products subject to this Regulation.</u></b></p> <p><b><u>However, Regulation (EU) No 2019/1020</u></b> <b><u>applies to products subject to this Regulation</u></b> <b><u>in so far as there are no specific provisions</u></b> <b><u>with the same objective, which regulate in a</u></b> <b><u>more specific manner particular aspects of</u></b> <b><u>market surveillance and enforcement.</u></b></p>		
<p><b><u>(7a) Regulation (EU) 2019/1020 imposes</u></b> <b><u>obligations on economic operators, in</u></b> <b><u>particular, fulfilment service providers,</u></b> <b><u>within the meaning of Regulation (EU) No</u></b> <b><u>2019/1020 which apply to the products</u></b> <b><u>subject to this Regulation.</u></b></p>		

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<p>(8) Decision No 768/2008/EC of the European Parliament and of the Council<sup>5</sup> lays down common principles and reference provisions intended to apply across sectoral legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the rules on presumption of conformity, the rules on EU declaration of conformity, the rules on CE marking, the requirements for conformity assessment bodies, the rules on notification procedures and conformity assessment</p>		

<sup>5</sup> Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.08.2008, p. 82).

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procedures and the rules on procedures to deal with machinery <b><u>or related</u></b> products <b><u>and, where applicable, with partly completed machinery,</u></b> presenting a risk should be adapted to the reference provisions laid down in that Decision.		
(9) This Regulation should cover <del>machinery</del> products which are new to the Union market when placed on the market, i.e. either new <del>machinery</del> products made by a manufacturer established in the Union or <del>machinery</del> products, whether new or second-hand, imported from a third country.		
(10) Where there is a possibility that the machinery <b><u>or related</u></b> products will be used by a consumer, that is to say, a non-professional operator, the manufacturer should take account		

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of the fact that the consumer does not have the same knowledge and experience with handling machinery <b><u>or related</u></b> products in the design and construction of the products. The same applies where a machinery <b><u>or related</u></b> product is normally used to provide a service to a consumer.		
(11) Recently, more advanced <del>machines</del> <b><u>machinery</u></b> , which <del>is</del> <b><u>are</u></b> less dependent on human operators, <del>have</del> <b><u>has</u></b> been introduced on the market. <b><u>Such machinery</u></b> <del>These machines,</del> <del>known as collaborative robots or cobots,</del> <b><u>are</u></b> <del>is</del> working on defined tasks and in structured environments, yet <del>they</del> <b><u>it</u></b> can learn to perform new actions in this context and become more autonomous. Further refinements to <b><u>machinery</u></b> <del>machines</del> , already in place or to be expected,		

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<p>include real-time processing of information, problem solving, mobility, sensor systems, learning, adaptability, and capability of operating in unstructured environments (e.g. construction sites). The Commission Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics<sup>6</sup>, states that the emergence of new digital technologies, like artificial intelligence, the Internet of things and robotics, raises new challenges in terms of product safety. The report concludes that the current product safety legislation, including Directive 2006/42/EC, contains a number of gaps in this respect that need to be addressed. Thus, this Regulation</p>		

<sup>6</sup> Report from the Commission to the European parliament, the Council and the European economic and social committee on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics (COM/2020/64 final)..

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should cover the safety risks stemming from new digital technologies.		
(12) In order to ensure protection of the health and safety of persons, <b><u>and, where appropriate,</u></b> domestic animals; <b><u>and</u></b> property and, where applicable, the environment, this Regulation should apply to all forms of supply of <del>machinery</del> products <b><u>subject to this Regulation,</u></b> including distance selling as referred to in Article 6 of Regulation (EU) 2019/1020.		
(13) In order to ensure legal certainty <del>for all users,</del> the scope of this Regulation should be set out in a clear manner and the concepts relating to its application should be defined as precisely as possible.		

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(14) In order to avoid legislating twice the same product, is appropriate to exclude from the scope of this Regulation weapons, including firearms that are subject to Directive (EU) 2017/853 of the European Parliament and of the Council <sup>7</sup> .		
(15) <b><u>The purpose of this Regulation is to address the risks stemming from the intended use of the machinery or related products and not from the transport of goods or persons. Consequently, this Regulation should not apply to means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of</u></b>		

<sup>7</sup> Directive (EU) 2017/853 of the European Parliament and of the Council of 17 May 2017 amending Council Directive 91/477/EEC on control of the acquisition and possession of weapons (OJ L 137, 24.5.2017, p.22).

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><b><u>transport. The means of transport on road that are not yet included in the scope of a specific Union legislation are regulated by this Regulation with the exception of the risks that may arise from the circulation of such means of transport on road. Since agricultural and forestry tractors and two- or three-wheel vehicles and quadricycles, and motor vehicles and their trailers, as well as systems, components, separate technical units, parts and equipment designed, constructed or intended for such vehicles, fall within the scope of Regulation (EU) No 167/2013 of the European Parliament and of the Council[1], Regulation (EU) No 168/2013 of the European Parliament and of the</u></b></p>		

[1] 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).



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>Council<sup>[2]</sup> or Regulation (EU) No 2018/858 of the European Parliament and of the Council [3] respectively, they should be excluded from the scope of this Regulation.</u></b>		
<p>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 forkmachinery or</p>		

<sup>[2]</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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<p><del>related products, 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>8</sup> and Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>9</sup> respectively, they should be excluded from the scope of this Regulation.</del></p>		

<sup>8</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>9</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).

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(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>10</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	IT:  (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>12</sup> and should therefore be excluded from the scope of this Regulation. <del>Some of those products are progressively incorporating Wi-Fi functions, e.g. washing machines, and are therefore</del>	IT:  It is suggest to clarify this sentence or to delete it because it could be misunderstood, in the sense that the presence of a Wifi would allow these products to be excluded from the machinery directive.

<sup>10</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>12</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).

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
European Parliament and of the Council <sup>11</sup> as radio equipment. Those products should also be excluded from the scope of this Regulation.	<del>covered by Directive 2014/53/EU of the European Parliament and of the Council<sup>13</sup> as radio equipment. Those products should also be excluded from the scope of this Regulation.</del>	
(17) The evolution of the machinery <b><u>field sector</u></b> has resulted in the growing use of digital means and software plays a more and more important role in the machinery design. Consequently, the definition of machinery should be adapted. In this respect, machinery missing only the upload of a software intended for the specific application <b><u>foreseen by the manufacturer and which is the subject of the conformity assessment procedure</u></b> of the		

<sup>11</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).

<sup>13</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).

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<p>machinery should fall under the definition of machinery and not under the definitions <u>of related products or</u> of partly completed machinery. Furthermore, the definition of safety components should cover not only physical devices but also digital devices. In order to take into account the increasing use of software as a safety component, software that performs a safety function and is placed independently on the market should be considered a safety component.</p>		
<p><b><u>(17a) Considering their critical protective function, certain components listed in Annex II should also be included in Annex I.</u></b></p>	<p>SE:</p> <p>(17a) Considering their critical protective function, certain components listed in Annex II <del>should</del><u>could</u> also be included in Annex I.</p>	<p>SE:</p> <p>We do not see any reason to prescribe that certain components listed in Annex II always has to be listed in Annex I. We suggest deleting recital (17a) or that "should" is replaced with "could" or "might".</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>(18) Partly completed machinery is a <del>machinery</del> product <b><u>subject to this Regulation</u></b> which must undergo further construction in order to be able to perform its specific application, i.e. the well-defined operations for which the <del>machinery</del> product is designed. It is not necessary that all requirements of this Regulation apply to partly completed machinery but in order to ensure the safety of the <del>machinery</del> product as a whole, it is nevertheless important that the free movement of such partly completed machinery be guaranteed by means of a specific procedure.</p>		
<p>(19) Where <del>machinery</del> products <b><u>subject to this Regulation present</u></b> pose risks that are addressed by the essential health and safety</p>		

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<p>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 <b><u>subject to this Regulation</u></b> may <del>pose</del> <b><u>present</u></b> 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 <del>pose</del> <b><u>present</u></b> 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</p>		

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<p>requirements for high-risk artificial intelligence systems. <b><u>In the specific case of the Union legislation on artificial intelligence,</u></b> <del>In</del> <b>in</b> order to avoid incoherence with regard to the type of conformity assessment and to avoid introducing requirements to perform two conformity assessments, those specific safety requirements should however be checked as part of the conformity assessment procedure set out in this Regulation. The essential health and safety requirements set out in this Regulation should in any case be applied in order to ensure, where applicable, the safe integration of the artificial intelligence system into the overall <b><u>product subject to this Regulation</u></b> <del>machinery</del>, so as not to compromise the safety of the <del>machinery</del> product as a whole.</p>		



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<p>(20) For trade fairs, exhibitions and similar events, it should be possible to exhibit <del>machinery</del> products <b><u>subject to this Regulation</u></b> which do not meet the requirements of this Regulation, since this would not pose <del>present</del> any safety risk. However, for the sake of transparency, interested parties should be properly informed that the <del>machinery</del> products <b><u>subject to this Regulation</u></b> are not compliant and cannot be purchased.</p>		
<p>(21) The evolution of the state of the art in the machinery <b><u>field</u></b> <del>sector</del> has an impact on the classification of high-risk machinery <b><u>or related</u></b> products. In view of properly reflecting all high-risk machinery <b><u>or related</u></b> products, criteria should be established for the assessment by the Commission of which <del>machinery</del> products</p>		

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should be included in the list of <b>potentially</b> high risk machinery <b><u>or related</u></b> products.		
<p>(22) Other risks related to new digital technologies are those provoked by malicious third parties that have an impact on the safety of <del>machinery</del> products <b><u>subject to this Regulation</u></b>.</p> <p>In this respect, manufacturers should be required to adopt proportionate measures which are limited to the protection of the safety of the <del>machinery</del> product <b><u>subject to this Regulation</u></b>.</p> <p>This does not preclude the application to <del>machinery</del> products <b><u>subject to this Regulation</u></b> of other Union legislation specifically addressing cybersecurity aspects.</p>		
(23) In order to ensure that machinery <b><u>or related</u></b> products, when placed on the market or		

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<p>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 <b><u>or related</u></b> products to be allowed on the market.</p> <p>Machinery or related products should comply with the essential health and safety requirements when placed on the market <b><u>and</u></b>/or put into service. Where such <del>machinery</del> products are subsequently modified, by physical or digital means, in a way that is not foreseen by the manufacturer and that may imply that <del>it</del> they no longer meets the relevant essential health and safety requirements, the modification should be considered as substantial. For example, <del>end-</del> <b><u>users</u></b> may upload software in a machinery <b><u>or</u></b></p>		

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<p><b><u>related</u></b> product that is not foreseen by the manufacturer and that may generate new risks. In order to ensure the compliance of such a <del>machinery</del> 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 <del>machinery</del> product on the market or putting it into service. That requirement should only apply with respect to the modified part of the machinery <b><u>or related</u></b> product, provided that the modification does not affect the machinery <b><u>or related</u></b> 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</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
aspects of the machinery- <b><u>or related</u></b> 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 <del>machinery</del> product as a whole.		
(24) In the machinery sector, around 98 % of the companies are small or medium sized enterprises (SMEs). In order to reduce the regulatory burden on SMEs, <b><u>it is important that</u></b> notified bodies <del>should</del> <b><u>consider</u></b> adapting the fees for conformity assessments and <del>reducing</del> <b><u>reducing</u></b> them proportionately to the specific interests and needs of SMEs.	<p><b>CZ:</b></p> <p><del>(24) In the machinery sector, around 98 % of the companies are small or medium sized enterprises (SMEs). In order to reduce the regulatory burden on SMEs, <b><u>it is important that</u></b> notified bodies should <b><u>consider</u></b> adapting the fees for conformity assessments and <del>reducing</del> <b><u>reducing</u></b> them proportionately to the specific interests and needs of SMEs.</del></p> <p>SE:</p>	<p><b>CZ:</b></p> <p>According to a discussion led on the meeting of the WG7 meeting on 15th of February, we support the deletion of this recital, as the conformity assessment fees are subject to private law relation between the manufacturer and the notified body, which should not be interfered in.</p> <p>SE:</p> <p>As has been discussed in the working party, we agree with those that have pointed out that it would be unfortunate to send signals implying</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p>We would prefer more neutral wording structured around concepts such as “<del>the importance of notified bodies taking the specificities and needs of SME’s into account</del>”</p> <p>PT:</p> <p><del>(24) In the machinery sector, around 98 % of the companies are small or medium-sized enterprises (SMEs). In order to reduce the regulatory burden on SMEs, it is important that notified bodies should consider adapting the fees for conformity assessments and reducing them proportionately to the specific interests and needs of SMEs.</del></p>	<p>notified bodies to adapt their fees when the applicable standards do not allow them to do so.</p> <p>PT:</p> <p><del>Instead of this, the recitals 50 and 51 of the Decision No 768/2008/EC of 9 July 2008 on a common framework for the marketing of products should be considered with the necessary adaptations.</del></p>
(25) Economic operators should be responsible for the compliance of machinery		

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<p>products <b><u>subject to this Regulation</u></b> with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as <b><u>protection of the health and safety of persons, where appropriate, domestic animals, property and, where applicable, the environment</u></b> <del>the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment</del>, as well as the fair competition on the Union market.</p>		
<p>(26) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only <del>machinery</del> products <b><u>subject to this Regulation</u></b>, which are</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
in conformity with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations, which correspond to the role of each economic operator in the supply and distribution chain.		
(27) In order to facilitate communication between economic operators, market surveillance authorities and users, Member States should encourage economic operators to include a <b><u>digital contact</u></b> <del>website address</del> in addition to the postal address.		
<b><u>(27a) A person who manufactures machinery or related products for his or her own use is considered as a manufacturer and must fulfil all the related obligations. In that case, the machinery or related product is not</u></b>		



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>placed on the market, since it is not made available by the manufacturer to another person but used by the manufacturer himself or herself. However, such machinery must comply with this Regulation before it is put into service.</u></b>		
(28) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.		
(29) The manufacturer <del>or the manufacturer's authorised representative</del> should also ensure that a risk assessment is carried out for the machinery product <b><u>subject to this Regulation</u></b> ,	IT:  (29) The manufacturer <del>or the manufacturer's authorised representative</del> should also ensure that	IT:  Artificial Intelligence is an innovative technology, whose paradigms and applications

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>which the manufacturer wishes to place on the market <b><u>or put into service</u></b>. For this purpose <b><u>In this context</u></b>, the manufacturer should determine which of the essential health and safety requirements that are applicable to the <del>machinery</del> product <b><u>subject to this Regulation</u></b> and in respect of which measures must be taken to address the risks that the <del>machinery</del> product may present. <b><u>The risk assessment should also address future updates or developments of a software installed in the machinery or related product, which are foreseen when the machinery or related product is placed on the market or put into service.</u></b> Where the <del>machinery</del> product <b><u>subject to this Regulation</u></b> integrates an artificial intelligence system, the risks identified during the risk assessment should include those risks that may appear</p>	<p>a risk assessment is carried out for the <del>machinery</del> product <b><u>subject to this Regulation</u></b>, which the manufacturer wishes to place on the market <b><u>or put into service</u></b>. For this purpose <b><u>In this context</u></b>, the manufacturer should determine which of the essential health and safety requirements that are applicable to the <del>machinery</del> product <b><u>subject to this Regulation</u></b> and in respect of which measures must be taken to address the risks that the <del>machinery</del> product may present. <b><u>The risk assessment should also address future updates or developments of a software installed in the machinery or related product, which are foreseen when the machinery or related product is placed on the market or put into service.</u></b> Where the <del>machinery</del> product <b><u>subject to this Regulation</u></b> integrates an artificial intelligence system, <b><u>an</u></b></p>	<p>are rapidly changing and expanding. For this reason, the AI legislation and the AI standards are expected to be subjected to a large integration and modification within the timeframe in which Machinery Regulation will be in force. So, should be useful a guideline (which is a more “dynamic” document than the Regulation) that considers the AI evolutions and applications related to machinery. Therefore, similarly to current Machine Directive, also for the AI legislation could be included a guideline.</p>

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<p>during the <del>machinery</del> product's lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy. In this respect, where the <del>machinery</del> product <b><u>subject to this Regulation</u></b> integrates an artificial intelligence system, the risk assessment for the <del>machinery</del> 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>+</sup>.</p>	<p><u>appropriate guideline will be developed, in order to correctly evaluate possible further risks</u> <del>the risks identified during the risk assessment should include those risks</del> that may appear during the <del>machinery</del> product's lifecycle due to an intended evolution of its behaviour to operate with varying levels of autonomy. In this respect, where the <del>machinery</del> product <b><u>subject to this Regulation</u></b> integrates an artificial intelligence system, <u>the guideline, defining the risk assessment procedures</u> for the <del>machinery</del> product <u>including AI</u> should <u>also</u> consider the risk assessment <u>(and related terminology and risk levels)</u> for that artificial intelligence system that has been carried out pursuant to Regulation</p>	

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

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	(EU) .../... of the European Parliament and of the Council+.	
<p>(30) The safety of the <del>integral</del> <b><u>entire</u></b> machinery <b><u>or related</u></b> product relies on the dependencies and interactions between its components <del>and</del>, <b><u>including</u></b> partly completed machinery, and <del>individual</del>, <b><u>if relevant, with other a</u></b> machinery <b><u>or related</u></b> product that participate in a coordinated assembly of a machinery system, <b><u>which can also result in an assembly of machinery</u></b>. Therefore, manufacturers should be required to assess all those interactions in the risk assessment. <del>The risk assessment should also address future updates or developments of a software installed in the machinery</del> <b><u>or related</u></b> product, which are</p>		

+ OJ: Please insert in the text the number of the Regulation contained in document ... .

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<del>foreseen when the machinery <u>or related</u> product is placed on the market <u>or put into service</u>.</del>		
<p><b><u>(30a) The manufacturer should ensure that distributors can provide, upon request of the purchaser at the time of the purchase or up to [XX years], the instructions in a paper format free of charge.</u></b></p>	<p>IT:</p> <p><b><u>(30a) The manufacturer should ensure that distributors can provide, upon request of the purchaser at the time of the purchase <del>or up to [XX years]</del>, the instructions in a paper format free of charge.</u></b></p>	<p>IT:</p> <p>It is important that the instruction in paper format is provided at the time of the purchase. However, appears not reasonable that the manufacturer should ensure that the distributors can provides paper instruction up to XX years because the distributor may no longer exist or have no relationship with the manufacturer.</p>
<p>(31) It is essential that, before drawing up the EU declaration of conformity <b><u>or the EU declaration of incorporation</u></b>, the manufacturer <del>or the manufacturer's authorised representative established in the Union</del> prepares a technical <b><u>documentation</u></b> construction file, which <del>they</del> <b><u>the manufacturer</u></b> should be required to make</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>available to national authorities <del>or notified bodies</del> on request <b><u>or to notified bodies in the frame of the relevant conformity assessment procedure</u></b>. Detailed plans of subassemblies used for the manufacture of the <del>machinery</del> product <b><u>subject to this Regulation</u></b> should only be required as part of the technical <b><u>documentation</u></b> <del>construction file</del> where knowledge of such plans is essential for assessing conformity with the essential health and safety requirements set out in this Regulation.</p>		
<p>(32) It is necessary to ensure that <del>machinery</del> products <b><u>subject to this Regulation</u></b> from third countries entering the Union market comply with the requirements of this Regulation and do not <b><u>present</u></b> <del>pose</del> a risk to the health and safety</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>of persons, where appropriate, domestic animals and property and, where applicable, the environment, and in particular, that appropriate conformity assessment procedures have been carried out by manufacturers with regard to such <del>machinery</del> products. Provision should therefore be made for importers to ensure that <del>machinery</del> products <b><u>subject to this Regulation</u></b> that they place on the market comply with the requirements of this Regulation and do not <b><u>present</u></b> pose a risk to the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment. For the same reason, provision should also be made for importers to ensure that the conformity assessment procedures have been carried out and that the CE marking, <b><u>where relevant</u></b>, and technical documentation</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
drawn up by manufacturers are available for inspection by the competent national authorities.		
<p><del>(32a) When deemed appropriate manufacturers and/or importers may consider testing products subject to this Regulation for health and safety reasons after they have been placed on the market and/or put into service, either because of a suspicion of non-compliance or due to the characteristics of the products, such as the evolving capacities during the life cycle.</del></p>		
(33) As the distributor makes machinery products <b><u>subject to this Regulation</u></b> available on the market after they have been placed on the		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
market by the manufacturer or the importer, the distributor should act with due care to ensure that his or her handling of the <del>machinery</del> product <b><u>subject to this Regulation</u></b> does not adversely affect its compliance with the requirements set out in this Regulation.		
(34) When placing <del>machinery</del> products <b><u>subject to this Regulation</u></b> on the market, the importer should indicate on the <del>machinery</del> product <b><u>subject to this Regulation</u></b> his or her name, registered trade name or registered trade mark and the postal address at which he or she can be contacted. Exceptions should be provided for in cases where the size or nature of the <del>machinery</del> product does not allow it. This includes cases where the importer would have to		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
open the packaging to put his or her name and address on the <del>machinery</del> product.		
<p>(35) In view of ensuring the health and safety of the users of <del>the machinery</del> products <b><u>subject to this Regulation</u></b>, economic operators should ensure that all relevant documentation, such as the <del>user's</del> instructions, whilst containing precise and comprehensible information, is easily understandable, takes into account technological developments and changes to <del>end</del>-user behaviour, and is as up to date as possible.</p> <p>When <del>machinery</del> products <b><u>subject to this Regulation</u></b> are made available on the market in packages containing multiple units, the instructions and information should accompany the smallest commercially available unit.</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(36) Any economic operator who either places a <del>machinery</del> product <b><u>subject to this Regulation</u></b> on the market under his or her own name or trademark or modifies a <del>machinery</del> product <b><u>subject to this Regulation</u></b> in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.		
(37) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
prepared to participate actively, providing those authorities with all necessary information relating to the <del>machinery</del> product <b><u>subject to this Regulation</u></b> concerned.		
(38) Ensuring traceability of <del>machinery</del> products <b><u>subject to this Regulation</u></b> throughout the whole supply chain enables a simpler and more efficient market surveillance. The economic operators should therefore be required to keep the information on their transactions of <del>machinery</del> products <b><u>subject to this Regulation</u></b> for a certain period of time. However, that obligation should be proportionate to the role of each economic operator in the supply chain and the economic operators should not be required to update information that they have not produced.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>(39) This Regulation should be limited to setting out the essential health and safety requirements, supplemented by a number of more specific requirements for certain categories of <del>machinery</del> products <b><u>subject to this Regulation</u></b>. In order to facilitate the assessment of conformity with those health and safety requirements it is necessary to provide for a presumption of conformity for products <b><u>subject to this Regulation</u></b> <del>machinery</del> which <b><u>are</u></b> in conformity with harmonised standards that are developed and which references are published in the <i>Official Journal of the European Union</i> in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council<sup>14</sup></p>		

<sup>14</sup> Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52), 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
for the purpose of expressing detailed <b><u>common</u></b> technical specifications of those requirements.		
<p>(40) <b><u>European standards should be market-driven, take into account the public interest, as well as the policy objectives clearly stated in the Commission's request to one or more European standardisation organisations to draft harmonised standards, and be based on consensus. <del>The current standardisation system following the New Approach and based on Regulation (EU) No.1025/2012 represents the prevalent mode of operation. The current EU standardisation framework which is based on the New Approach principles and on Regulation (EU)</del></u></b></p>	<p><b>CZ:</b></p> <p>European standards should be market-driven, take into account the public interest, as well as the policy objectives clearly stated in the Commission's request to one or more European standardisation organisations to draft harmonised standards, and be based on consensus. The current EU standardisation framework which is based on the New Approach principles and on Regulation (EU) No.1025/2012 represents the framework by default to elaborate standards that provide presumption of conformity with the relevant essential health and safety requirements of this Regulation. However, in the absence of relevant harmonised standards, the Commission should be able to establish</p>	<p><b>CZ:</b></p> <p>The Czech Republic still maintains its reservation to confere this power on the Commission. Specifications adopted in this way do not guarantee the same level of transparency and involvement of all stakeholders as the procedure for drawing up harmonised technical standards. If this alternative is retained in the proposal, it must be used only as a fallback solution in exceptional cases with clearly defined conditions for such a procedure.</p> <p>We support the proposal of Sweden (see 2nd column "Drafting Suggestions", in the document WK 2655/2022 INIT on pages 5 and 6) concerning the Commission's power to adopt implementing acts laying down</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><b><u>No.1025/2012 represents the framework by default to elaborate standards that provide presumption of conformity with the relevant essential health and safety requirements of this Regulation. However, in</u></b> the absence of relevant harmonised standards, the Commission should be able to establish <b><u>common</u></b> technical specifications for the essential health and safety requirements. <del>Recourse to <b><u>common</u></b> technical specifications should <b><u>only</u></b> be used</del> as a fall back solution to facilitate the manufacturer's obligation to comply with the health and safety requirements, for instance when the standardisation process is blocked due to a lack of consensus between stakeholders or there are undue delays in the establishment of an <b><u>appropriate</u></b> harmonised standard. Such delays could for example occur when the required</p>	<p>common technical specifications for the essential health and safety requirements. <b>Recourse to common technical specifications should only be used</b> as a fall back solution to facilitate the manufacturer's obligation to comply with the health and safety requirements, <del>for instance when the standardisation process is blocked due to a lack of consensus between stakeholders or there are undue delays in the establishment of an appropriate harmonised standard. Such delays could for example occur when the required quality is not reached.</del> <b>The Commission should not be allowed to adopt a common specification if it has not tried to have the essential health and safety requirements covered through the European standardisation system.</b></p> <p>SE:</p> <p>European standards should be market-driven, take into account the public interest, as well as the policy objectives clearly stated in the Commission's request to one or more European</p>	<p>common/technical specifications and specifying the cases in which the Commission may use the power to adopt implementing acts laying down common/technical specifications.</p> <p>Decidedly, the harmonised standards are preferred as well as limitations to the power of Commission to create technical specifications and the involvement of the Committee on Standardization. This measure will enable members states and stakeholders to have a clear overview. If the par. 3 of the Art. 17 and related recitals will remain in the proposal, we support its adjusting accordint to the SE proposal.</p> <p>MT:</p> <p><b><u>Recital 40a</u></b> – MT supports the new amendment in the latest compromise text whereby the Commission is to involve all relevant stakeholders <i>including the Committee of Standards</i>, in the process.</p> <p>Furthermore, a typo error is noted in recital 40a: the word 'stakeholders' is listed twice in the same sentence.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p>quality is not reached. <del><u>The Commission should not be allowed to adopt a common specification if it has not previously tried to have the essential health and safety requirements covered through the European standardisation system.</u></del></p>	<p>standardisation organisations to draft harmonised standards, and be based on consensus. <del><u>The current standardisation system following the New Approach and based on Regulation (EU) No.1025/2012 represents the prevalent mode of operation.</u></del></p> <p>The current EU standardisation framework which is based on the New Approach principles and on Regulation (EU) No. 1025/2012 represents the framework by default to elaborate standards that provide presumption of conformity with the relevant essential health and safety requirements of this Regulation.</p> <p>However, in the absence of relevant harmonised standards, the Commission should be able to establish common technical specifications for the essential health and safety requirements.</p> <p><u>Recourse to common technical specifications</u></p>	<p>SE:</p> <p>See overall comment under article 17.</p> <p>As part of a balanced approach to common specifications, we see a need to revert this recital to an earlier stage that have wording which underscores how common specifications should only be used as a fall-back solution rather than wording which might amplify the current friction in the standardization system.</p>



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p><u>should only be used</u> as a fall back solution to facilitate the manufacturer's obligation to comply with the health and safety requirements;  <del>for instance when the standardisation process is blocked due to a lack of consensus between stakeholders or there are undue delays in the establishment of an appropriate harmonised standard. Such delays could for example occur when the required quality is not reached. The Commission should not be allowed to adopt a common specification if it has not tried to have the essential health and safety requirements covered through the European standardisation system.</del></p>	
<p><b><u>(40a) With a view to establishing, in the most efficient way, harmonised standards and common specifications that meet the</u></b></p>		<p>CZ:</p> <p>We agree with a new recital (40a).</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>essential health and safety requirements of this Regulation, the Commission should involve relevant stakeholders stakeholders, including the Committee of Standards, in the process.</u>		
(41) Compliance with harmonised standards and with <b>common</b> technical specifications established by the Commission should be voluntary. Alternative technical solutions should therefore be acceptable where compliance of the machinery with the relevant essential health and safety requirements is demonstrated in the technical file.		
(42) The essential health and safety requirements should be satisfied in order to ensure that the <del>machinery</del> product <b>subject to</b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>this Regulation</u></b> is safe. Those requirements should be applied with discernment to take account of the state of the art at the time of construction and of technical and economic requirements.		
(43) In view of addressing the risks stemming from malicious third party actions that have an impact on the safety of machinery products <b><u>subject to this Regulation</u></b> , this Regulation should include essential health and safety requirements for which a presumption of conformity may be given to the appropriate extent by a certificate or statement of conformity issued under a relevant cybersecurity scheme adopted pursuant to and in accordance with Article 54(3) of Regulation		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(EU) 2019/881 of the European Parliament and of the Council <sup>15</sup> .		
(44) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not satisfy or entirely satisfy the requirements of this Regulation.		
(45) <del>The list of high-risk machinery <b>products</b> in Annex I <b>IV</b> to Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of <b>those products</b> that machinery. Nevertheless, the machinery <b>field</b> sector embraces new ways of designing and constructing machinery <b>or</b></del>		

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

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p> <del><b>related</b></del> products that may <del><b>present</b></del> imply high risks, regardless of such intended use or any reasonably foreseeable misuse. For example, software ensuring safety functions of machinery based on artificial intelligence, embedded or not in the machinery <del><b>or related</b></del> product, should be classified as a high-risk machinery <del><b>or related</b></del> product due to the characteristics of artificial intelligence such as data dependency, opacity, autonomy and connectivity, which might <del><b>considerably</b></del> increase very much the probability and severity of harm and seriously affect the safety of the machinery <del><b>or related</b></del> product. Furthermore, the market for software ensuring safety functions of machinery <del><b>or related</b></del> products based on artificial intelligence is so far very small, which results in a lack of experience and data. Therefore, the conformity           </p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<del>assessment of software ensuring safety functions based on artificial intelligence should be carried out by a third party. (moved to 46a)</del>		
<p>(46) Manufacturers should draw up an EU declaration of conformity to provide information on the conformity of machinery <b><u>or related</u></b> products with this Regulation.</p> <p>Manufacturers may also be required to draw up an EU declaration of conformity by other Union legislation. To ensure effective access to information for market surveillance purposes, a single EU declaration of conformity should be drawn up in respect of all Union acts. In order to reduce the administrative burden on economic operators, it should be possible for that single EU declaration of conformity to be a dossier</p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
made up of relevant individual declarations of conformity.		
<p><b><u>(46a) The list of products in Annex IV <del>to</del> of Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of those products <del>or their critical protective function</del>. Nevertheless, the machinery field embraces new ways of designing and constructing machinery or related products that may present high risks, regardless of such intended use or any reasonably foreseeable misuse. For example, <del>software components with fully or partially evolving behavior</del> ensuring safety functions of machinery <del>based on artificial intelligence</del>, embedded or not in the machinery or related product, should <del>be</del></u></b></p>	<p><b><u>CZ:</u></b></p> <p><b><u>(46a) The list of products in Annex IV <del>to</del> of Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of those products <del>or their critical protective function</del>. Nevertheless, the machinery field embraces new ways of designing and constructing machinery or related products that may present high risks, regardless of such intended use or any reasonably foreseeable misuse. For example, <del>software components with fully or partially evolving behavior</del> ensuring safety functions of machinery <del>based</del></u></b></p>	<p><b><u>CZ:</u></b></p> <p>We suggest using the term „artificial intelligence“ and not adjusting it with wording „with fully or partially evolving behaviour“. This wording could be misleading and could cause implementation problems.</p> <p><b><u>PT:</u></b></p> <p>Takes out the high-risk machine concept that is in contradiction with the objective of this Regulation.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><del>included in Annex I classified as potentially high-risk machinery or related product</del> due to <del>their</del> characteristics <del>of artificial intelligence</del> such as data dependency, opacity, autonomy and connectivity, which might considerably increase the probability and severity of harm and seriously affect the safety of the machinery or related product. Furthermore, the market for <del>software ensuring safety functions of machinery or related products based on artificial intelligence</del> these components is so far very small, which results in a lack of experience and data. Therefore, the conformity assessment of <del>software ensuring safety functions based on artificial intelligence</del> components with fully or partially evolving</p>	<p><del>on artificial intelligence</del>, embedded or not in the machinery or related product, should <del>be included in Annex I classified as potentially high-risk machinery or related product</del> due to <del>their</del> characteristics <del>of artificial intelligence</del> such as data dependency, opacity, autonomy and connectivity, which might considerably increase the probability and severity of harm and seriously affect the safety of the machinery or related product. Furthermore, the market for <del>software ensuring safety functions of machinery or related products based on artificial intelligence</del> these components is so far very small, which results in a lack of experience and data. Therefore, the conformity assessment of <del>component</del> <del>software ensuring safety functions based on artificial</del></p>	



<p><b>Presidency compromise:</b></p>	<p><b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT</p>	<p><b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT</p>
<p><u>behavior ensuring safety functions should be carried out by a third party.</u></p>	<p><u>intelligence components with fully or partially evolving behavior ensuring safety functions should be carried out by a third party.</u></p> <p><b>PT:</b></p> <p>(46a) The list of products in Annex IV of Directive 2006/42/EC is so far based on the risk emanating from the intended use or any reasonably foreseeable misuse of those products or their critical protective function. Nevertheless, the machinery field sector embraces new ways of designing and constructing machinery or related products that may present <b>high</b> new risks, regardless of such intended use or any reasonably foreseeable misuse. For example, components with fully or partially evolving behavior ensuring safety</p>	

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	<p>functions of machinery, embedded or not in the machinery or related product, should be included in Annex I due to their characteristics classified such as data dependency, opacity, autonomy and connectivity, which might considerably increase the probability and severity of harm and seriously affect the safety of the machinery or related product.</p> <p>Furthermore, the market for these compounds is so far very small, which results in a lack of experience and data. Therefore, the conformity assessment of compounds with fully or partially evolving behavior ensuring safety functions should be carried out by a third party.</p>	

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(47) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on machinery <b><u>or related</u></b> products should be laid down in this Regulation.		
(48) The CE marking should be the only marking, which guarantees that machinery <b><u>or related</u></b> products comply with the requirements of this Regulation. Member States should therefore take appropriate action as regards other markings which are likely to mislead third parties as to the meaning or the form of the CE marking.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>(49) In order to enable economic operators to demonstrate and the competent authorities to ensure that machinery <b><u>or related products</u></b> made available on the market <b><u>are</u></b> is in conformity with the essential health and safety requirements, it is necessary to provide for conformity assessment procedures. Decision No 768/2008/EC establishes modules for conformity assessment procedures, which include procedures from the least to the most stringent, in proportion to the level of risk involved and the level of safety required. In order to ensure inter-sectoral coherence and to avoid ad-hoc variants, conformity assessment procedures should be chosen from among those modules.</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>(50) Manufacturers should be responsible for certifying the conformity of their machinery <b><u>or related</u></b> products with this Regulation.</p> <p>Nevertheless, for certain types of machinery <b><u>or related</u></b> products that have a higher risk factor, a stricter certification procedure requiring participation of a notified body should be required.</p>		
<p>(51) It is essential that all notified bodies perform their functions to the same level and under conditions of fair competition. That requires the setting of obligatory requirements for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(52) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.		
(53) In order to ensure a consistent level of quality in the performance of conformity assessment of machinery <b><u>or related</u></b> products, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.		
(54) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.		
(55) Transparent accreditation as provided for in Regulation (EC) No 765/2008, ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies. However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements.		
(56) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the machinery to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
already notified, cover also activities carried out by subcontractors and subsidiaries.		
(57) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.		
(58) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.		
(59) Market surveillance is an essential instrument inasmuch as it ensures the proper and uniform application of Union legislation. It is therefore appropriate to put in place a legal framework within which market surveillance can be carried out in an appropriate manner.		
(60) Member States should take all appropriate measures to ensure that <del>machinery</del> <b><u>products subject to</u></b> covered by this Regulation may be placed on the market <b><u>or put into</u></b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p><b>service</b> only if, when properly installed and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment. <del>Machinery</del> <b>Products <u>subject to</u></b> covered by this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use, which could result from lawful and readily predictable human behaviour.</p>		
(61) In the context of market surveillance, a clear distinction should be established between the disputing of a harmonised standard conferring a presumption of conformity on		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<del>machinery</del> products <b><u>subject to this Regulation</u></b> and the safeguard clause relating to <del>machinery</del> products <b><u>subject to this Regulation</u></b> .		
(62) Directive 2006/42/EC already provides for a safeguard procedure, which is necessary to allow for the possibility of contesting the conformity of <del>machinery</del> products <b><u>subject to this Regulation</u></b> . In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.		
(63) The existing safeguard procedure should be supplemented by a procedure under which interested parties are informed of measures		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
intended to be taken with regard to <del>machinery</del> products <b><u>subject to this Regulation</u></b> posing a risk to the health or safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment. It should allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such <del>machinery</del> products.		
(64) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>(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 <del>the list of</del> <b><u>Annexes I and II</u></b> <del>potentially high-risk machinery or related products and the indicative list of safety components</del>. 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.</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission establishing <b>common</b> technical specifications for the essential health and safety requirements, requesting the notifying Member State to take the necessary corrective measures in respect of a notified body that does not meet the requirements for its notification and establishing whether a national measure in respect of compliant machinery which a Member State finds to pose a risk to health and safety of persons is justified. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>16</sup>.</p>		

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

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(67) The Commission should adopt immediately applicable implementing acts determining whether a national measure taken in respect of compliant <del>machinery</del> products <b><u>subject to this Regulation</u></b> that poses a risk is justified or not where, in duly justified cases relating to the protection of the health or safety of persons, imperative grounds of urgency so require.		
(68) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(69) When matters relating to this Regulation, other than its implementation or infringements, are being examined in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.		
(70) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant <del>machinery</del> products <b><u>subject to this Regulation</u></b> are justified or not.		
(71) The traceability of machinery data required for the technical file and for market		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
surveillance purposes, must comply with confidentiality rules to protect manufacturers.		
(72) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.		
(73) Since the objective of this Regulation, namely to ensure that <del>machinery</del> products <b><u>subject to this Regulation</u></b> placed on the market fulfils the requirements providing for a high level of protection of health and safety of persons, and, where appropriate, domestic animals and property and, where applicable, the environment, while guaranteeing the functioning of the internal market, cannot be		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
sufficiently achieved by the Member States, but can rather, by reason of the need for harmonisation, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.		
(74) Council Directive 73/361/EEC <sup>17</sup> on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire-ropes, chains and hooks should be repealed as		

<sup>17</sup> Council Directive 73/361/EEC of 19 November 1973 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the certification and marking of wire-ropes, chains and hooks (OJ L 335, 5.12.1973, p. 51–55).

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Directive 2006/42/EC took over its scope by including machinery or <del>related-producing</del> <b><u>lifting</u></b> accessories and chains and ropes.		
(75) Directive 2006/42/EC has been amended several times. Since further substantial amendments are needed, and in order to ensure a uniform implementation of the rules on <del>machinery</del> products <b><u>subject to this Regulation</u></b> throughout the Union, Directive 2006/42/EC should be repealed.		
(76) It is necessary to provide for sufficient time for economic operators to comply with their obligations under this Regulation, and for Member States to set up the administrative infrastructure necessary for its application. The		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
application of this Regulation should therefore be deferred,		
HAVE ADOPTED THIS REGULATION:		
CHAPTER I		
GENERAL PROVISIONS		
Article 1		
<b>Subject matter</b>		
This Regulation lays down <b><u>health and safety</u></b> requirements for the design and construction of machinery, <b><u>related products and partly completed machinery</u></b> products to allow their making available on the market or putting into		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p>service of machinery products <b><u>ensuring a high level of protection of the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment, when properly installed, maintained and used for its intended purpose or under reasonably foreseeable conditions,</u></b> and <b><u>It also</u></b> establishes rules on the free movement of machinery, <b><u>related products and partly completed machinery</u></b> products in the Union.</p>		
Article 2		
Scope		
(1) This Regulation applies to <b><u>machinery</u></b> <b><u>and</u></b> the following <del>machinery</del> <b><u>related</u></b> products		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(a) <del>machinery</del> ;		
(b) interchangeable equipment;		
(c) safety components;		
(d) <del>machinery or related producting</del> lifting accessories;		
(e) chains, ropes, <del>slings</del> and webbing;		
(f) removable mechanical transmission devices;		
(g) <del>partly completed machinery</del> .		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>This Regulation also applies to partly completed machinery.</u></b>		
(2) This Regulation does not apply to:		
(a) safety components that are intended to be used as spare parts to replace identical components and are supplied by the manufacturer of the original machinery, <b><u>related product or partly completed machinery</u></b> ;		
(b) specific equipment for use in fairgrounds or amusement parks;		
(c) machinery <b><u>and related products</u></b> <b><u>equipment</u></b> specially designed <b><u>for use within or used in a nuclear</u></b> installation <del>or put into service for nuclear purposes</del> <b><u>and whose conformity</u></b>		FI:  We support the modifications made on the wording of this scope exclusion.



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p><u>with this Regulation where its failure may undermine the nuclear safety</u> which, in the event of failure, may result in an emission of radioactivity;</p>		<p>We consider that the aim of the scope exclusion should be to rule out machinery from the scope of the future Regulation only when absolutely necessary. The present clause in the Machinery Directive has been widely misinterpreted leading in some cases to inadequate level of machinery safety.</p> <p>The scope exclusion is currently set out in Art 1(2)(c) of the Machinery Directive. Practice has shown that too often only the beginning of the sentence given in Art 1(2)(c) of the MD has been taken into account: "<i>(c) machinery specially designed or put into service for nuclear purposes...</i>". The fact is that especially the main cranes (e.g. polar cranes) in the reactor hall have many non-nuclear tasks also during the operation of nuclear facilities (besides that they are also used during the construction phase). Nuclear hoisting is only part of the use. The clause continues: "<i>...which, in the event of failure, may result in an emission of radioactivity;</i>".</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>The Guide to application of the Machinery Directive, §50, tries to clarify the scope exclusion: <i>“The exclusion set out in Article 1 (2) (c) concerns machinery specially designed for the purposes of the nuclear power industry or for the production or processing of radioactive materials, the failure of which may result in an emission of radioactivity. Machinery used in the nuclear power industry, such as fork lift trucks, cranes and generators, which do not give rise to a risk of emission of radioactivity and/or failure of which do not directly generate radioactive emission, are not excluded from the scope of the Machinery Directive ... It should be noted that the use of radioactive sources may be subject to authorisation and control according to the national provisions implementing Directive 96/29/Euratom and Directive 2003/122/Euratom.”</i></p> <p>Not the directive nor the guide define “radioactive emission” and “directly generate radioactive emission” whether internal or</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
		<p>external emission or small or large emission is regarded. As there is no definition for the emission (substances, amount, internal/external etc.), the clause is ambiguous. To put into practice, refueling machinery and nuclear fuel handling machinery inside spent fuel repositories might be considered here, but there is no danger for emissions in air, while spent fuel is handled underwater. Cranes for spent fuel cask handling might be another application, but the casks are designed to remain intact. Besides, there should be analysis to show the possibility and severity of emission – however, no analyses have been carried out.</p> <p>Thus, the exclusion as currently stated in the Machinery Directive is non-specific. <b>The exclusion has been quite generally misinterpreted to concern all safety classified cranes and nuclear fuel handling machinery (especially bridge cranes in reactor halls and spent fuel storages and nuclear fuel handling machines) without further consideration. The interpretation leads to less occupational</b></p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p><b>safety than intended by the MD – which should not be the situation.</b></p> <p>We understand that the exclusion is generic within e.g. PED, where the exclusion will not cause lesser occupational safety. But the structural integrity and operability ensure both nuclear/radiation and occupational safety for pressure equipment when nuclear design standards are followed. In case of machinery, occupational safety is not covered with structural safety alone. Functional safety has to be addressed, too. Nuclear requirements concern only the safety of nuclear fuel and systems/equipment important for nuclear safety. Occupational safety (e.g. crushing, cutting by moving/rotating objects) is not dealt with. On the contrary: safety level of the MD is the strong basis, that partly ensures nuclear safety – and additional requirements guarantee that the adequate level of total safety is reached.</p> <p>Nuclear legislation, regulations and few nuclear crane standards (like KTA 3902) point out</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>nuclear safety only. If the Machinery Directive or the future Regulation is misinterpreted as regards the scope exclusion, machinery safety of nuclear applications is endangered. We consider that the safety of machinery should always be the basis, on which nuclear safety rules create an additional level of safety when needed (additional safety functions, safety design margins, redundancies etc.).</p> <p>We consider that the suggested reformulation of the scope exclusion “<i>machinery and related products specially designed for use within or used in a nuclear installation and whose conformity with this Regulation may undermine the nuclear safety</i>” is the most practical and clear expression for the scope exclusion. It points out the start point: machinery safety shall be involved. It also points out the necessity of unequivocal risk assessment for the need of ruling out. In practice, taking into account the total lifespan of machinery (installation and maintenance included) there will be no</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>machinery and related products to be totally ruled out.</p> <p>It is difficult even to the best experts to think of an entire machinery that should reasonably be excluded from the scope of future Machinery regulation. They see that contradictions between machinery safety requirements and nuclear safety may only arise in sporadic safety functions. In any case, these issues should be addressed with risk assessments and analysis.</p> <p>Furthermore, in order to further explain the need to clarify the scope exclusion, it shall be taken into account that the exclusion as present causes confusion and disputes among and between manufacturers, customers and authorities about interpretation of the exclusion (cranes and nuclear fuel handling machinery). The few nuclear design standards do not take into account the EHSRs defined in MD, but the safety should be at the same level. The means to fulfil both machine safety and nuclear safety are actually the same, and they are written in</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>harmonized design standards for cranes (high risk applications). The suggested modification of the scope exclusion would benefit the markets by lower costs but no decrease in safety. On the contrary, both machinery and nuclear safety would be ensured with consistent and unambiguous means.</p> <p>Finally, we are of the opinion that the wording proposed in the earlier Presidency compromise text on 9<sup>th</sup> of February (“<i>equipment specially designed or put into service for nuclear purposes where its failure may undermine the nuclear safety</i>”) does not really change the content of this scope exclusion into a more comprehensible direction. Especially we consider that it is not reasonable to use the term “<i>equipment</i>” although we realize that experts in the field of nuclear energy may be in favor of this term, as it is familiar to them since used in e.g. the PED. However, in the context of the future Machinery Regulation the term “<i>equipment</i>” is not used elsewhere neither defined, so it should not be used here.</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		For the reasons given above, we support the wording used in the latest Presidency proposal.
(d) weapons, including firearms;		
(e) <del>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</del>		
<b><u>means of transport by air, on water and on rail networks with the exclusion of machinery mounted on these means of transport;</u></b>		
(f) two- or three-wheel vehicles and quadricycles, as well as systems, components, separate technical units, parts and equipment		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
designed and constructed for such vehicles, that fall within the scope of application of Regulation (EU) No 168/2013, <b><u>except for machinery mounted on those vehicles;</u></b>		
<b><u>(fa) motor vehicles and their trailers, as well as systems, components and separate technical units, parts and equipment designed and constructed for such vehicles, that fall within the scope of application of Regulation (EU) 2018/858, except for machinery mounted on those vehicles;</u></b>		
<b><u>(fb) vehicles exclusively intended for competition;</u></b>		
(g) agricultural and forestry <b><u>tractors</u></b> <del>vehicles</del> , as well as systems, components,		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
separate technical units, parts and equipment designed and constructed for such <b><u>tractors</u></b> <del>vehicles</del> , that fall within the scope of application of Regulation (EU) No 167/2013, <b><u>except for machinery mounted on those vehicles;</u></b>		
(h) seagoing vessels and mobile offshore units <b><u>as well as machinery installed on board intended for the functioning or navigation of the vessel or intended for safety of life at sea</u></b> and machinery <b><u>and related products</u></b> installed <del>on board such vessels or units;</del>	<p>FI:</p> <p>(h) seagoing vessels and mobile offshore units <del>as well as machinery installed on board intended for the functioning or navigation of the vessel or intended for safety of life at sea and machinery and related products installed on board such vessels or units;</del></p> <p>SE:</p> <p>seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;</p>	<p>FI:</p> <p>We do not support the proposed amendment to this scope exclusion for the reasons explained e.g. by DK and SE. We prefer keeping the original wording that is used in the Machinery Directive.</p> <p>SE:</p> <p>We would like to keep the original wording of the exemption for seagoing vessels and mobile offshore units i.e. the same as in the current Machinery Directive 2006/42/EC (“<b>seagoing vessels and mobile offshore units and machinery installed on board such vessels or units;</b>”).</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>Especially since, it is already regulated through the International Maritime Organisation. In the current guidance (§ 58) it says that "Seagoing vessels and mobile offshore units such as, for example, mobile drilling rigs, and machinery installed on them are excluded from the scope of the Machinery Directive by Article 1 (2) (f) since they are subject to the Conventions of the International Maritime Organisation. Some of the equipment concerned by this exclusion may also be subject to the Marine Equipment Directive 96/98/EC as amended by Directive 2002/75/EC."</p> <p>MT:</p> <p><i>MT would like to see the text returned to the simple text as currently stands in Directive 2006/42/EC, Article 1 (2)(f) which reads:</i></p> <p><i>"seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;"</i></p> <p><i>The current text within 2006/42/EC Article 1 (2)(f), excludes from the Machinery Directive machinery that is installed on board seagoing vessels and offshore units, whilst the text as</i></p>

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		<p><i>currently tabled in the proposal for a regulation, WK 2844/2022 only seem to exclude machinery on board vessels /offshore units that are “intended for the functioning or navigation of the vessel or intended for safety of life at sea”.</i></p> <p><i>Machinery installed on seagoing vessels / offshore units is marine equipment falling under the scope of Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and therefore a different text from that laid down in the current Directive 2006/42/EC, Article 1(2)(f) would result in incompatibility and overlap with the Marine equipment Directive.</i></p> <p><i>Article 3 of Marine Equipment Directive 2014/90/EU states:</i></p> <p><b><i>Scope</i></b></p> <p><i>1. This Directive shall apply to equipment placed or to be placed on board an EU ship and for which the approval of the flag State administration is required by the international instruments, regardless of whether the ship is situated in the Union at the time when it is fitted with the equipment.</i></p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
		2. Notwithstanding the fact that the equipment referred to in paragraph 1 may also fall within the scope of instruments of Union law other than this Directive, that equipment shall, for the purpose set out in Article 1, be subject only to this Directive.
(i) machinery <b><u>or related products and partly-completed machinery</u></b> specially designed and constructed for military or police purposes;		
(j) machinery <b><u>or related products and partly-completed machinery</u></b> specially designed and constructed for research purposes for temporary use in laboratories;		
(k) mine winding gear;		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(l) machinery <u>or related products and partly completed machinery</u> intended to move performers during artistic performances;		
(m) the following electrical and electronic products, insofar as they fall within the scope of application of Directive 2014/35/EU or Directive 2014/53/EU :		
(i) household appliances intended for domestic use which are not electrically operated furniture;		
(ii) audio and video equipment;		
(iii) information technology equipment;		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(iv) office machinery, <b><u>except additive printing machinery for producing three-dimensional products</u></b> ;		
(v) low-voltage switchgear and control gear;		
(vi) electric motors;		
(n) the following high-voltage electrical products:		
(i) switch gear and control gear;		
(ii) transformers.		
Article 3		
<b>Definitions</b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
For the purposes of this Regulation, the following definitions shall apply:		
(1) 'machinery' means:		
(a) an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application;		
(b) an assembly referred to in point (a), missing only the components to connect it on site or to sources of energy and motion;		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(c) an assembly referred to points (a) and (b), ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or a structure;		
(d) assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point <b>(10)</b> <del>(7)</del> which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;		
(e) an assembly of linked parts or components, at least one of which moves and which are joined together, intended for <del>machinery or related product</del> producing lifting loads		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
and whose only power source is directly applied human effort;		
(f) an assembly as referred to in points (a), (b), (c), (d) and (e) missing only the upload of a software intended for its specific application.		
(2) ‘interchangeable equipment’ means a device which, after the putting into service of a machinery <del>product</del> <b><u>or an agricultural or forestry tractor</u></b> , is assembled with that machinery <b><u>or agricultural or forestry tractor product</u></b> by the operator himself in order to change its function or attribute to it a new function, in so far as that equipment is not a tool;		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p>(3) ‘safety component’ means a <b><u>component of physical, or digital or mixed nature</u></b> <del>component</del>, including software, of <del>machinery</del> <b><u>products subject to this Regulation</u></b> 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 <del>machinery</del> <b><u>products subject to this Regulation</u></b> to function or may be substituted by normal components in order for the <del>machinery</del> <b><u>products subject to this Regulation</u></b> to function;</p>		
<p><b><u>(3a) ‘safety function’ means a function that serves to fulfil a protective measure, as the primary purpose, to eliminate or, if not possible, to reduce risks and where its failure</u></b></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>can result in an <b>immediate</b> increase of the risks;</u>		
(4) ‘ <del>machinery or related producting</del> lifting accessory’ means a component or equipment not attached to the <del>machinery or related producting</del> <b>lifting</b> machinery, allowing the load to be held, which is placed between the machinery and the load or on the load itself, or which is intended to constitute an integral part of the load and which is independently placed on the market, including slings and their components;		
(5) ‘chains’ means chains designed and constructed for <del>machinery or related producting</del> lifting purposes as part of <del>machinery or related producting</del> lifting machinery or <del>machinery or related producting</del> lifting accessories;		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(6) 'ropes' means ropes designed and constructed for <del>machinery or related producing</del> lifting purposes as part of <del>machinery or related producing</del> lifting machinery or <del>machinery or related producing</del> lifting accessories;		
(7) 'slings' means <del>slings designed and constructed for machinery or related producing</del> purposes as part of <del>machinery or related producing</del> <del>machinery or machinery or related producing</del> accessories;		
(8) 'webbing' means webbing designed and constructed for <del>machinery or related producing</del> lifting purposes as part of <del>machinery or related producing</del> lifting machinery or <del>machinery or related producing</del> lifting accessories;		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p>(9) ‘removable mechanical transmission device’ means a removable component for transmitting power between self-propelled machinery or a tractor and another machinery <u>by joining them at the first fixed bearing. <b>When it is placed on the market with the guard it shall be regarded as one item;</b></u></p>		
<p>(10) ‘partly completed machinery’ means an assembly which is <b>not yet a</b> machinery <b>as but</b> <del>for the fact that</del> 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;</p>	<p>IT:</p> <p>(10) ‘partly completed machinery’ means an assembly which is <b>not yet a</b> machinery <b>as but</b> <del>for the fact that</del> 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</p>	<p>IT:</p> <p>It is suggested to delete the wording "yet" because partly completed machinery do not "become" machines, but are assembled with other machines, partly completed machines or equipment to form a machine.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	completed machinery or equipment, thereby forming a machinery <del>product</del> ;	
(11) ‘making available on the market’ means any supply of a <b><u>product subject to this Regulation</u></b> a machinery, <del>related products or partly completed machinery</del> for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;		
(12) ‘placing on the market’ means the first making available of a <b><u>product subject to this Regulation</u></b> machinery, <del>related products or partly completed machinery</del> on the Union market;		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(13) 'putting into service' means the first use, for its intended purpose, in the Union, of a machinery <b><u>or related</u></b> products;		
(13a) <b><u>'essential health and safety requirements' means mandatory provisions relating to the design and construction of the products subject to this Regulation to ensure a high level of protection of the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment, as set out in Annex III;</u></b>		
(13b) <b><u>'presenting a risk' means that products subject to this Regulation pose a risk against the health and safety of persons, where appropriate, domestic animals and</u></b>	<b>CZ:</b>	<b>CZ:</b>  We consider this definition to be redundant and misleading. Regulation (EU) 2019/1020 contains



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>property and, where applicable, the environment;</u>	<del>(13b) ‘presenting a risk’ means that products subject to this Regulation pose a risk against the health and safety of persons, where appropriate, domestic animals and property and, where applicable, the environment;</del>	a definition of the “ <i>product presenting a risk</i> ”, which is sufficient and wide enough. It is inappropriate to define “ <i>presenting a risk</i> ” without reference to the product as the risk must always be related to a specific product, so we suggest deleting the definition.
(14) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products;		
(15) ‘artificial intelligence system’ means an artificial intelligence system as defined in Article 3(1) of Regulation (EU) .../... of the European Parliament and of the Council <sup>+</sup>		

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

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p>(16) ‘substantial modification’ means a modification of a machinery <del>product</del> <b><u>or related product</u></b>, by physical or digital means after that machinery <b><u>or related</u></b> product has been placed on the market or put into service, which is not foreseen by the manufacturer and <del>as a result of which the compliance of the machinery <b><u>or related</u></b> product with the relevant essential health and safety requirements may be affected;</del> <b><u>changes its original specific application and or intended use and which affects its safety by creating a new hazard or by increasing an existing risk which requires so that it is required to implement new significant protective measures;</u></b></p>	<p>DK:</p> <p>(16) ‘substantial modification’ means a modification of a machinery or related product, by physical or digital means after that machinery or related product has been placed on the market or put into service, which is not foreseen by the manufacturer and which affects its safety by creating a new hazard or by increasing an existing risk; <del>so that it is required to implement new significant protective measures;</del></p> <p>ES:</p> <p>(16) ‘substantial modification’ means a modification of a machinery <del>product</del> <b><u>or related product</u></b>, by physical or digital means after that machinery <b><u>or related</u></b> product has been placed on the market or put into service, which is not foreseen by the manufacturer and <del>as a result of which the compliance of the machinery <b><u>or related</u></b> product with the relevant essential health and safety requirements may be affected;</del> <b><u>changes its original specific application and</u></b></p>	<p><b>CZ:</b></p> <p><b>We agree with the new definition of substantial modification.</b></p> <p><b>DK:</b></p> <p><b>The necessity for new protective measures should not determin whether it is af substantial modification or not. If for instance the capacity of a crane is increased, this should be considered a substantial modification, but no new protective measures may be needed. The safety must be obtained by reinforcing the design (inherent safety).</b></p> <p><b>Therefore DK finds that the last part of the definition should be deleted.</b></p> <p><b>ES:</b></p> <p><b>The concept of ‘significant protective measure’ limits the scope of a substantial modification to those cases where the control</b></p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p><del>or intended use and which</del> affects its safety by creating a new hazard or by increasing an existing risk <del>which requires so that it is required to implement new significant protective measures or enhance existing ones</del>;</p> <p>IT:</p> <p>(16) ‘substantial modification’ means a modification of a machinery <del>product</del> <b>or related product</b>, by physical or digital means after that machinery <b>or related</b> product has been placed on the market or put into service, which is not foreseen <b>or planned</b> by the manufacturer and as a result of which the compliance of the machinery <del>or related</del> product with the relevant essential health and safety requirements may be affected; <del>changes its original specific application and or intended use and which</del> <b>affects its safety by creating a new hazard or by increasing an existing risk which requires so that it is required to implement new significant protective measures</b>;</p> <p>MT:</p>	<p><b>system of a machinery or related product is modified. This might lead to legal uncertainty, as there are other cases where new hazards or risks are created that would not fall under this definition.</b></p> <p>IT:</p> <p>It is proposed to modify the point (16) and to add the wording underline in bold and in green because the article should cover two distinct cases and include also the hypothesis of the not planning modification.</p> <p>MT:</p> <p><b>Article 3(16) and 3(16a)</b> - the text as tabled in WK 2844 seems to directly link substantial modification to the instant the machinery requires <b>new significant protective measures</b>.</p> <p>The important issue is whether the hazard or risk has changed and if there is an increased risk or a new hazard, then the modification should be deemed to be substantial.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p><b>‘substantial modification’</b> means a modification of a machinery <del>product</del> <b>or related product</b>, by physical or digital means after that machinery <b>or related</b> product has been placed on the market or put into service, which is not foreseen by the manufacturer and <del>as a result of which the compliance of the machinery or related product with the relevant essential health and safety requirements may be affected;</del> <b><u>changes its original specific application and or intended use and which</u></b> affects its safety by creating a new hazard or by increasing an existing risk <b><u>which requires so that it is required</u></b> to implement new <b>significant</b> protective measures;</p>	<p>Thus in our opinion if the modification affects its safety by introducing new hazards or increasing existing risks, this should be enough to consider that who modifies the machine as the manufacturer of a new product with all the obligations pertaining to it.</p> <p>Therefore, MT is inclined to prefer the following text whilst deleting new definition 16a:</p>
<p><b><u>(16a) ‘significant protective measure’ means a protective measure that modifies the control system of the machinery or related product;</u></b></p>	<p>DK:</p> <p>Delete</p> <p>ES:</p>	<p>DK:</p> <p>First of all we find that ‘significant protective measure’ should be deleted in definition 3.16. But even if the terminology is kept in 3.16, we find that 3.16a should be deleted. Limiting it to</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p><del>(16a) ‘significant protective measure’ means a protective measure that modifies the control system of the machinery or related product;</del></p> <p>FI:</p> <p>(16a) ‘significant protective measure’ means a protective measure that <u>significantly modifies the control system</u> <u>interferes the inherently safe design measures or the safeguarding</u> of the machinery or related product;</p> <p>IT:</p> <p><del>(16a) ‘significant protective measure’ means a protective measure that modifies the control system of the machinery or related product;</del></p> <p>MT:</p>	<p>modification of control systems is too narrow. In case the terminology is kept in 3.16, it will be sufficient to explain in the guide to the Machinery Regulation what is meant by ‘significant protective measure’.</p> <p>FI:</p> <p>We see the need for the definition of significant protective measure, but we think that this definition should be further clarified.</p> <p>We see that is not possible that the definition of substantial modification would simply depend on the fact whether there is such a new hazard or increase in an existing risk that requires such protective measures, which modify the control system of the machinery. For us it seems strange that only the need to implement new, certain kind of so-called 2nd step protective measures (as defined in the order of priority established in annex III, point 1.1.2b) would lead to a</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p data-bbox="813 316 1440 419"><del>(16a) ‘significant protective measure’ means a protective measure that modifies the control system of the machinery or related product.</del></p> <p data-bbox="813 459 869 483">SE:</p> <p data-bbox="813 563 1059 587">Delete or rephrase.</p>	<p data-bbox="1462 308 2022 379">conclusion that the modification should be regarded as substantial.</p> <p data-bbox="1462 467 2089 1050">If, for example, in a modification process of a crane, a crash prevention system is added based on a risk assessment, the modification would be regarded as substantial, according to the latest proposal. But if a modification process intends to increase the capacity of e.g. a bridge crane so that instead of 100 tons, it would be able to lift 150 tons after the modification. There would be no need to implement new “significant protective measures” (according to the latest compromise proposal), as the control system could stay untouched. According to the proposed definition, the modification would then not be regarded as substantial.</p> <p data-bbox="1462 1137 2089 1297">We consider that it should be possible to use inherently safe design and construction measures (1st step safety measures) to address the risk that has increased or emerged due to the</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>substantial modification. In our opinion, we can not leave this kind of measures out of the definition of “significant protective measures”.</p> <p>We also think that the reference to “control system” should be changed so that it addresses the whole 2<sup>nd</sup> step protective measure, not only the ones that modify the control system. We see that “simple safeguards” would still be excluded, as we also suggest adding (repeating) the word “significant” in the definition.</p> <p>For these reasons, we propose some changes to this definition.</p> <p>IT:</p> <p>It is suggested to delete point (16a) because many modifications on the machinery made after its placing on the market do not imply modifications of the control systems of the machinery but could compromise its safety introducing new hazards.</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>Then, it's important that this aspect is considered as a substantial modification.</p> <p>MT:</p> <p>As explained above</p> <p>SE:</p> <p>Significant protective measure” - is in our opinion a broader concept than just the control system. Any action taken to make a machine more safe can be seen as a "significant protective measure".</p> <p>PT:</p> <p>To add this concept, it should be very clear and objective, otherwise, the definition of substantial modification stays vaguer than in its last review.</p>



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p>(17) ‘manufacturer’ means any natural or legal person who manufactures <u>a product subject to this Regulation</u> <del>machinery, related products or partly completed machinery</del>, or who has <u>a product subject to this Regulation</u> <del>machinery, related products or partly completed machinery</del> designed or manufactured, and markets <u>such a product</u> <del>those machinery, related products or partly completed machinery</del> under his or her name or trademark or <u>manufactures a product subject to this Regulation and puts it</u> <del>who designs and constructs machinery or related products into service</del> for his or her own use;</p>	<p>MT:</p> <p>‘manufacturer’ means any natural or legal person who manufactures <u>a product subject to this Regulation</u> <del>machinery, related products or partly completed machinery</del>, or <u>who</u> <del>has</del> <u>a product subject to this Regulation</u> <del>machinery, related products or partly completed machinery</del> designed or manufactured, and markets <u>such a product</u> <del>those machinery, related products or partly completed machinery</del> under <u>his or her</u> <del>its</del> name or trademark or <u>manufactures a product subject to this Regulation and puts it</u> <del>who designs and constructs machinery or related products into service</del> for <u>his or her</u> <del>its</del> own use;</p>	<p>MT:</p> <p><u>Article 3(17)</u> - MT recommends the following minor modification to bring it closer to the definition as laid in Regulation 2019/1020</p>
<p><del>(17a) ‘user’ means the manufacturer who incorporates partly completed machinery into machinery or related products;</del></p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>(18) ‘instructions <del>for use</del>’ means the information provided by the manufacturer when the machinery <b><u>or related</u></b> product is placed on the market or put into service to inform the user of the machinery <b><u>or related</u></b> product of the intended <del>purpose</del> and the proper use of that machinery <b><u>or related</u></b> product as well as information on any precautions to be taken when using or installing the machinery <b><u>or related</u></b> product, including information on the safety aspects;</p>		
<p>(19) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks;</p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
(20) ‘importer’ means any natural or legal person established within the Union who places <b><u>a product subject to this Regulation</u></b> machinery, <del>related products</del> <b><u>or partly completed machinery</u></b> from a third country on the Union market;		
(21) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes <b><u>a product subject to this Regulation</u></b> machinery products, <del>related products</del> <b><u>or partly completed machinery</u></b> available on the market;		
(22) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;	MT:	MT:

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	economic operators' means <b><u>the fulfilment service providers</u></b> , the manufacturer, the authorised representative, the importer and the distributor;	<b><u>Article 3 (22)</u></b> Malta recommends including the fulfilment service provider as one of the economic operators within definition 3(22). This also brings this definition in line with that within Regulation 2019/1020.
(23) 'technical specification' means a document that prescribes technical requirements to be fulfilled by machinery <b><u>or related</u></b> products;		
<b><u>(23a) 'common specification' means a technical specification as defined in point 4 of Article 2 of Regulation (EU) No 1025/2012 that provides a means to comply with the essential requirements for machinery and related products;</u></b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(24) ‘harmonised standard’ means a harmonised standard as defined in Article 2(1), point (c) of Regulation (EU) No 1025/2012;		
(25) ‘CE marking’ means a marking by which the manufacturer indicates that a machinery <b><u>or related</u></b> product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;		
(26) ‘accreditation’ means accreditation as defined in Article 2, point (10) of Regulation (EC) No 765/2008;		
(27) ‘national accreditation body’ means a national accreditation body as defined in Article 2 <b><u>point</u></b> (11) of Regulation (EC) No 765/2008;		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(28) ‘conformity assessment’ means the process demonstrating whether the <b><u>applicable</u></b> essential health and safety requirements of this Regulation relating to machinery <b><u>or related</u></b> products have been fulfilled;		
(29) ‘conformity assessment body’ means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;		
(30) ‘notified body’ means a conformity assessment body notified in accordance with Article <del>26</del> <b><u>28</u></b> of this Regulation;		
(31) ‘market surveillance authority’ means a market surveillance authority as defined in		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Article 3, point (4) of Regulation (EU) 2019/1020;		
(32) 'recall' means any measure aimed at achieving the return of a <del>machinery product, or</del> <b><u>related product subject to this Regulation</u></b> that has already been made available to the <del>end</del> -user;		
(33) 'withdrawal' means any measure aimed at preventing a <del>machinery, or related product</del> <b><u>subject to this Regulation</u></b> in the supply chain from being made available on the market.		
(33a) 'Source code' means the <del>currently installed version of a safety-related the software of a product covered by this Regulation, that is</del> <b><u>written in a programming language with the purpose of being</u></b>	MT:  (33a) 'Source code' means the currently installed version of a <del>safety-related</del> the software <b><u>of within</u></b> a product covered by this Regulation, <del>that is</del> written in a programming	MT:  <b><u>Article 3 (33a)</u></b> - MT recommends replacing 'of' with 'within' for grammatical clarity. Software is installed <b><u>within</u></b> a product.

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>understood by humans so that it is unambiguous, understandable to humans;</u>	<p>language with the purpose of being understood by humans so that it is unambiguous, understandable to humans;</p> <p>SE:</p> <p>Delete</p>	<p>SE:</p> <p>We do not see added value in the proposed definition in art 3(33a) seeing as it does not entail any clarification of the term “source code”. In the absence of better definitions, we prefer deletion.</p>
<u>(33b) ‘Programming logic’ means logical operations on safety-related hard data that work according to logical principles and quantifiable results, created with the purpose of being understood by humans;</u>		
Article 4		



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<b>Free movement</b>		
<p>1. Member States shall not impede, for reasons relating to the aspects covered by this Regulation, the making available on the market <b><u>of products subject to this Regulation</u></b> or the putting into service of machinery <b><u>or related</u></b> products which comply with this Regulation.</p>		
<p>2. At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the display of a <b><u>product subject to this Regulation</u></b> <del>machinery, a <b><u>related</u></b> product <b><u>or a partly completed machinery</u></b></del> which does not comply with this Regulation, provided that a visible sign clearly indicates that it does not comply with this</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Regulation and will not be available on the market until it has been brought into conformity.		
During demonstrations, adequate measures shall be taken to ensure the protection of persons.		
Article 4a (ex-Article 23)		
<b>Protection of persons during installation <del>and</del> use of machinery <u>or related</u> products</b>		
Member States may lay down requirements to ensure that persons, including workers, are protected when installing <u>or</u> <del>and</del> using machinery <u>or related</u> products, provided that such rules do not allow for modification of a machinery <u>or related</u> product in a way that is not compatible with this Regulation.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Article 5		<p>FI:</p> <p>The problem with Article 5 of the latest compromise proposal is that if the machinery complies with the applicable EHSRs, the assessment which is carried out according to Article 5.3 results in a low or acceptable risk, when the subject of the assessment is a compliant machinery. How could Article 5.3 then be properly used to justify the inclusion of a category of machinery into Annex I? In our opinion, with the text proposed in the latest compromise this is not possible, and therefore we suggest it should be slightly modified.</p> <p>Is not reasonable to assess in the risk assessment referred to in Art 5.3 the residual risk of a compliant machinery, because the result of such</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>an assessment should definitely only show, that the risk is at an acceptable level. Neither can we assess the risk of a non-compliant machinery, because we would then see, that almost all categories of machinery would pose serious risks when not complying with the the most crucial EHSRs. Therefore the very important question is: what is the risk that is being assessed in the risk assessment referred to in Art 5.3?</p> <p>We consider that in Article 5.3 the reference to “the assessment of the seriousness of the potential risk” of a machinery or related product should be changed to a reference to a <i>high inherent risk</i>, which needs to be substantially reduced with suitable protective measures during the design and construction process, because without a successful reduction of this risk by means of suitable and adequate safety measures, the machinery would indeed pose a high risk.</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>So the risk which we suggest addressing here is <b>the risk that is inherent to the function of the machinery type</b>. Therefore we propose adding the word “inherent” in Art 5.3, together with some other additions.</p> <p>According to our understanding, such machinery, which pose a very high inherent risk, which is then reduced to an acceptable level with a combination of suitable protective measures, <b>should, in the first place, be included in part B of annex I</b>. We also think that the manufacturers of these categories of machinery should be allowed to use Module A, but only if they had fully followed, when removing and reducing this inherently high risk as well as other risks, the applicable harmonised C-type standard that covers all the EHSRs applicable to the machinery in question.</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>For this reason, we also propose some modifications to Art 21 (see our drafting suggestion above in this table, where Art 21 is discussed).</p> <p>Part A of Annex I should in turn list those categories of machinery, in which the high inherent risk has also been significantly reduced by safety measures (such as in part B machinery) but for which an applicable harmonised C-type standard does not exist or whose the inclusion is justified by the new (yet unknown) technology this category of machinery or related product contains. Also the level of complexity in designing and constructing the product in order to achieve compliance with the EHSRs could be taken into account.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><del>Potentially High-risk Machinery</del> and related products listed in Annex I</p>	<p>FI:</p> <p>Machinery and related products listed in Annex I</p>	<p>DK:</p> <p>Denmark welcomes that the terminology ‘high risk’ has been deleted. However we could also accept the terminology ‘potentially high risk’.</p> <p>We can support that annex I is divided into two parts as a compromise solution. However the criteria for the different parts should be specified in art.5, although this seems to be difficult.</p> <p>MT:</p> <p><b>Article 5</b> – renaming of the Article to “<del>Potentially High-risk Machinery</del> and related products listed in Annex I”. MT supports this change thus removing the words ‘potentially’ and ‘high risk’ and simply refer to such machinery as those listed in Annex I.</p> <p>The Amendments proposed in the latest presidency text are deemed acceptable.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
1. <del>Potentially High-risk Machinery</del> <b>and related</b> products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Article 21(2).	FI:  1. Machinery and related products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Articles 21(2) <b>and 21(2a)</b> .	FI:  See comments above.
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 <del>potentially high-risk</del> machinery <b>and related</b> products <b>in Annex I</b> a new machinery <b>or related</b> product or withdrawing an existing machinery <b>or related</b>	FI:  2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I <del>in view of technical progress and knowledge or new scientific evidence</del> by including in the list of machinery and related products in Annex I a new machinery or related product or withdrawing an existing machinery or related product from that list,	FI:  We suggest moving the reference to <i>technical progress and knowledge or new scientific evidence</i> to an other paragraph in Art 5.3 (see our drafting suggestions below).  IT:  It is necessary a complete revision of Annex I.



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.	<p>pursuant to the criteria laid down in paragraphs 3 and 4.</p> <p>IT:</p> <p>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 <del>potentially high-risk</del> machinery <b><u>and related</u></b> products <b><u>in Annex I, if there are no harmonized standards stating the satisfaction of safety criteria stated by the Machinery Regulation</u></b>, a new machinery <b><u>or related</u></b> product or withdrawing an existing machinery <b><u>or related</u></b> product from that list, pursuant to the criteria laid down in paragraphs 3 and 4 <b><u>and/or if a related harmonized standards become available.</u></b></p>	<p>However, it is suggest to specify that if there aren't no harmonized standards stating the satisfaction of safety criteria stated by the Machinery Regulation, a new machinery or related product could be included or excluded from the Annex I pursuant to the criteria laid down at points 3 and 4 and/or if a related harmonized standards become available.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p>3. A machinery <u>or related</u> product shall be included in the list of <u>potentially</u> high-risk machinery <u>or related</u> products in Annex I if its risk is serious based on the combination of the probability of occurrence of harm and the severity of that harm it <u>presents</u> poses a <u>potential</u> risk to human health <u>or safety</u> taking into account its design and intended purpose. A machinery <u>or related</u> product shall be withdrawn from the list of <u>potentially</u> high-risk machinery <u>or related</u> products in Annex I if it no longer <u>presents</u> poses such risk. <u>The inclusion or removal of a machinery or related product to Annex I shall rely on the assessment of the seriousness of the potential risk. That assessment</u> The risk <u>presented</u> posed by a certain machinery <u>or related</u> product</p>	<p>FI:</p> <p>3. The inclusion or removal of a machinery or related product to Annex I, <u>parts A and B</u>, shall rely on the assessment of the seriousness of the <u>inherent</u> potential risk <u>relating to the function of the machinery and the role of protective measures in reduction of this risk, or in case of a safety component, the</u></p>	<p>FI:</p> <p>When we carried out a risk assessment on jacks in accordance with Article 5.3 (i.e. the version or Art 5 that is included in the latest Presidency compromise proposal released on 25<sup>th</sup> February), we observed that some of the criteria are somewhat ambiguous, and people carrying out the assessment would most probably interpret them in a very different way. On the basis of this experience, we suggest that some modifications should be made to the criteria listed in Art 5.3.</p> <p>We suggest using the criteria listed in Art 5.3 (after the first paragraph) for the inclusion or removal of a machinery or related product to Annex I, parts A and B. We propose that the inclusion or removal should rely on the assessment of the seriousness of <b>the inherent potential risk relating to the function</b> of the</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p>shall be established based on the combination of the probability of occurrence of harm and the severity of that harm. <b><u>In the case of new types of machinery, that assessment shall take into account the anticipation justifiable by technical considerations on risks.</u></b></p>	<p><b><u>likelihood of serious consequences for the safety of persons exposed in the event of failure.</u></b></p> <p><del>That assessment shall be established based on the combination of the probability of occurrence of harm and the severity of that harm. In the case of new types of machinery, that assessment shall take into account the anticipation justifiable by technical considerations on risks.</del></p> <p>IT:</p> <p>3. <del>A machinery <b><u>or related</u></b> product shall be included in the list of <b><u>potentially</u></b> high risk machinery <b><u>or related</u></b> products in Annex I if its risk is serious based on the combination of the probability of occurrence of harm and the severity of that harm it <b><u>presents</u></b> poses a <b><u>potential</u></b> risk to human health <b><u>or safety</u></b> taking into account its design and intended purpose. A machinery <b><u>or related</u></b> product shall be withdrawn from the list of <b><u>potentially</u></b> high risk machinery <b><u>or related</u></b> products in Annex I if it</del></p>	<p>machinery or related product, <b>and the role (significance) of protective measures in reduction of this risk.</b> When the inherent potential risk is very high and the role of protective measures in reduction of this risk is of utmost importance, the machinery or related product should be included in part B of Annex I.</p> <p>Moreover, safety component are such “related products”, that can not be subject to the assessment using the same criteria that are used for machinery and other related products. That is why we should have own criteria for the inclusion or removal of safety components, and that is why we suggest some additions in the first sentence of Art 5.3 also in this regard.</p> <p>Furthermore, we believe that we should be able to justify, taking into account the criteria set out in Art 5.3, as to why certain product categories are listed in Annex I, part A. This is why we have drafted a suggestion, according to which</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	<p>no longer <del>presents</del> poses such risk. <u>If the related harmonized standards are not yet available <del>the inclusion or removal of a machinery or related product to Annex I shall rely on the assessment of the seriousness of the potential risk. That assessment</del></u> The risk <del>presented</del> posed by a certain machinery <del>or related product</del> shall be established based on the combination of the probability of occurrence of harm and the severity of that harm. <u>In the case of new types of machinery, that assessment shall take into account the anticipation justifiable by technical considerations on risks and by the results achieved by technical commissions involved in the development of safety standards or technical specifications.</u></p> <p><u>In consideration of this, machinery having all the following characteristics are, in principle, excluded from the list of categories of machinery or related products in Annex I:</u></p> <ul style="list-style-type: none"> <li>○ <u>operation phases are fully controlled by a programmable system</u></li> </ul>	<p>there are certain criteria which would be used for the justification in general (for both the parts A and B), but we have also drafted some additional criteria, which should also be considered, when assessing whether a certain machinery or related product should be included in part A of Annex I. Some of these suggested criteria may still need to be further clarified and improved, but we hope that the suggestions would enable us to improve Article 5 so that it would serve us in the future whenever there is a duly justified reason to update Annex I.</p> <p>IT:</p> <p>The exclusion of machines controlled by computerized systems and with segregated process is justified by the fact that if the operator, during the normal working of the machine (fully managed by the computerized system), cannot access the process without causing alarms and/or safety related stops and if specific harmonized standards of type B or C are available and applied by the manufacturer, then it is not possible to</p>

Presidency compromise:	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	<ul style="list-style-type: none"> <li>○ <u>the process is segregated (i.e. in normal working conditions, the operator cannot directly access the working space when the machine is operating, without causing a safety related stop)</u></li> <li>○ <u>harmonized standards are available, that stating presumption of conformity to the Machinery Regulation for the specific type of machinery, provided that those standards cover all of the relevant essential health and safety requirements;</u></li> </ul>	<p>assume situations of high risk for the operator himself. Indeed, for machines with these characteristics the operator could be seen as a simple "supervisor" of the regularity of the process and/or operate unattended, further excluding the probability of dangerous events.</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
In determining the probability and severity of harm, the following <b>criteria</b> shall be taken into account, where applicable <b>relevant</b> :	FI:  In <b>the assessment</b> , determining the probability and severity of harm, the following criteria shall be taken into account, where relevant:	<b>CZ:</b>  We agree with these criteria.
	FI:  <b><u>a) the nature of the hazard inherent to the function of the machinery or related product type, taking into account the intended use and reasonably foreseeable misuse</u></b>	FI:  See comments above.
(a) the <b>severity of harm with by</b> degree to which each affected <b>a</b> person would be <b>affected</b> , <b><u>including the degree of reversibility of such harm</u></b> impacted by the harm;	FI:  ( <b>a b</b> ) the severity of harm by which a person would be affected, including the degree of reversibility of such harm	

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(b) the number of persons potentially affected <b><u>by the harm</u></b> ;	FI:  <del>(b) the number of persons potentially affected <b><u>by the harm</u></b>;</del>	FI:  We suggest deleting “the number of persons potentially affected by the harm”, because according to our understanding, already one death is too much, and we should not base this assessment on the number of persons affected by the serious harm. It should be enough that this number $\geq 1$
	FI:  <u>c) the frequency and the duration of the exposure to the hazard that a person would be exposed to in course of the intended use or</u>	FI:  We suggest that after the assesement of the severity of harm in point (b), we should, at some level, assess the probability with two factors, which are not too subjective. We consider that this would be possible by assessing the frequency

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<u>reasonably foreseeable misuse of the machinery or related product</u>	and duration of the exposure, and possibility of avoiding or limiting the harm (see point d).
(c) the degree to which potentially affected parties are dependent on the outcome produced by the machinery <u>or related</u> product;		
(d) the degree to which <u>the behavior of the machinery or related product is foreseeable by the</u> potentially affected parties are in a vulnerable position vis-à-vis the <u>end</u> -user of the machinery <u>or related</u> product <u>possibilities of avoiding or limiting harm</u> ;	FI:  d) possibilities of avoiding or limiting the harm	
(e) — the degree of reversibility of the harm produced by the machinery <u>or related</u> product;		
(f) — the degree to which the machinery <u>or related</u> product has been used for <u>its intended</u>		



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<del>use or any reasonably foreseeable misuse a specific purpose;</del>		
<p>(g) indications of harm that have been caused in the past by machinery <b><u>or related</u></b> products which have been used for <b><u>its intended use or any reasonably foreseeable misuse</u></b> a specific purpose.</p>	<p>FI:</p> <p><del>(g) — indications of harm that have been caused in the past by machinery or related products which have been used for its intended use or any reasonably foreseeable misuse</del></p> <p><b><u>e) the significance of the risk reduction achieved by the implementation of adequate protective measures.</u></b></p> <p><b><u>f) in case of safety components, the likelihood of serious consequences for the safety of persons exposed in the event of failure.</u></b></p>	<p>FI:</p> <p>When we carried out our assessment on jacks, this turned out to be a difficult criterium to interpret without ambiguity. We suggest deleting this, or at least it should be further clarified.</p> <p>On e) and f), see comments above.</p>
	FI:	FI:

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	<p><u>The inclusion or removal of a machinery or related product to Annex I, part A, shall also rely on the assessment of the following, where relevant:</u></p> <p>a) <u>the level of complexity in designing and constructing machinery or related product in order to achieve compliance with the essential health and safety requirements set out in Annex III;</u></p> <p>b) <u>the existence of applicable harmonised C-type standards covering all the inherent potential hazards that the machinery or related product may pose</u></p> <p>c) <u>in the case of new types of machinery or related products, the anticipation justifiable by technical considerations of inherent and unknown risks.</u></p> <p>SE:</p>	<p>See comments above.</p> <p>SE:</p> <p>Annex I should in our opinion not reflect the residual hazard that is inherent in different types of machinery before identified risks are properly addressed (seeing as any hazards ought to be eliminated before the machinery is allowed to be placed on the market), but rather risks that would stem from the actual usage of machinery that can be CE-marked in accordance with the regulation. From our point of view, in order for a notified body to be able to make a meaningful difference is that it either lacks a C-standard or that the manufacturer deviates from the level of safety in a specific harmonized C-standard.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p>add a new points (h) and (g):</p> <p>- (h) <u>the level of complexity in designing and constructing machinery or related products so that they are in compliance with the essential health and safety requirements set out in Annex III;</u></p> <p>- (g) <u>the existence of applicable harmonised machinery specific standards (C-standards) that could help in the safe design and construction of the machinery or related products.</u></p>	
<p>4. The Commission <del>shall thoroughly assess</del> <b><u>may initiate the procedure laid down in paragraph 2 after a thorough assessment of the risks as referred to in paragraph 3. In addition, the Commission may consider any of the following elements provided</u></b> <del>the criteria laid down in paragraph 3 on the basis of available information. In particular the</del></p>	<p>FI:</p> <p>4. The Commission may initiate the procedure laid down in paragraph 2 <del>after a thorough assessment of the risks as referred to in paragraph 3</del> <b><u>either on its own initiative or upon request of Member States</u></b>. In addition <del>to the criteria laid down in paragraph 3</del>, the Commission may consider <del>any of the following elements provided by the Member States when</del></p>	

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p><del>following information shall be communicated to the Commission</del> by the Member States when it becomes available to them in connection with market surveillance or as a result of the concerns referred to in the fifth paragraph:</p>	<p>it becomes available to them in connection with market surveillance or as a result of the concerns referred to in the fifth paragraph, <u>such as</u>:</p> <p>IT:</p> <p>4. <u>In case no activities related to standardization or technical specifications have been already started</u> <del>the</del> Commission shall thoroughly assess <u>may initiate the procedure laid down in paragraph 2 after a thorough assessment of the risks as referred to in paragraph 3. In addition, the Commission may consider any of the following elements provided</u> <del>the criteria laid down in paragraph 3 on the basis of available information. In particular the following information shall be communicated to the Commission</del> by the Member States when it</p>	

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	becomes available to them in connection with market surveillance or as a result of the concerns referred to in the fifth paragraph:	
(a) — <del>an assessment of the risks as referred to in paragraph 3;</del>		
(b) — <del>a cost effectiveness analysis;</del>		
<b><u>(ba) information about safety defects detected in the course of market surveillance, and possible available material in the information systems administered by the Commission;</u></b>	FI:  ( <del>ba</del> <b>a</b> ) information about safety defects detected in the course of market surveillance, and possible available material in the information systems administered by the Commission;	
(c) — <del>a machinery accident analysis;</del>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>(ca) known accidents and serious close call, including characteristics of these accidents or close call;</u></b>	FI:  (ea <b>b</b> ) known accidents and serious close calls, including characteristics of these accidents or close calls;	SE:  We would like to see a clarification in that the risks should relate to the machine function of machinery or related products, as opposed to some products that might have a high degree of risks inherit in, for instance, their road circulation usage.
<b><u>(d) statistics <u>data</u> on accidents <u>or damage to the health</u> caused by the machinery <u>or related</u> product <u>at least</u> 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.</u></b>	FI:  (d <b>c</b> ) data on accidents or damage to the health caused by the machinery or related product at least for the preceding four years;	
	FI:	

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<u>(d) absence of or shortcomings in the relevant harmonised standards</u>	
<del>(da) — anticipation justifiable by technical considerations on risks related to new types of machinery.</del>	FI:  <u>(e) where relevant, technical progress and knowledge or new scientific evidence.</u>	
5. A Member State which has concerns about a machinery <b><u>or related</u></b> product being listed or not listed in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof.		
	FI:  5. A Member State which has concerns about a machinery or related product being listed or not listed in Annex I shall immediately	

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	inform the Commission of its concerns and provide reasons in support thereof.	
Article 6		
<b>Safety components</b>		
1. An indicative list of safety components is set out in Annex II.		
2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex II in view of technical progress and knowledge or new scientific evidence by including a new safety component in the indicative list of safety components or withdrawing an existing safety component from that list.		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
3. <del>The Commission shall thoroughly assess the risks that require the inclusion of a new safety component in the list of safety components in Annex II or a withdrawal of a safety component from that list.</del>		
4. A Member State which has concerns about a safety component being listed or not listed in Annex II shall immediately inform the Commission of its concerns and provide reasons in support thereof.		
Article 7		
<b><u>Essential health and safety Requirements for machinery products subject to this Regulation</u></b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>Machinery <del>P</del>products <b><u>subject to this Regulation</u></b> shall only be made available on the market or put into service if, where properly installed and maintained and <del>or</del> used for their intended <b><u>use</u></b> <del>purpose</del> or under conditions which can reasonably be foreseen, they meet the <b><u>applicable</u></b> essential health and safety requirements set out in Annex III.</p>		
Article 8		
<b>Specific Union harmonisation legislation</b>		
<p>Where, for a certain <b><u>product subject to this Regulation</u></b> <del>machinery product</del>, the risks addressed by the essential health and safety requirements set out in Annex III are wholly or partly covered by other more specific Union</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
harmonisation legislation, this Regulation shall not apply to that <del>machinery</del> product <b><u>subject to this Regulation</u></b> to the extent that that specific Union legislation covers such risks.		
Article 9		
<b>Regulation (EU) .../... of the European Parliament and of the Council<sup>+</sup></b>		
Where <del>machinery</del> products <b><u>subject to this Regulation</u></b> contain an artificial intelligence system, to which the essential health and safety requirements of Regulation (EU) .../... apply, this Regulation shall, in relation to that artificial intelligence system, only apply with regard to its safe integration into the overall <del>machinery</del>		

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

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>product</u></b> , so as not to compromise the safety of the <del>machinery</del> product <b><u>subject to this Regulation</u></b> as a whole.		
CHAPTER II		
OBLIGATIONS OF ECONOMIC OPERATORS		
Article 10		
<b><u>Obligations of manufacturers of machinery and related products</u></b>		MT:  The amendments as proposed in the latest presidency text are deemed acceptable as these

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		address concerns flagged by Malta in previous WP.
1. When placing a machinery <b><u>or a related</u></b> product on the market <b><u>and/or putting it into service</u></b> , manufacturers shall ensure that it has been designed and constructed in accordance with the essential health and safety requirements set out in Annex III.		
2. Before placing a machinery <b><u>or related</u></b> product on the market <b><u>and/or putting it into service</u></b> , manufacturers shall draw up the technical documentation <del>referred</del> <b><u>set out</u></b> to in <b><u>part A of</u></b> Annex IV ( <del>technical documentation</del> ) and carry out the relevant conformity		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
assessment procedures referred to in Article 21 <del>or Article 22</del> or have them <u>it</u> carried out.		
Where compliance of <del>the a</del> machinery <u>or related</u> product with the-essential health and safety requirements laid down in Annex III has been demonstrated by <del>that</del> <u>those that</u> conformity assessment procedures, manufacturers shall draw up the EU declaration of conformity in accordance with Article 18 and affix the CE marking in accordance with Article 20, <del>except for partially completed machinery.</del>		
3. Manufacturers shall keep the technical documentation and the EU declaration of conformity, <del>where relevant</del> , at the disposal of the market surveillance authorities for ten years		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>after the machinery <b><u>or the related</u></b> product has been placed on the market <b><u>and/or put into service</u></b>. <del>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.</del></p>		
<p>4. Manufacturers shall ensure that procedures are in place for machinery <b><u>or related</u></b> products that are part of a series production to remain in conformity with this Regulation. Changes in the production process or in the design or characteristics of the machinery <b><u>or related</u></b> product and changes in</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
the harmonised standards or the <del>technical</del> <b><u>common</u></b> specifications referred to in Article 17 by reference to which the conformity of the machinery <b><u>or related</u></b> product is declared <del>or by application of which its conformity is verified</del> shall be adequately taken into account.		
When deemed appropriate with regard to the risks presented by machinery <b><u>or related</u></b> products, manufacturers shall, <b><u>in order</u></b> to protect the health and safety of <del>persons, and/or,</del> <b><u>where appropriate, domestic animals and/or property and/or, where applicable, the environment</u></b> <del>end-users</del> , carry out sample testing of machinery <b><u>or related</u></b> products made available on the market or put into service <b><u>and</u></b> , investigate, <del>and</del> , <b><u>If necessary, manufacturers shall</u></b> keep a register of complaints, of non-	SE:  When deemed appropriate with regard to the risks presented by machinery <b><u>or related</u></b> products, manufacturers shall, <b><u>in order</u></b> to protect the health and safety of <del>persons, and/or,</del> <b><u>where appropriate, domestic animals and/or property and/or, where applicable, the environment</u></b> <del>end-users</del> , carry out sample testing of machinery <b><u>or related</u></b> products made available on the market or put into service <b><u>and</u></b> ,	SE:  We propose the wording “...and, investigate <b><u>complaints</u></b> .” instead of the vague and abruptly ended term “and, investigate.”.



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
conforming machinery <b><u>or related</u></b> products and machinery <b><u>or related</u></b> products recalls, and shall keep distributors informed of any such monitoring.	investigate <b><u>complaints</u></b> , and, <b><u>if necessary</u></b> , <b><u>manufacturers shall</u></b> keep a register of complaints, of non-conforming machinery <b><u>or related</u></b> products and machinery <b><u>or related</u></b> products recalls, and shall keep distributors informed of any such monitoring.	
5. Manufacturers shall ensure that the machinery <b><u>or related</u></b> product which they place on the market <b><u>and/or put into service</u></b> bears <b><u>at least a designation of the machinery, series or type, the year of construction, that is the year in which the manufacturing process is completed, and, if any,</u></b> batch or serial number <b><u>if any</u></b> or other element allowing its identification, or, where the size or nature of the machinery <b><u>or related</u></b> products does not allow it, that the required information is provided on the		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
packaging or in a document accompanying the machinery <b><u>or related</u></b> products.		
<p>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and, <b><u>if available, a digital contact</u></b> the email address at which they can be contacted on the machinery <b><u>or related</u></b> product or, where that is not possible, on its packaging or in a document accompanying the machinery <b><u>or related</u></b> products. 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 <del>end</del>-users and market surveillance authorities.</p>	<p>SE:</p> <p>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and, <b><u>if available, a digital contact</u></b> the email address at which they can be contacted on the machinery <b><u>or related</u></b> product or, where that is not possible, on its packaging or in a document accompanying the machinery <b><u>or related</u></b> products. 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 <del>end</del>-users and market surveillance authorities.</p>	<p>SE:</p> <p>We want to maintain our previous comments that we prefer references throughout the text to say "e-mail address" instead of "digital contact". It is important for the person who wants to have a contact with the manufacturer to be able to receive a receipt that an e-mail has been sent, both for consumers and market surveillance authorities. <b>This should be changed also in art 10a(6) and art 12(3).</b></p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>7. Manufacturers shall ensure that the machinery <b><u>or related</u></b> products are accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by <del>end</del>-users, as determined by the Member State concerned.</p>		<p>SE:</p> <p>We support the idea behind moving the provisions on digital documentation from Annex III to articles but suggest that they are grouped together in a single article so that the provisions can apply uniformly by all economic actors. Seeing as these provisions are not standard NLF provisions which regulate the product as such, but rather regulate the sales modalities of the product, we do not agree with the notion that the obligations should vary depending on the economic actor's place in the distribution chain – especially in light of the fact that end-users are probably more likely to approach the distributor he or she bought the product from rather than a manufacturer that he or she has not had any contact with. In order to avoid questions about their applicability/inapplicability in contractual</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>relations between different economic actors in the distribution chain, we see a need to limit any additional obligations (other than the possibility to supply the instruction in a digital format) to instances where products are made available to end-users.</p> <p>We propose that it should be possible to require the instructions in paper format free of charge within a limited time period after the purchase. As a minimum, we believe that such a period should be at least 14 days (which would be in line with directive 2011/83/EU on consumer rights), but we would prefer a slightly longer period.</p> <p>We have repeatedly questioned the effects of and the practical application of any obligation to under certain circumstances provide some information in paper format for putting a machinery or related product into service and for using it in a safe way (also known as a quick-start guide). Such proposal would mean that only some of the requirements of point</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>1.7.4.2 in Annex III would be provided, and it is unclear to us how this selection should take place or how Market Surveillance Authorities should be able to enforce it in a uniform fashion. Seeing as the quick-start guide might be provided separately to a complete digital instruction, it seems likely that many machinery users might consider the quick-start guide as the only instruction without reflecting over the possibility to request a full version in paper format free of charge if that is his or her preference. Under these conditions, we see a possibility in that users might even feel encouraged to start up machinery after having only read the quick-start guides, and that there is an enhanced risk of them never accessing or completely reading through the full set of instructions.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
Such instructions and information <b><u>Instructions set out in section 1.7.4 of Annex III may be provided in a digital format and shall be clear, understandable, intelligible and legible. However, upon purchaser request [time of the request to be discussed], instructions should be provided in paper format free of charge.</u></b>		
<b><u>Such instructions and information shall be clear, understandable, intelligible and legible.</u></b>		
<b><u>Instructions set out in Annex III may be provided in a digital format.</u></b>		
<b><u>When the instructions are provided in digital format, the manufacturer shall:</u></b>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
(a) <u>mark on the machinery or related product and in an accompanying paper how to access the digital instructions;</u>		
(b) <u>be presented in a format that makes it possible for the user to download the instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machinery or related product. This requirement also applies to a machinery or related product subject to this regulation where the instructions are embedded in the software of the machinery or related product.</u>		
(c) <u>make them available online during the expected lifetime of the machinery or related</u>		<b>CZ:</b>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>product and not less than 10 years after the placing on the market of the product.</u>		We agree with this obligation of manufacturer.
<u>However, upon purchaser request at the time of the purchase or up to [XX years], the manufacturer shall provide the instructions in paper format free of charge.</u>		
<u>In the case of a machinery or related product intended for use by non-professional operators or which can, under reasonably foreseeable conditions, be used by non-professional operators, the manufacturer shall provide in paper format the instructions that are essential for putting the machinery or related product into service and for using it in a safe way.</u>		



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p>FI:</p> <p>In the case of a machinery or related product intended for use by non-professional operators or which can, under reasonably foreseeable conditions, be used by non-professional operators <u>even if not intended for them</u>, the manufacturer shall provide in paper format the instructions that are essential for putting the machinery or related product into service and for using it in a safe way.</p>	<p>FI:</p> <p>We agree with DE on this: the proposed text misses the aspect that products can be intended for professional operators, but are also available at the hardware shop and will thereby also be used by non-professional operators. The wording we propose is the same that is already used in the existing GPSD and also in the proposal for a new GPS Regulation.</p> <p>The proposed changes to Art. 10 (7) should also be made to Art. 12 (4) and Art. 13 (2).</p>
<p>8. Manufacturers shall <b><u>ensure that</u></b> <del>either provide the EU declaration of conformity with</del></p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>the machinery <b><u>or related</u></b> products <del>or include</del> <b><u>is accompanied by the EU declaration of conformity set out in Part A of Annex V or shall provide the internet address at which it can be accessed</u></b> in the instructions and information set out in section 1.7 of Annex III <del>the internet address at which the EU declaration of conformity can be accessed.</del></p>		
<p><b><u>Digital EU declarations of conformity shall be made available online for at least 10 years after placing on the market or putting into service of the machinery or related product.</u></b></p>		
<p>9. Manufacturers who consider or have reason to believe that a machinery <b><u>or related</u></b> product, which they have placed on the market or put into service is not in conformity with the</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p><del>essential health and safety requirements set out in Annex III</del> <b><u>this Regulation</u></b> shall immediately take the corrective <del>measures</del> <b><u>actions</u></b> necessary to bring that machinery <b><u>or related</u></b> products into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the machinery <b><u>or related</u></b> product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the machinery <b><u>or related</u></b> product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective <del>measures</del> <b><u>actions</u></b> taken.</p>		
<p>10. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery <b><u>or related</u></b> products with the <del>essential health and safety requirements set out in Annex III</del> <b><u>this Regulation</u></b> , in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any <del>measures</del> <b><u>actions</u></b> taken to eliminate the risks <b><u>presented</u></b> <del>posed</del> by the machinery <b><u>or related</u></b> products, which they have placed on the market or put into service.		
<b><u>Article 10a (ex-22)</u></b>		
<b>Obligations of manufacturers of partly completed machinery</b>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><b>1. <u>When placing a partly completed machinery on the market, manufacturers shall ensure that it has been designed and constructed in accordance with the applicable <b>relevant</b> essential health and safety requirements set out in Annex III <del>in relation with the partly completed machinery risk assessment.</del></u></b></p>		
<p><b>2. <u>Before placing a partly completed machinery on the market, manufacturers shall draw up the technical documentation set out in part B of Annex IV, <del>the assembly instructions that satisfy the requirements laid down in Annex X</del> and and carry out the relevant conformity assessment procedure referred to in Article 21a or have it carried out.</u></b></p>	<p>PT:</p> <p>Before placing a partly completed machinery on the market, manufacturers shall draw up the technical documentation set out in part B of Annex IV, the assembly instructions that satisfy the requirements laid down in Annex X <del>and and carry out the relevant conformity</del></p>	<p><b><u>PT:</u></b></p> <p>In the actual Regulation the partly completed machinery is not subject to a conformity assessment (see §132 Diagram of the procedures for the placing on the market of machinery and partly completed machinery from Guide to application of the Machinery Directive 2006/42/EC Edition 2.2 – October 2019). If</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<del>assessment procedure referred to in Article 21a or have it carried out</del>	there is a change on this matter we should analyze the implications more carefully.
<b><u>Where the partly completed machinery has been found to be in compliance with these requirements, manufacturers shall draw up and the EU declaration of incorporation as set out in part B of Annex V.</u></b>		
<b><u>3. Manufacturers shall keep the technical documentation and the EU declaration of incorporation at the disposal of the market surveillance authorities for ten years after the partly completed machinery has been placed on the market.</u></b>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><b><u>4. Manufacturers shall ensure that procedures are in place for partly completed machinery that are part of a series production to remain in conformity with this Regulation. Changes in the production process or in the design or characteristics of the partly completed machinery and changes in the harmonised standards or the common specifications referred to in Article 17 by reference to which the conformity of the partly completed machinery is declared or by application of which its conformity is verified shall be adequately taken into account.</u></b></p>		
<p><b><u><del>When deemed appropriate with regard to the risks presented by partly completed machinery, manufacturers shall, to protect the health and safety of persons and/or</del></u></b></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<del><u>domestic animals and/or property and/or the environment, carry out sample testing of partly completed machinery made available on the market and, investigate. If necessary, manufacturers shall keep a register of complaints, of non-conforming partly completed machinery and partly completed machinery recalls, and shall keep distributors informed of any such monitoring.</u></del>		
<u>5. Manufacturers shall ensure that the partly completed machinery which they place on the market bears at least a type; the designation of the the partly completed machinery, the year of construction, that is the year in which the manufacturing process is completed, and, <b>if any</b>, batch or serial</u>		



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>number <del>if any</del> or other element allowing its identification, or, where the size or nature of the partly completed machinery does not allow it, that the required information is provided on the packaging or in a document accompanying the partly completed machinery.</u>		
<u>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and, if available, a digital contact <del>the email address</del> at which they can be contacted on the partly completed machinery or, where that is not possible, on its packaging or in a document accompanying the partly completed machinery. The address shall indicate a single point at which the manufacturer can</u>	SE:  <u>6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and, if available, <del>a digital contact the email address</del> at which they can be contacted on the partly completed machinery or, where that is not possible, on its packaging or in a document accompanying the partly completed</u>	SE:  We want to maintain our previous comments that we prefer references throughout the text to say "e-mail address" instead of "digital contact". It is important for the person who wants to have a contact with the manufacturer to be able to receive a receipt that an e-mail has been sent, both for consumers and market surveillance authorities.

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><u>be contacted. The contact details shall be in a language easily understood by <del>end-users the person who incorporates the partly completed machinery into a machinery and market surveillance authorities.</del></u></p>	<p><u>machinery. 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 <del>end-users the person who incorporates the partly completed machinery into a machinery and market surveillance authorities.</del></u></p>	
<p><u>7. Manufacturers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Annex X in a language which can be easily understood by <del>users the person who incorporates the partly completed machinery, as determined by the Member State concerned.</del></u></p>	<p>SE:</p> <p><u>7. Manufacturers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Annex X in a language which can be easily understood by <del>users the person who incorporates the partly completed machinery, as determined by the Member State concerned.</del></u></p>	<p>SE:</p> <p>While manufacturers of machinery and related products can produce both highly specialized machinery and widely available consumer machinery, manufacturers of PCM's always produces a speciality product tailored to a limited market of machinery producers who are themselves expected to ensure compliance with a complex set of obligations. It is therefore not unreasonable to adapt some provisions mainly designed for consumer protection when it comes to PCM producers.</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		In article 10a(7), references to “as determined by the Member State concerned” should be removed as this would fragmentize an already small market into potentially 24 subsets. The person who incorporates the partly completed machinery contractually needs to ensure that he or she understand the language of the assembly instructions seeing as he or she will be a manufacturer who in turn will be responsible for that product’s subsequent instructions.
<b><u>Such assembly instructions shall be clear, understandable, intelligible and legible.</u></b>		
<b><u>Assembly instructions set out in Annex X may be provided in a digital format.</u></b>		
<b><u>When the assembly instructions are provided in digital format, the manufacturer shall:</u></b>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
(a) <u>mark on the partly completed machinery and in an accompanying paper how to access the digital assembly instructions;</u>		
(b) <u>be presented in a format that makes it is possible for the person who incorporates the partly completed machinery to download the assembly instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the partly completed machinery. This requirement also applies to a partly completed machinery where the assembly instructions are embedded in the software of the partly completed machinery.</u>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
(c) <u>make them available online during the expected lifetime of the partly completed machinery and not less than 10 years after the placing on the market of the partly completed machinery.</u>		<b>CZ:</b>  <b>We agree with this obligation of manufacturer.</b>
<u>However, upon purchaser request [time of the request to be discussed], assembly instructions should be provided in paper format free of charge.</u>		
<u>8. Manufacturers shall ensure that the partly completed machinery is accompanied by the EU declaration of incorporation set out in Part B of Annex V or shall provide the internet address at which it can be accessed</u>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>in the assembly instructions set out in Annex X.</u>		
<p><b><u>9. Manufacturers who consider or have reason to believe that a partly completed machinery which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures actions necessary to bring that partly completed machinery machinery into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk as regards the applicable essential health and safety requirements, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the partly</u></b></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures actions taken.</u>		
<p><b>10. <u>Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the partly completed machinery with this Regulation, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures actions taken to eliminate the risks as regards the <u>applicable</u> essential health and safety requirements presented by the partly</u></b></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>completed machinery, which they have placed on the market.</u></b>		
Article 11		
<b>Authorised representatives</b>		
1. A manufacturer <b><u>of a product subject to this Regulation</u></b> may, by a written mandate, appoint an authorised representative.		
The obligations laid down in Article 10(1) and <b><u>Article 10a(1)</u></b> and the obligation to draw up the technical documentation <b><u>set out in Annex IV</u></b> shall not form part of the authorised representative's mandate.	MT:  “The obligations laid down in Article 10(1) and <b><u>Article 10a (1)</u></b> and the obligation to draw up the technical documentation <b><u>set out in Annex IV</u></b> ”	MT:  The manufacturer’s obligation to draw up the technical documentation is set out in Article 10(2). Annex IV prescribes what the technical documentation should consists of, therefore



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	<b>Article 10(2)</b> shall not form part of the authorised representative's mandate."	Article 11 should refer to Article 10(2) not Annex IV.
	FI:  The obligations laid down in Article 10(1) and Article 10a(1) and the obligation to draw up the technical documentation set out in <del>Annex IV</del> <b>Article 10(2)</b> shall not form part of the authorised representative's mandate.	FI:  The manufacturer's obligation to draw up the technical documentation is set out in Art 10(2), not in Annex IV, which includes the detailed description on what should be included in that documentation.
2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
(a) keep the <b><u>technical documentation and the</u></b> EU declaration of conformity <b><u>of machinery and related products or the EU declaration of incorporation of partly completed machinery</u></b> and the <del>technical documentation</del> at the disposal of the national market surveillance authorities for ten years after the <del>machinery</del> product has been placed on the market;		
(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the <del>machinery</del> product <b><u>subject to this Regulation</u></b> ;		
(c) cooperate with the competent national authorities, at their request, on any <del>measures</del>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>actions</u></b> taken to eliminate the risks <b><u>presented</u></b> posed by a machinery product <b><u>subject to this Regulation</u></b> covered by the authorised representative's mandate.		
Article 12		
<b><u>Obligations of importers of machinery and related products</u></b>		MT:  The amendments as proposed in the latest presidency text are deemed acceptable as these address concerns flagged by Malta in previous WP.
1. Importers shall <del>only</del> place <b><u>only</u></b> <del><b><u>compliant on the market</u></b></del> machinery <b><u>or related</u></b> products <del>that comply with the essential health</del>	SE:	SE:  We want to maintain our previous comment comments that, in order to avoid loopholes, the

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<del>and safety requirements set out in Annex III</del> on the market <del>machinery</del> .	Importers shall <del>only place only compliant on the market</del> machinery <u>or related</u> products that <del>comply with the essential health and safety requirements set out in Annex III on the market</del> <b><u>or put them into service</u></b> , machinery.	text in paragraphs 1 and 2 should be completed with references to " <b><u>or putting it into service</u></b> ". See the Commission's proposal for a Battery Regulation as an example.
2. Before placing a machinery <b><u>or related</u></b> product on the market, importers shall ensure that the appropriate conformity assessment procedures referred to in Article 21 <del>or Article 22</del> have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation <b><u>set out in Part A of Annex IV</u></b> , that the machinery <b><u>or related</u></b> product bears the CE marking referred to in Article 19 and is accompanied by the required documents, and that the manufacturer has	SE:  2. Before placing a machinery <b><u>or related</u></b> product on the market <b><u>or putting it into service</u></b> , importers shall ensure that the appropriate conformity assessment procedures referred to in Article 21 <del>or Article 22</del> have been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation <b><u>set out in Part A of Annex IV</u></b> , that the machinery <b><u>or related</u></b> product bears the CE marking referred to in	SE:  We want to maintain our previous comment comments that, in order to avoid loopholes, the text in paragraphs 1 and 2 should be completed with references to " <b><u>or putting it into service</u></b> ". See the parallel negotiation of a Battery Regulation as an example.

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>complied with the requirements set out in Article 10(5) and (6).</p>	<p>Article 19 and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 10(5) and (6).</p>	
<p>Where an importer considers or has reason to believe that a machinery <b><u>or related</u></b> product is not in conformity with the <b>applicable</b> essential health and safety requirements set out in Annex III, the importer shall not place it on the market until it has been brought into conformity.</p> <p>Furthermore, where the machinery <b><u>or related</u></b> product <del>poses</del> <b>presents</b> a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and, <b><u>if available, a digital contact</u></b> <del>the email address</del> at which they can be contacted on the machinery <b><u>or related product</u></b> or, where that is not possible, on its packaging or in a document accompanying the machinery <b><u>or related</u></b> product. The contact details shall be in a language easily understood by <del>end</del>-users and market surveillance authorities.</p>	<p>SE:</p> <p>3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and, <b><u>if available, a digital contact</u></b> <del>the email address</del> at which they can be contacted on the machinery <b><u>or related product</u></b> or, where that is not possible, on its packaging or in a document accompanying the machinery <b><u>or related</u></b> product. The contact details shall be in a language easily understood by <del>end</del>-users and market surveillance authorities.</p>	<p>SE:</p> <p>We want to maintain our previous comments that we prefer references throughout the text to say "e-mail address" instead of "digital contact". It is important for the person who wants to have a contact with the manufacturer to be able to receive a receipt that an e-mail has been sent, both for consumers and market surveillance authorities.</p>
<p>4. Importers shall ensure that the machinery <b><u>or related</u></b> product is accompanied by the instructions and information set out in section 1.7 of Annex III in a language which can</p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p>be easily understood by <del>end</del>-users, as determined by the Member State concerned.</p> <p><b><u>Instructions set out in section 1.7.4 of Annex III may be provided in a digital format and shall be clear, understandable, intelligible and legible. However, upon purchaser request [time of the request to be discussed], instructions should be provided in paper format free of charge.</u></b></p>		
<p><b><u>In the case of a machinery or related product intended for use by non-professional operators or which can, under reasonably foreseeable conditions, be used by non-professional operators, the importer shall ensure that such product is accompanied by the instructions in paper format that are essential for putting the machinery or related</u></b></p>		<p>CZ:</p> <p>We agree with this obligation of importer.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>product into service and for using it in a safe way.</u></b>		
	<p>FI:</p> <p>In the case of a machinery or related product intended for use by non-professional operators or which can, under reasonably foreseeable conditions, be used by non-professional operators <b><u>even if not intended for them</u></b>, the importer shall ensure that such product is accompanied by the instructions in paper format that are essential for putting the machinery or related product into service and for using it in a safe way.</p>	<p>FI:</p> <p>See our comments on Art 10(7).</p> <p>The same comment also applies to Art 13(2).</p>
<p>5. Importers shall ensure that, while the machinery <b><u>or related</u></b> product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the essential</p>		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
health and safety requirements set out in Annex III.		
<p>6.——When deemed appropriate with regard to the risks <del>to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment,</del> presented by a machinery <b><u>or related</u></b> product, importers shall, <b><u>in order to protect health and safety of persons, and where appropriate, domestic animals and property and, where applicable, the environment</u></b> carry out sample testing of machinery <b><u>or related</u></b> products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery <b><u>or related</u></b> products and machinery <b><u>or related</u></b> products recalls, and shall</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
keep distributors informed of any such monitoring.		
<p>7. Importers who consider or have reason to believe that a machinery <b><u>or related</u></b> product, which they have placed on the market, is not in conformity with <del>the essential health and safety requirements set out in Annex III</del> <b><u>this Regulation</u></b> shall immediately take the corrective <del>measures</del> <b><u>actions</u></b> necessary to bring that machinery <b><u>or related</u></b> product into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the machinery <b><u>or related</u></b> product <del>poses</del> <b><u>presents</u></b> a risk <del>to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment</del>, importers shall immediately inform the competent national</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
authorities of the Member States in which they made the machinery <b><u>or related</u></b> product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective <del>measures</del> <b><u>actions</u></b> taken.		
8. Importers shall, for ten years after the machinery <b><u>or related</u></b> product has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation <b><u>set out in Part A of Annex IV</u></b> can be made available to those authorities <b><u>upon request</u></b> . <del>Where relevant, the source code or programmed logic included in the technical documentation shall be made available upon a reasoned request from competent national authorities provided that it is</del>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<del>necessary in order for those authorities to be able to check compliance with the essential health and safety requirements set out in Annex III.</del>		
<p>9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery <b><u>or related</u></b> products with the <del>essential health and safety requirements set out in Annex III</del> <b><u>this Regulation</u></b> in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any <del>measures</del> <b><u>actions</u></b> taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
property and, where applicable, the environment posed <b><u>presented</u></b> by a machinery <b><u>or related</u></b> products, which they have placed on the market.		
<b><u>Article 12a</u></b>		
<b>Obligations of importers of partly completed machinery</b>		
<b>1. Importers shall place <u>only compliant on the market</u> partly completed machinery <u>on the market that complies with the essential health and safety requirements set out in Annex III.</u></b>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><b><u>2. Before placing a partly completed machinery on the market, importers shall ensure that the manufacturer has drawn up the technical documentation set out in Part B of Annex IV, that it is accompanied by the required documents and that the manufacturer has complied with the requirements set out in Article 10a (5) and (6).</u></b></p>		
<p><b><u>Where an importer considers or has reason to believe that a partly completed machinery is not in conformity with the <b>applicable relevant</b> essential health and safety requirements set out in Annex III, the importer shall not place it on the market until it has been brought into conformity. Furthermore, where the partly completed</u></b></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><u>machinery presents a risk as regards the <del>applicable relevant</del> essential health and safety requirements to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the importer shall inform the manufacturer and the market surveillance authorities to that effect.</u></p>		
<p><u>3. Importers shall indicate their name, registered trade name or registered trade mark, the postal address and, if available, a digital contact the email address at which they can be contacted on the partly completed machinery or related product or, where that is not possible, on its packaging or in a document accompanying the partly completed machinery or related product. The</u></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>contact details shall be in a language easily understood by <del>users</del> the person who incorporates the partly completed machinery and market surveillance authorities.</u>		
<p><b>4. Importers shall ensure that the partly completed machinery is accompanied by the assembly instructions set out in Annex X in a language which can be easily understood by <del>users</del> the person who incorporates the partly completed machinery, as determined by the Member State concerned. Such assembly instructions may be provided in a digital format and shall be clear, understandable, intelligible and legible . However, upon purchaser request [time of the request to be discussed], instructions <del>should</del> <b>shall</b> be provided in paper format free of charge.</b></p>		



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><b><u>5. Importers shall ensure that partly completed machinery, while it is under their responsibility, storage or transport conditions do not jeopardise its conformity with the <span style="color: red;">relevant</span> essential health and safety requirements set out in Annex III.</u></b></p>		
<p><b><u>6. — When deemed appropriate with regard to the risks presented by a partly completed machinery, importers shall carry out sample testing of partly completed machinery made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming partly completed machinery and partly completed machinery recalls, and shall keep</u></b></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>distributors informed of any such monitoring.</u>		
<p><b><u>7. Importers who consider or have reason to believe that a partly completed machinery , which they have placed on the market, is not in conformity with <del>the applicable essential health and safety requirements set out in Annex III this Regulation</del> shall immediately take the corrective measures actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate. Furthermore, where the partly completed machinery presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the partly</u></b></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>completed machinery available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures actions taken.</u>		
<u>8. Importers shall, for ten years after the partly completed machinery has been placed on the market, keep a copy of the EU declaration of incorporation at the disposal of the market surveillance authorities and ensure that the technical documentation set out in Part B of Annex IV can be made available to those authorities upon request.</u>		
<u>9. Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form,</u>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>necessary to demonstrate the conformity of the partly completed machinery with this Regulation in a language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any <del>measures</del> actions taken to eliminate the risks presented by a partly completed machinery, which they have placed on the market.</u>		
Article 13		
<b>Obligations of distributors <u>of machinery and related product</u></b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
1. When making a machinery <b><u>or related</u></b> product available on the market, distributors shall act with due care in relation to the requirements of this Regulation.		
2. Before making a machinery <b><u>or related</u></b> product available on the market, distributors shall verify that:		
(a) the machinery <b><u>or related</u></b> product bears the CE marking;		
(b) the machinery <b><u>or related</u></b> product is accompanied by the <b><u>EU</u></b> declaration of conformity <b><u>set out in Part A of Annex V</u></b> <del>required documents</del> and by the instructions and information set out in section 1.7 of Annex III in a language which can be easily understood by		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<del>end</del> -users <b><u>as determined by</u></b> in the Member State in which the machinery <b><u>or related</u></b> product is to be made available on the market;		
<b><u>In the case of a machinery or related product intended for use by non-professional operators or which can, under reasonably foreseeable conditions, be used by non-professional operators, such product is accompanied by the instructions in paper format that are essential for putting the machinery or related product into service and for using it in a safe way.</u></b>		CZ:  We agree with this obligation of distributor.
	FI:  In the case of a machinery or related product intended for use by non-professional operators or which can, under reasonably	FI:  See above our comments on Art 10(7) and Art 12(4).

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	foreseeable conditions, be used by non-professional operators <u>even if not intended for them</u> , such product is accompanied by the instructions in paper format that are essential for putting the machinery or related product into service and for using it in a safe way.	
(c) the manufacturer and the importer have complied with the requirements set out in Article 10(5) and (6) and Article 12(3) respectively.		
3. Where a distributor considers or has reason to believe that a machinery <b><u>or related</u></b> product is not in conformity with the essential health and safety requirements set out in Annex III, the distributor shall not make the machinery <b><u>or related</u></b> product available on the market until it has been brought into conformity.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Furthermore, where the machinery <b><u>or related</u></b> product <b><u>presents</u></b> poses a risk to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the distributor shall inform the manufacturer <b><u>or the importer to that effect as well as</u></b> and the market surveillance authorities to that effect.		
4. Distributors shall ensure that, while a machinery <b><u>or related</u></b> product is under their responsibility, storage or transport conditions do not jeopardise its conformity with the essential health and safety requirements set out in Annex III.		
5. Distributors who consider or have reason to believe that a machinery <b><u>or related</u></b> product,		



Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p>which they have made available on the market, is not in conformity with <del>the essential health and safety requirements set out in Annex III</del> <b><u>this Regulation</u></b> shall make sure that the corrective <del>measures</del> <b><u>actions</u></b> necessary to bring that machinery <b><u>or related</u></b> product into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the machinery <b><u>or related product presents</u></b> poses a risk to the <del>health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment,</del> distributors shall immediately inform the competent national authorities of the Member States in which they have made the machinery <b><u>or related</u></b> product available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective <del>measures</del> <b><u>actions</u></b> taken.</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>6. Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the machinery <b><u>or related</u></b> product <del>with the essential health and safety requirements set out in Annex III in a language that can be easily understood by that authority.</del> They shall cooperate with that authority, at its request, on any <del>measures</del> <b><u>actions</u></b> taken to eliminate the risks <del>to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment,</del> <b><u>presented</u></b> posed by a machinery <b><u>or related</u></b> product, which they have made available on the market.</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<b>Article 13a</b>		
<b>Obligations of distributors of partly completed machinery</b>		
<b><u>1. When making a partly completed machinery available on the market, distributors shall act with due care in relation to the requirements of this Regulation.</u></b>		
<b><u>2. Before making a partly completed machinery available on the market, distributors shall verify that:</u></b>		
<b><u>(a) the partly completed machinery is accompanied by the required documents and by the assembly instructions set out in</u></b>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>Annex X in a language which can be easily understood by users the person who incorporates the partly completed machinery as determined by the Member State in which the partly completed machinery is to be made available on the market;</u>		
(b) <u>the manufacturer and the importer have complied with the requirements set out in Article 10a (5) and (6) and Article 12a (3) respectively.</u>		
3. <u>Where a distributor considers or has reason to believe that a partly completed machinery is not in conformity with the <b>applicable relevant</b> essential health and safety requirements set out in Annex III, the distributor shall not make the partly</u>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><u>completed machinery available on the market until it has been brought into conformity. Furthermore, where the partly completed machinery presents <del>poses</del> a risk as regards <b>applicable relevant</b> essential health and safety requirements <del>to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, the distributor shall inform the manufacturer or the importer to that effect as well as and the market surveillance authorities to that effect.</del></u></p>		
<p><u>4. Distributors shall ensure that, while a partly completed machinery is under their responsibility, storage or transport conditions do not jeopardise its conformity</u></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>with the <b>relevant</b> essential health and safety requirements set out in Annex III.</u>		
<p><u>5. Distributors who consider or have reason to believe that a partly completed machinery which they have made available on the market, is not in conformity with <del>the applicable essential health and safety requirements set out in Annex III</del> this <b>Regulation</b> shall make sure that the corrective <del>measures</del> actions necessary to bring that partly completed machinery into conformity, to withdraw it or recall it, as appropriate, are taken. Furthermore, where the partly completed machinery <del>poses</del> presents a risk as regards applicable essential health and safety requirements to the health and safety of persons and, where</u></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><del><u>appropriate, domestic animals and property</u></del>  <del><u>and, where applicable, the environment,</u></del>  <u>distributors shall immediately inform the</u>  <u>competent national authorities of the</u>  <u>Member States in which they have made the</u>  <u>partly completed machinery available on the</u>  <u>market to that effect, giving details, in</u>  <u>particular, of the non-conformity and of any</u>  <u>corrective measures actions taken.</u></p>		
<p><u>6. Distributors shall, further to a</u>  <u>reasoned request from a competent national</u>  <u>authority, provide it with all the information</u>  <u>and documentation, in paper or electronic</u>  <u>form, necessary to demonstrate the</u>  <u>conformity of the partly completed</u>  <u>machinery with the essential health and</u>  <u>safety requirements set out in Annex III in a</u></p>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>language that can be easily understood by that authority. They shall cooperate with that authority, at its request, on any measures actions taken to eliminate the risks to the health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment, presented posed by a partly completed machinery, which they have made available on the market.</u>		
Article 14		
Cases in which obligations of manufacturers apply to importers and distributors		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article <b><u>10 and 10a</u></b> where that importer or distributor places a <b><u>product subject to this Regulation</u></b> machinery product on the market under his or her name or trademark, <del>or substantially modifies</del> carries out a substantial modification of a <b><u>product subject to this Regulation</u></b> machinery product that has already been placed on the market or put into service.</p>		
Article 15		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
Other cases in which obligations of manufacturers apply		
<p>A natural or legal person, <del>other than the manufacturer, the importer or the distributor,</del> that carries out a substantial modification of a <u><b>machinery or related product subject to this Regulation and placed on the market since the [OJ: please insert the date 10 years before the date of entry into force of this Regulation]</b></u>, the machinery product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for the part of the <u><b>machinery or related product subject to this Regulation</b></u> that is affected by the <u><b>substantial</b></u> modification or, if the substantial</p>	<p>CZ:</p> <p>A natural or legal person, <del>other than the manufacturer, the importer or the distributor,</del> that carries out a substantial modification of a <u><b>machinery or related product subject to this Regulation and placed on the market since the [OJ: please insert the date 10 years before the date of entry into force of this Regulation]</b></u>, the machinery product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for the <u><b>part of the machinery or related product subject to this Regulation</b></u> that is affected by the <u><b>substantial</b></u> modification or, if the substantial modification has an impact on the safety of the machinery product as a whole, for the entire machinery product <u><b>or, if the substantial modification has</b></u></p>	<p>CZ:</p> <p>We suggest deleting “<i>part of the</i>” wording, otherwise we agree with this new definition.</p> <p>DK:</p> <p>Denmark does not support the last revised part of article 15. We think it is unclear what the meaning is. We want it to be clear, that a partial modification is possible. Therefore, we want to keep the original text proposed by the COM.</p> <p>Concerning the discussion about ‘own use’, DK finds that a substantial modification made by a</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><del>modification has an impact on the safety of the machinery product as a whole, for the entire machinery product</del> <b><u>or, if the substantial modification has only an impact on the safety of a part of an assembly, for the affected part of this assembly.</u></b></p>	<p><b><u>only an impact on the safety of a part of an assembly, for the affected part of this assembly.</u></b></p> <p>DK:</p> <p>A natural or legal person, that carries out a substantial modification of a machinery or related product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for the part of the machinery or related product <del>or, if the substantial modification has only an impact on the safety of a part of an assembly, for the affected part of this assembly</del> <b><u>that is affected by the modification or, if the substantial modification has an impact on the safety of the machinery product as a whole, for the entire machinery product.</u></b></p> <p>ES:</p> <p>A natural or legal person, <del>other than the manufacturer, the importer or the distributor,</del> that carries out a substantial modification of a</p>	<p>person or company for their own use must be covered.</p> <p>The Machinery Regulation is applicable when a person or company manufactures a new machine for their own use. Therefore, it makes no sense if the same person can make a substantial modification of a machine and the modification would not be covered by the MR. A substantial modification is considered as a new machine and therefore the rules must be the same.</p> <p>ES:</p> <p><b>This article should also foresee those cases where the substantial modification has an impact on the safety of the machinery or related product as a whole, as it was stated in the wording of previous Presidency compromise texts.</b></p> <p>MT:</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p><del>machinery or related product subject to this Regulation and placed on the market since the [OJ: please insert the date 10 years before the date of entry into force of this Regulation];</del> the machinery product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for the part of the <b>machinery or related product</b> that is affected by the substantial modification or, if the substantial modification has an impact on the safety of the machinery or related product as a whole, for the entire machinery or related product <b>subject to this Regulation</b> that is affected by the <b>substantial</b> modification or, if the substantial modification has an impact on the safety of the machinery product as a whole, for the entire machinery product <b>or, if the substantial modification has only an impact on the safety of a part of an assembly, for the affected part of this assembly.</b></p> <p>SE:</p> <p>A natural or legal person, that carries out a substantial modification of a machinery or related products shall be considered a</p>	<p>Malta welcomes the deletion of text that was within the closed brackets [re 10 years]. However, the proposed amendments fall short from addressing a substantial modification that has an impact <b>on the safety of the whole product</b>.</p> <p>The current text of Article 15 only foresees substantial modifications which has an effect on part of the machinery or the part of assembly.</p> <p>Article 15 should be amended to reflect that a substantial modification can have an impact on the safety of the whole product.</p> <p>Furthermore, MT would like to seek clarification on what it is being understood by the text <b>“impact on the safety of a part of an assembly, for the affected part of this assembly.”?</b></p> <p>Provisions related to machinery manufactured for own use but which is never made available on the market, present significant difficulties in terms of enforcement on the ground. It is easy to understand how and why it would be very difficult to identify machinery that is put into service for personal use and within a private</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	<p>manufacturer for the purpose of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10. <del>for the part of the machinery or related product or,</del></p> <p>If the substantial modification <del>has</del> only <del>has</del> an impact on the safety of a part of <del>machinery or related products an assembly,</del> for the obligations of the manufacturer set out in article 10 applies to the affected part <del>of this assembly.</del></p>	<p>setting, even though it is never made available on the market.</p> <p>The same notion also applies to the enforcement with respect to machinery which was already made available on the market and which is subsequently modified substantially by the user and re-put into service for personal use within a private setting. For this reason and due to the logistical and practical difficulties related to implementation and enforcement, it is urged that alternative wording is found.</p> <p>SE:</p> <p>We would like retain the clear reference machinery or related products. We don't see any need to forego established terminology and instead use unclear terms that might need additional definitions. In addition, we suggest separating the paragraph into two separate subparagraphs or sentences to improve the readability of it.</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	<p>FI:</p> <p>A natural or legal person, that carries out a substantial modification of a machinery or related product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 <del>for the part of the machinery or related product</del> or, if the substantial modification has only an impact on the safety of a part of an assembly <u>of machinery</u>, for the affected part of this assembly.</p>	<p>FI:</p> <p>Our position still is that it is practically impossible for the person, who substantially modifies the machinery, to only focus on the part of the machinery, which has been substantially modified - except for an assembly of machinery (and as to assemblies of machinery, an editorial addition is suggested at the end of the sentence, as the term “assembly” is not defined).</p> <p>This is why we suggest deleting the words “for the part of the machinery or related product”.</p>
Article 16		
<b>Identification of economic operators</b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
1. Economic operators shall, on request, identify the following to the market surveillance authorities:		
(a) any economic operator who has supplied them with a <del>machinery</del> product <b><u>subject to this Regulation;</u></b>		
(b) any economic operator to whom they have supplied a <del>machinery</del> product <b><u>subject to this Regulation.</u></b>		
2. Economic operators shall be able to present the information referred to in paragraph 1 for ten years after they have been supplied with the <del>machinery</del> product <b><u>subject to this Regulation</u></b> and for ten years after they have		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
supplied the <del>machinery</del> product <b><u>subject to this Regulation</u></b> .		
CHAPTER III		
CONFORMITY OF <u>PRODUCTS SUBJECT TO THIS REGULATION</u> <del>THE MACHINERY</del>		
Article 17		
<b>Presumption of conformity of <del>machinery</del> products <u>subject to this Regulation</u></b>		
1. A <del>machinery</del> product <b><u>subject to this Regulation</u></b> which is in conformity with harmonised standards or parts thereof the references of which have been published in the <i>Official Journal of the European Union</i> shall be		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those standards or parts thereof.		
2. The Commission shall, as provided in Article 10(1) of Regulation (EU) No 1025/2012, request one or more European standardisation organisations to draft harmonised standards for the essential health and safety requirements set out in Annex III.		
3. The Commission is empowered to adopt implementing acts establishing <b>common</b> <del>technical</del> specifications for the essential health and safety requirements set out in Annex III where <b>both of</b> the following conditions have been fulfilled:	CZ:	CZ:  We agree with this wording of paragraph 3.

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(a) no reference to harmonised standards covering the relevant essential health and safety requirements is published in the <i>Official Journal of the European Union</i> in accordance with Regulation (EU) No 1025/2012;		CZ:  We agree with this wording of point (a).
(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements <b><u>set out in Annex III</u></b> and there are undue delays in the standardisation procedure or the request has not been accepted by any of the European standardisation organisations <b><u>or a European standardisation organisation has delivered a standard that does not entirely correspond with the request of the Commission.</u></b>	CZ:  (b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements set out in Annex III <b>and there are undue delays in the standardisation procedure or the request has not been accepted by any of the European standardisation organisations. or a European standardisation organisation has delivered a standard that does not entirely correspond with the request of the Commission.</b>  SE:	CZ:  The Czech Republic still maintains its reservation to confere this power on the Commission. Specifications adopted in this way do not guarantee the same level of transparency and involvement of all stakeholders as the procedure for drawing up harmonised technical standards. If this alternative is retained in the proposal, it must be used only as a fallback solution in exceptional cases with clearly defined conditions for such a procedure.  We support the proposal of Sweden (see 2nd column "Drafting Suggestions", in the document WK 2655/2022 INIT on pages 5 and 6)

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p>(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard for the essential health and safety requirements set out in Annex III and <del>there are undue delays in the standardisation procedure</del> of the request has not been accepted by any of the European standardisation organisations or a European standardisation organisation has <u>not</u> delivered a standard that <del>does not entirely</del> correspond with the request of the Commission <u>within four years of accepting the request</u>.</p>	<p>concerning the Commission's power to adopt implementing acts laying down common/technical specifications and specifying the cases in which the Commission may use the power to adopt implementing acts laying down common/technical specifications.</p> <p>Decidedly, the harmonised standards are preferred as well as limitations to the power of Commission to create technical specifications and the involvement of the Committee on Standardization. This measure will enable members states and stakeholders to have a clear overview. If the par. 3 of the Art. 17 and related recitals will remain in the proposal, we support its adjusting accordint to the SE proposal.</p> <p>SE:</p> <p>As discussed during the last Working Party, we see a landing zone where:</p> <ul style="list-style-type: none"> <li>• the current article is adapted so the current phrase “undue delay” is clarified into a specific timeframe (we suggest 4 years),</li> <li>• where consultations with the Committee of Standards are replaced by an obligation so that</li> </ul>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>the Commission inform the Committee when they deem that the standardization path has failed,</p> <ul style="list-style-type: none"> <li>• a no opinion clause is introduced in article 46, and</li> <li>• where the accompanying recital is reverted to an earlier stage that have wording which underscores how common specifications should only be used as a fall-back solution rather than wording which might amplify the current friction in the standardization system.</li> </ul>
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).	<p>CZ:</p> <p>Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46(3).</p> <p>SE:</p>	

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 46( <del>3</del> <i>reference to no-opinion clause</i> ).	
<p><b><u>3a. Before adopting an implementing act, the Commission shall consult national experts and other relevant stakeholders. Based on that consultation, the Commission shall prepare the draft implementing act.</u></b></p>	<p>CZ:</p> <p>3a. Before adopting an implementing act, the Commission shall consult <b>the Committee on Standards and</b> national experts <b>as well as</b> other relevant stakeholders. Based on that consultation, the Commission shall prepare the draft implementing act.</p> <p>SE:</p> <p>3a. Before adopting an implementing act, the Commission shall <u>inform the committee referred to in Article 22 of Regulation EU (No) 1025/2012 that it considers that the conditions in</u></p>	<p>SE:</p> <p>See overall comment above.</p> <p>Instead of consultations with the Committee of Standards, we would like to see an obligation on the Commission to inform the Committee when they deem that the standardization path has failed</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<u>paragraph 3 are fulfilled and then</u> consult national experts and other relevant stakeholders. Based on that consultation, the Commission shall prepare the draft implementing act.	
4. A machinery product <b><u>subject to this Regulation</u></b> which is in conformity with the <b><u>common</u></b> technical specifications <b><u>referred to in paragraph 3</u></b> or parts thereof shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those <b><u>common</u></b> technical specifications or parts thereof.		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><b><u>4a. When references of a harmonised standard adopted by the European standardisation organisations and are published in the <i>Official Journal of the European Union</i>, implementing acts referred to in paragraph 3, or parts thereof which cover the same essential health and safety requirements set out in Annex III shall be repealed adequately covers the same essential health and safety requirements as an existing common specification adopted under this Regulation published in the <i>Official Journal of the European Union</i>, it replaces this common specification.</u></b></p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>5. Machinery <b><u>and related</u></b> products that have been certified or for which a statement of conformity has been issued under a cybersecurity scheme adopted in accordance with Regulation (EU) 2019/881 and the references of which have been published in the <i>Official Journal of the European Union</i> shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III, sections 1.1.9 and 1.2.1, as regards protection against corruption and safety and reliability of control systems in so far as those requirements are covered by the cybersecurity certificate or statement of conformity or parts thereof.</p>		
Article 18		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>EU declaration of conformity of machinery and related products</u></b>		
1. The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex III has been demonstrated.		
2. The EU declaration of conformity shall have the model structure set out in <b><u>part A of Annex V, and</u></b> shall contain the elements specified in the relevant modules set out in Annexes VI, <del>VII</del> , VIII, <del>and IX</del> , <b><u>and IXa</u></b> and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the machinery <b><u>or related</u></b> product is placed on the	PT:  2. The EU declaration of conformity shall have the model structure set out in part A of Annex V and shall contain the elements specified in the relevant modules set out in Annexes VI, <b><u>VII</u></b> , VIII, IX, and IXa <del>and shall be continuously updated</del> . It shall be translated into the language or languages required by the Member State in which the machinery or related product is	PT:  It is unclear what is meant by the provision “shall be continuously updated”. This requirement conflicts with the current provisions of the NLF which ensures that before placing a machinery or related product on the market, the manufacturer will make sure that it will remain safe throughout its life cycle.

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
market, <del>or</del> is made available on the market <b><u>or put into service</u></b> .	placed on the market or is made available on the market or put into service.	Lack of coherence with Annex V: ‘This declaration relates exclusively to machinery or related products, except for partly completed machinery, in the state in which it was placed on the market, and excludes components, which are added and/or operations carried out subsequently by the final user unless there is a substantial modification of the machinery product.’ Already in our previous comments WK 11725/2021 and WK 02569/2022.  Lack of Lack of coherence with art. 21 2(a): <i>EU type-examination procedure (module B) <del>provided for</del> <b><u>set out</u></b> in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;</i>
3. Where a machinery <b><u>or related</u></b> product is subject to more than one Union act requiring an		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.		
4. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the machinery <b><u>or related</u></b> product with the requirements laid down in this Regulation.		
<b><i>Article 18a</i></b>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<i>EU declaration of incorporation of partly completed machinery</i>		
<b><u>1. The EU declaration of incorporation shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex III has been demonstrated.</u></b>		
<b><u>2. The EU declaration of incorporation shall have the model structure set out in part B of Annex V. It shall be translated into the language or languages required by the Member State in which the partly completed machinery is placed on the market or is made available on the market.</u></b>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>3. Where a partly completed machinery is subject to more than one Union act requiring an EU declaration of conformity, the EU declaration of incorporation shall include a sentence declaring the conformity with such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.</u></b>		
<b><u>4. By drawing up the EU declaration of incorporation, the manufacturer shall assume responsibility for the compliance of the partly completed machinery with the requirements laid down in this Regulation.</u></b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Article 19		
<b>General principles of the CE marking <del>for</del> <u>machinery and related products</u></b>		
The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.		
Article 20		
<b>Rules for affixing the CE marking <u>to</u> <u>machinery and related products</u></b>		
1. The CE marking shall be affixed visibly, legibly and indelibly to the machinery <b><u>or</u></b> <b><u>related</u></b> product. Where that is not possible or not warranted on account of the nature of the		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
machinery <b><u>or related</u></b> product, it shall be affixed to the packaging and to the documents accompanying the machinery <b><u>or related</u></b> product.		
2. The CE marking shall be affixed before the machinery <b><u>or related</u></b> product is placed on the market <b><u>or put into service</u></b> .		
3. <b><u>Where the conformity of machinery or related products is assessed</u></b> For a machinery product in the conformity assessment of which a notified body participates in accordance with <b><u>the conformity procedure set out referred to in Article 21 (2) points a), b) and c) Annexes VII plus VIII, IX and IXa,</u></b> the CE marking shall be followed by the		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
identification number of <del>that</del> <b>the</b> notified body <b><u>involved in that procedure.</u></b>		
The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or the manufacturer's authorised representative.		
4. The CE marking and, where applicable, the identification number of the notified body may be followed by a pictogram or <b><u>any</u></b> other marking indicating a special risk or use.		
5. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
CHAPTER IV		
CONFORMITY ASSESSMENT		
Article 21		
<b>Conformity assessment procedures for machinery <u>and related</u> products <del>except partly completed machinery</del></b>		
1. <del>In order to certify the conformity of a machinery <u>or related</u> product with this Regulation, <u>the manufacturer of machinery or a related product</u> or its authorised representative and the person who has carried</del>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<del>out a substantial modification to the machinery product</del> , shall apply one of the procedures for assessment of conformity referred to in paragraphs 2 and 3.		
2. Where the machinery <b><u>or related</u></b> product is a <del>high-risk machinery product</del> listed in Annex I <b><u>part A</u></b> , the manufacturer <del>or the manufacturer's authorised representative and the person who has carried out a substantial modification to the machinery product</del> shall apply one of the following procedures:	PT:  2. Where the machinery or related product is listed in Annex I <b><u>part A</u></b> , the manufacturer shall apply one of the following procedures:	PT:  We think that the best way to resolve the issue with Annex I is to restrict it at the minimum and to machinery that is for sure going to be there after its review otherwise would create unpredictability to the market with a doubtful gain in safety and security to the consumer.
(a) EU type-examination procedure (module B) <del>provided for</del> <b><u>set out</u></b> in Annex VII, followed by conformity to type based on internal		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
production control (module C) set out in Annex VIII;		
(b) Conformity based on full quality assurance (module H) set out in Annex IX;		
<b><u>(c) Conformity based on unit verification (module G) set out in Annex IXa.</u></b>		
<b><u>2a. Where the machinery or related product is listed in Annex I part B, the manufacturer shall apply one of the following procedures:</u></b>	CZ:  Where the machinery or related product is listed to in Annex I part B and manufactured in accordance with the harmonised standards referred to in Article 17(1), and provided that those standards cover all of the relevant essential	<b><u>CZ:</u></b>  <b><u>We suggest, module A could be used only under the condition, that the machinery or related product was also manufactured in accordance with the harmonised standards referred to in Article 17(1), and provided that those standards cover all of the relevant</u></b>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p><b>health and safety requirements</b>, the manufacturer shall apply one of the following procedures:</p> <p>ES:</p> <p><b>2a. Where the machinery or related product is listed in Annex I part B and manufactured in accordance with the harmonised standards or the common specifications referred to in Article 17 that are specific for that category of machinery or related product, and provided that those standards or specifications cover all the relevant essential health and safety requirement, the manufacturer shall apply one of the following procedures:</b></p>	<p><b><u>essential health and safety requirements (that means usage of the module A should be enabled under the same condition as in the current Annex IV of the directive 2006/42/ES).</u></b></p> <p>DK:</p> <p>DK can accept the proposal as a compromise solution. We could also accept a revision where point 2a (a), Internal production control, is deleted, so the procedure is the same as in the Machinery Directive.</p> <p>ES:</p> <p><b>We propose this wording to keep the same level of ambition of the Machinery Directive, where distinction is made based on the existence of standards or specifications.</b></p> <p><b>We think specific standards that cover all the EHSR represent a safety benchmark that could justify the use of module A.</b></p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p>FI:</p> <p>2a. Where the machinery or related product is listed in Annex I, part B, <u>and it fully complies with an applicable harmonised C-type standard, which covers all the applicable essential health and safety requirements</u>, the manufacturer shall apply one of the following procedures:</p>	<p>FI:</p> <p>See comments above, in comments on Art 5.</p>
<p><b><u>(a) Conformity with the internal production control procedure (module A) set out in Annex VI;</u></b></p>	<p>ES:</p> <p><b><u>(a) Conformity with the internal production control procedure (module A) set out in Annex VI, part A;</u></b></p> <p>PT:</p>	

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<del>(a) — Conformity with the internal production control procedure (module A) set out in Annex VI;</del>	
<u>(b) EU type-examination procedure (module B) set out in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;</u>	PT:  <del>(b) — EU type-examination procedure (module B) set out in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;</del>	
<u>(c) Conformity based on full quality assurance (module H) set out in Annex IX;</u>	PT:  <del>(c) — Conformity based on full quality assurance (module H) set out in Annex IX;</del>	

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<b><u>(d) Conformity based on unit verification (module G) set out in Annex IXa.</u></b>	PT:  <del><b>(d) — Conformity based on unit verification (module G) set out in Annex IXa.</b></del>	
	<p><b><u>CZ:</u></b></p> <p>2b. Where the machinery is referred to in Annex I part B and has not been manufactured in accordance with the harmonised standards referred to in Article 17(1), or only partly in accordance with such standards, or if the harmonised standards do not cover all the relevant essential health and safety requirements</p> <p>or if no harmonised standards exist for the machinery in question, the manufacturer shall apply one of the following procedures:</p> <p>(a) EU type-examination procedure (module B) set out in Annex VII, followed by conformity</p>	<p><b><u>CZ:</u></b></p> <p><b><u>If the machinery or related product was not manufactured in accordance with the harmonised standards referred to in Art. 17(1), or if those harmonised standards do not cover all the relevant essential health and safety requirements, we suggest an involvement of the third independent party in the conformity assessment process (same conditioning as in the current directive). strojní zařízení nebo související výrobek</u></b></p> <p>ES:</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p>to type based on internal production control (module C) set out in Annex VIII;</p> <p>(b) Conformity based on full quality assurance (module H) set out in Annex IX;</p> <p>(c) Conformity based on unit verification (module G) set out in Annex IXa.</p> <p>ES:</p> <p><u>2b (new). Where the machinery or related product is listed in Annex I part B and has not been manufactured in accordance with the harmonised standards or the common specifications referred to in Article 17 that are specific for that category of machinery or related product, or only partly in accordance with such standards or specifications, or if those standards or specifications do not cover all the relevant essential health and safety requirements or if no specific harmonised standards or common specifications exist for the machinery or related product in question, the manufacturer shall apply one of the following procedures:</u></p>	<p>We propose this wording to keep the same level of ambition of the Machinery Directive, where distinction is made based on the existence of standards or specifications.</p> <p>We think specific standards that cover all the EHSR represent a safety benchmark that could justify the use of module A.</p>



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	<p>(a) <u>EU type-examination procedure (module B) set out in Annex VII, followed by conformity to type based on internal production control (module C) set out in Annex VIII;</u></p> <p>(b) <u>Conformity based on full quality assurance (module H) set out in Annex IX;.</u></p> <p><u>Conformity based on unit verification (module G) set out in Annex IXa</u></p>	
	<p>FI:</p> <p><u>Where the machinery or related product is listed in Annex I, part B, and it does not fully comply with an applicable harmonised C-type standard, which covers all the applicable essential health and safety requirements, the</u></p>	<p>FI:</p> <p>We propose adding new text, which describes what are the conformity assessment procedures available for machinery listed in part B of Annex I, in case the machinery does not fully comply with an applicable harmonised C-type standard.</p>

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<a href="#"><u>manufacturer shall apply one of the procedures referred to in paragraph 2.</u></a>	
3. Where the machinery <b><u>or related</u></b> product is not a <del>high-risk machinery product</del> listed in Annex I, the manufacturer <del>or the manufacturer's authorised representative and the person who has made a substantial modification to the machinery product</del> shall apply the internal production control procedure (module A) set out in Annex VI, <b><u>part A</u></b> .	PT:  3. Where the machinery or related product is not listed in Annex I, the manufacturer shall apply the internal production control procedure (module A) set out in Annex VI, <del>part A</del> .	PT:  We think that the best way to resolve the issue with Annex I is to restrict it at the minimum and to machinery that is for sure going to be there after its review otherwise would create unpredictability to the market with a doubtful gain in safety and security to the consumer.
<b><u>3a. Any person before placing on the market or putting into service a substantially modified machinery or related products, shall apply the procedure set up in the Annex IX b.</u></b>	<b><u>CZ:</u></b>  <b><u>3a. — Any person before placing on the market or putting into service a substantially modified machinery or related products, shall apply the procedure set up in the Annex IX b.</u></b>  SE:	<b><u>CZ:</u></b>  We suggest omitting the paragraphs 3a) in Article 21, Part C of the Annexes IV and V, and Annex IXb, which have been newly added to the text by the document WK 1923/2022 INIT in connection with a substantial modification. In connection with the Article 15 we consider this information redundant. This detailed information

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
	<p>Any person before placing on the market or putting into service a <b>partial</b> substantially modified machinery or related products, shall apply the procedure set up in Annex IX b. <b><u>The technical documentation shall be drawn up according to Annex IV part C.</u></b></p> <p>FI:</p> <p><b><u>3a. — Any person before placing on the market or putting into service a substantially modified machinery or related products, shall apply the procedure set up in the Annex IX b.</u></b></p>	<p>could possibly be included in the Guide to the Machinery Regulation. However if there is a prevailing opinion on keeping these parts, we could agree on this matter.</p> <p>DK:</p> <p>DK does not see the need for this point and the annex IXb. We find that both should be deleted.</p> <p>If other MS wants to keep the requirement for marking with ‘substantial modification’ we find that this marking request should be added to the other marking requests in article 10 (5).</p> <p>SE:</p> <p>The person who makes a partial substantially modified change must both make an assessment of conformity for the rebuilt part and also check that the original machine meets the requirements that apply to it.</p> <p>FI:</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		<p>We do not support this addition, as the person making the substantial modification is considered a manufacturer, and the obligations of the manufacturers should apply in every respect.</p> <p>A separate Annex describing the conformity assessment procedure for substantially modified machinery should not be introduced, as it is superfluous, make the Regulation more complicated and create confusion as regards the requirements of the manufacturers.</p> <p>The person who makes a substantial modification will most probably read so that this is an extra requirement, which should be followed in addition to following all the requirements of manufacturers (which already include a requirement concerning e.g. conformity assessment of machinery).</p> <p>PT:</p>

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
		Maybe there is another way to put this information and the one in annex IXb. Like this is confusing.
4. Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment and reduce those fees proportionately to their specific interests and needs.		
<i>Article 21a</i>	PT:  <i>Article 21a</i>	

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<i>Conformity assessment procedure for partly completed machinery</i>	<i>PT:</i>  <i>Conformity assessment procedure for partly completed machinery</i>	DK:
<b><u>The manufacturer of partly completed machinery shall apply the internal production control procedure (module A) set out in Annex VI, part B.</u></b>	PT:  <del>The manufacturer of partly completed machinery shall apply the internal production control procedure (module A) set out in Annex VI, part B.</del>	
Article 22 (moved to Art.10a)		
<del>Conformity assessment procedures for partly completed machinery</del>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
1.——The manufacturer of partly completed machinery or the manufacturer's authorised representative shall, before placing partly completed machinery on the market, ensure that the following documents are drawn up:		
(a)——the relevant technical documentation that satisfies the requirements laid down in Annex IV, part B;		
(b)——assembly instructions that satisfy the requirements laid down in Annex X;		
(c)——the EU declaration of incorporation that has the model structure set out in Annex V.		
2.——Where relevant, the manufacturer of partly completed machinery or the		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>manufacturer's authorised representative shall make available to the competent national authority upon its request the source code or programmed logic included in the technical documentation referred to in paragraph 1, point (a),, provided that it is needed in order for that authority to be able to check compliance with the essential health and safety requirements set out in Annex III. The assembly instructions referred to in paragraphs 1, point (b), and the declaration of incorporation referred to in paragraph 1, point (c), shall accompany the partly completed machinery until it is incorporated into the final machinery product and shall afterwards form part of the technical file for that machinery product.</p>		
Article 23 (moved to Article 4a)		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<b>Protection of persons during installation and use of machinery products</b>		
Member States may lay down requirements to ensure that persons, including workers, are protected when installing and using machinery products, provided that such rules do not allow for modification of a machinery product in a way that is not compatible with this Regulation.		
CHAPTER V		
NOTIFICATION OF CONFORMITY ASSESSMENT BODIES		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Article 24		
<b>Notification</b>		
Member States shall notify the Commission and the other Member States of <del>conformity assessment</del> bodies authorised to carry out <b><u>third-party</u></b> conformity assessments <b><u>tasks</u></b> in accordance with this Regulation.		
Article 25		
<b>Notifying authorities</b>		
1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article <del>30</del> 32.		
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.		
3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body, which is not a governmental entity that body shall be a legal entity and shall comply <i>mutatis mutandis</i> with the requirements laid down in Article 26.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
In addition, that body shall have arrangements to cover liabilities arising out of its activities.		
4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.		
Article 26		
<b>Requirements relating to notifying authorities</b>		
1. A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
2. A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.		
3. A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment of the machinery product.		
4. A notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy services on a commercial or competitive basis.		
5. A notifying authority shall safeguard the confidentiality of the information it obtains.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
6. A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.		
Article 27		
<b>Information obligation on notifying authorities</b>		
Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.		
The Commission shall make that information publicly available.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Article 28		
<b>Requirements relating to notified bodies</b>		
1. For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.		
2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.		
3. A conformity assessment body shall be a third-party body independent of the organisation or the machinery <b><u>or related</u></b> product it assesses.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
A body belonging to a business association or professional federation representing undertakings involved in the design, manufacture, provision, assembly, use or maintenance of machinery <b><u>or related</u></b> products which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a conformity assessment body.		
4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of <del>a</del> machinery <b><u>or related</u></b> products, that they assess, nor the representative of any of those parties. This shall not preclude the use of a	SE:  4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of machinery or related products that they assess, nor <u>fulfil any of those roles in relation to partly completed machinery that has been incorporated</u>	SE:  In order to avoid a possible conflict of interest that have emerged through the separation of machinery products into three separate categories, we would like to make it clear that an actor that partakes in any of the listed roles in relation to a PCM that has been incorporated into the assessed product should also not be able to



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<u>assessed</u> machinery <u>or related</u> products that is <u>are</u> necessary for the operations of the conformity assessment body or the use of a machinery <u>or related</u> products for personal purposes.	<u>into the assessed product or be</u> the representative of any of those parties.	carry out conformity assessment tasks according to this Regulation.
A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, installation, use or maintenance of <u>those</u> machinery or <u>related</u> products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
which they are notified. This shall in particular apply to consultancy services.		
A conformity assessment body shall ensure that the activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of its conformity assessment activities.		
5. A conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence its judgement or the results of its conformity assessment activities, especially as regards		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
persons or groups of persons with an interest in the results of those activities.		
6. A conformity assessment body shall be capable of carrying out all the conformity assessment <del>activities mentioned in</del> <b><u>tasks assigned to it by</u></b> Annexes VII, <del>VIII</del> and IX <b><u>and IXa</u></b> and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.		
At all times, and for each conformity assessment procedure and each kind of <del>a</del> machinery <b><u>or related</u></b> products for which it has been notified, a conformity assessment body shall have at its disposal the necessary:		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment <b>tasks</b> activities;		
(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures;		
(c) appropriate policies and procedures to distinguish between <del>activities</del> <b>tasks</b> that it carries out as a notified body and other activities;		
(d) procedures for the performance of conformity assessment activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
complexity of the machinery technology in question and the mass or serial nature of the production process.		
A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.		
7. The personnel responsible for carrying out conformity assessment tasks shall have the following:		
(a) sound technical and vocational training covering all the conformity assessment activities		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
in relation to which the conformity assessment body has been notified;		
(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;		
(c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex III, of the applicable harmonised standards <b><u>and common specifications</u></b> referred to in Article 17, and of the relevant provisions of Union harmonisation legislation and of national legislation;		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(d) the ability to draw up certificates, records and reports demonstrating that conformity assessments have been carried out.		
8. The impartiality of a conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment <b>tasks</b> activities shall be guaranteed.		
The remuneration of the top-level management and the personnel responsible for carrying out the conformity assessment <b>tasks</b> activities shall not depend on the number of conformity assessments carried out or on the results of those assessments.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
9. A conformity assessment body shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.		
10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out the conformity assessment <b>tasks</b> activities in accordance with Annexes VII, <del>VIII</del> <b>and IX and IXa</b> , except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights, intellectual property rights and trade secrets shall be protected.		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
11. A conformity assessment body shall participate in, or ensure that its personnel responsible for carrying out the conformity assessment <b>tasks</b> activities are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 40 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.		
Article 29		
<b>Presumption of conformity of notified bodies</b>		
Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
parts thereof the references of which have been published in the <i>Official Journal of the European Union</i> , it shall be presumed to comply with the requirements set out in Article 28 in so far as the applicable harmonised standards cover those requirements.		
Article 30		
<b>Subsidiaries of and subcontracting by notified bodies</b>		
1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Article 28 and shall inform the notifying authority accordingly.		
2. A notified body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever those are established.		
3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.		
4. A notified body shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes VII, <del>VIII</del> and IX <b><u>and IXa</u></b> .		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Article 31		
<b>Application for notification</b>		
1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.		
2. The application for notification shall be accompanied by a description of the conformity assessment activities, of the conformity assessment procedures set out in Annexes VII, <del>VIII and IX</del> <b><u>and IXa</u></b> and of the kinds of machinery <b><u>or related</u></b> products for which the conformity assessment body claims to be competent, as well as by an accreditation		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 28.		
3. Where the conformity assessment body concerned cannot provide an accreditation certificate as referred to in paragraph 2, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 28.		
Article 32		
<b>Notification procedure</b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
1. A notifying authority shall notify only conformity assessment bodies which have satisfied the requirements laid down in Article 28.		
2. The notifying authority shall send a notification to the Commission and the other Member States of each conformity assessment body referred to in paragraph 1, using the electronic notification tool developed and managed by the Commission.		
3. The notification referred to in paragraph 2 shall include the following:		
(a) full details of the conformity assessment activities to be performed;		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(b) an indication of the conformity assessment module or modules and the kinds of machinery <b><u>or related</u></b> products concerned;		
(c) the relevant attestation of competence.		
4. Where a notification is not based on an accreditation certificate referred to in Article 31(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 28.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
5. The conformity assessment body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of the validation of the notification where it includes an accreditation certificate referred to in Article 31(2), or within two months of the notification where it includes documentary evidence referred to in Article 31(3) <b><u>and in paragraph 4 of this Article.</u></b>		
Only such a body shall be considered a notified body for the purposes of this Regulation.		
6. The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification referred to in paragraph 2.		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Article 33		
<b>Identification numbers and lists of notified bodies</b>		
1. The Commission shall assign an identification number to a notified body.		
It shall assign a single such number even where the body is notified under several Union acts.		
2. The Commission shall make publicly available the list of <del>notified</del> bodies <b><u>notified under this Regulation</u></b> including the identification numbers that have been assigned to them and the conformity assessment activities for which they have been notified.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
The Commission shall ensure that the list is kept up to date.		
Article 34		
<b>Changes to notifications</b>		
1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 28, or that it is failing to fulfil its obligations as set out in Article <del>35</del> <b>36</b> the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Commission and the other Member States accordingly.		
2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.		
Article 35		
<b>Challenge of the competence of notified bodies</b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.		
2. The notifying <b>Member State</b> authority shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.		
3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying <b>Member State</b> authority to take the necessary corrective measures, including the withdrawal of the notification if necessary.		
That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 46(2).		
Article 36		
<b>Operational obligations of notified bodies</b>		
1. A notified body shall carry out conformity assessments in accordance with the		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
conformity assessment <del>modules</del> procedures set out in Annexes VII, VIII and IX <b><u>and IXa</u></b> .		
2. A notified body shall <b><u>carry out conformity assessments</u></b> <del>perform its activities</del> in a proportionate manner, avoiding unnecessary burdens for economic operators, and taking due account of the size of an undertaking, the sector in which the undertaking operates, the structure of the undertaking, the degree of complexity of the machinery technology in question and the mass or serial nature of the production process.		
<del>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</del>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<u>those fees proportionately to their specific interests and needs.</u>		
In so doing, the notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the machinery <b><u>or related</u></b> product with the requirements of this Regulation.		
3. Where a notified body finds that the essential health and safety requirements set out in Annex III, or the <b><u>corresponding</u></b> harmonised standards <b><u>or common specifications</u></b> referred to in Article 17, <del>or other technical specifications</del> have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures <b><u>actions</u></b> and shall not issue		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
a certificate of conformity or adopt an approval decision.		
<p>4. Where, in the course of the monitoring of conformity following the <del>issue</del> issuance of a <del>certificate of conformity or the adoption of an approval decision</del> <b>according to Annex IX</b>, a notified body finds that a machinery <b>or related</b> product no longer complies, it shall require the manufacturer to take appropriate corrective <del>measures</del> <b>actions</b> and shall suspend or withdraw the <del>certificate of conformity or</del> the approval decision, if necessary.</p>		
<p>5. Where corrective <del>measures</del> <b>actions</b> are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw</p>		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
any certificates of conformity or approval decisions, as appropriate.		
Article 37		
<b>Appeals against decisions of notified bodies</b>		
A notified body shall ensure that a transparent and accessible appeals procedure against its decisions is available.	SE:  An appeal procedure against decisions of the notified body shall be available.	SE:  We propose using the wording used in decision No 768/2008 regarding appeal procedures and the same wording used in the current Machinery Directive 2006/42/EC.
Article 38		
<b>Information obligation on notified bodies</b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
1. A notified body shall inform the notifying authority of the following:		
(a) any refusal, restriction, suspension or withdrawal of a certificate of conformity or approval decision;		
(b) any circumstances affecting the scope of, or the conditions for, its notification;		
(c) any request for information which it has received from market surveillance authorities regarding its conformity assessment activities;		
(d) on request, any conformity assessment activities performed within the scope of its notification and any other activity performed,		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
including cross-border activities and subcontracting.		
2. A notified body shall provide <del>the</del> other notified bodies <b><u>notified under this Regulation</u></b> carrying out similar conformity assessment activities covering the same kinds of machinery <b><u>or related</u></b> products with relevant information on issues relating to negative and, on request, positive conformity assessment results.		
Article 39		
<b>Exchange of experience</b>		
The Commission shall provide for the organisation of exchange of experience between		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
the Member States' national authorities responsible for notification policy.		
Article 40		
<b>Coordination of notified bodies</b>		
The Commission shall ensure that appropriate coordination and cooperation between <del>notified</del> bodies <b><u>notified under this Regulation</u></b> are put in place and properly operated in the form of a sectoral group of notified bodies.		
<del>A notified body</del> <b><u>Notified bodies</u></b> shall participate in the work of that group, directly or by means of designated representatives.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
CHAPTER VI		
<del>UNION MARKET SURVEILLANCE,</del> <del>CONTROL OF MACHINERY PRODUCTS</del> <del>ENTERING THE UNION MARKET AND</del> <del>UNION</del> SAFEGUARD PROCEDURES		CZ:  We agree with the new title of chapter VI.
Article 41		
<b>Procedure at national level for dealing with machinery products presenting a risk</b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>1. Where the market surveillance authorities of one Member State have sufficient reason to believe that a <del>machinery</del> product <b><u>subject to this Regulation</u></b> <del>covered by this Regulation</del> 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 <del>machinery</del> <b><u>that</u></b> 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.</p>		
<p>Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the <del>machinery</del></p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<p>product <b><u>subject to this Regulation</u></b> 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 <del>machinery</del> product <b><u>subject to this Regulation</u></b> into compliance with those requirements, to withdraw the <del>machinery</del> product <b><u>subject to this Regulation</u></b> 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.</p>		
<p>The market surveillance authorities shall inform the relevant notified body accordingly.</p>		
<p>2. Where the market surveillance authorities consider that non-compliance is not</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.		
3. The economic operator shall ensure that all appropriate corrective action is taken in respect of all the <del>machinery</del> <b>concerned</b> products <b><u>subject to this Regulation</u></b> <del>concerned</del> that the economic operator has made available on the market throughout the Union.		
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		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
measures to prohibit or restrict the <del>machinery</del> product <b><u>subject to this Regulation</u></b> being made available on their national market, to withdraw the <del>machinery</del> product <b><u>subject to this Regulation</u></b> from that market or to recall it.		
The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.		
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 <del>machinery</del> product <b><u>subject to this Regulation</u></b> , the origin of that <del>machinery</del> product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
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:		
(a) failure of the <del>machinery</del> product to meet the requirements relating to the essential health and safety requirements set out in Annex III;		
(b) shortcomings in the harmonised standards referred to in Article 17(1);		
(c) shortcomings in the <b>common</b> technical specifications referred to in Article 17(4).		
6. Member States other than the Member State initiating the procedure under this Article		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the machinery <b>concerned</b> product <b>subject to this Regulation</b> concerned, and, in the event of disagreement with the adopted national measure, of their objections.		
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.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
8. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the <del>machinery</del> product from the <del>market</del> , are taken in respect of the <del>machinery</del> <b>concerned</b> product <b><u>subject to this Regulation</u></b> <del>concerned</del> without delay.		
Article 42		
<b>Union safeguard procedure</b>		
1. Where, on completion of the procedure set out in Article 41 <del>(3)</del> and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not.		
The Commission shall address its decision to all Member States and shall without delay communicate it to them and to the relevant economic operator or operators.		
That implementing act shall be adopted in accordance with the examination procedure referred to in Article 46(3).		
2. If the national measure is considered justified, all Member States shall <del>take the</del>		

Presidency compromise:	Drafting Suggestions CZ, DK, ES, FI, IT, MT, SE, PT	Comments CZ, DK, ES, FI, IT, MT, SE, PT
<p><del>necessary measures to ensure that</del> <b><u>appropriate restrictive measures, such as withdrawal, are taken in respect of</u></b> the non-compliant <del>machinery product</del> <b><u>subject to this Regulation</u></b> <del>is withdrawn from their market, and shall inform the Commission accordingly.</del></p>		
<p>If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.</p>		
<p>3. Where the national measure is considered justified and the non-compliance of the <del>machinery</del> product <b><u>subject to this Regulation</u></b> is attributed to shortcomings in the harmonised standards or <b><u>common</u></b> <del>technical</del> specifications referred to in Article 41(5), points (b) and (c), of this Regulation, the Commission</p>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.		
Article 43		
<b>Compliant machinery products which present a risk</b>		
1. Where, having carried out an evaluation under Article 41(1), a Member State finds that although a <del>machinery</del> product <b><u>subject to this Regulation</u></b> is in compliance with the essential health and safety requirements set out in Annex III, it <b><u>presents</u></b> poses a risk to the health and safety of persons and, where appropriate, domestic animals or to property and, where applicable, the environment, it shall require the relevant economic operator to take all		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw <del>the machinery</del> <b>that</b> product <del>from the market</del> or to recall it within a reasonable period which is commensurate with the nature of the risk, <b><u>as it may prescribe.</u></b>		
2. The economic operator shall ensure that corrective action is taken in respect of all the <del>machinery</del> products concerned that the economic operator has made available on the market throughout the Union.		
3. The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
for the identification of the <del>machinery</del> product concerned, the origin and the supply chain of <del>the machinery</del> <b>that</b> product, the nature of the risk involved and the nature and duration of the national measures taken.		
4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall adopt an implementing act in the form of a decision determining whether the national measure is justified or not and, where necessary, order appropriate measures.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
That implementing act shall be adopted in accordance with the examination procedure referred to in Article 46(3).		
On duly justified imperative grounds of urgency relating to the protection of the health and safety of persons, the Commission shall adopt an immediately applicable implementing act in accordance with the procedure referred to in Article 46(4).		
5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator or operators.		
Article 44		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<b>Formal non-compliance</b>		
1. Without prejudice to Article 41, where a Member State makes one of the following findings with regard to a <del>machinery</del> product <b><u>subject to this Regulation</u></b> , it shall require the relevant economic operator to put an end to the non-compliance concerned:		
(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 20 of this Regulation;		
(b) the CE marking has not been affixed;	PT:  (b) the CE marking has not been affixed in violation <b><u>of Article 20 of this Regulation;</u></b>	PT:  Not for PCM. This suggestion was already done (done WK 2569/2022).

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(c) the identification number of the notified body involved in the production control phase has been affixed in violation of Article 20(3) or has not been affixed;		
(d) the EU declaration of conformity <b><u>or EU declaration of incorporation</u></b> has not been drawn up or has not been drawn up correctly;		
(e) the technical documentation is either not available or not complete;		
(f) the information referred to in Article 10(6) or Article 12(3) is absent, false or incomplete;		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(g) any other administrative requirement provided for in Article 10 or Article 12 is not fulfilled.		
2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the <del>machinery</del> <b>concerned</b> product <b>subject to this Regulation</b> being made available on the market or ensure that it is recalled or withdrawn from the market.		
CHAPTER VII		
DELEGATED POWERS AND COMMITTEE PROCEDURE		
Article 45		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<b>Exercise of the delegation</b>		
1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.		
2. The power to adopt delegated acts referred to in Articles 5(2) and 6(2) shall be conferred on the Commission for a period of five years from ... [ <i>the date of entry into force of this Regulation</i> ]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Council opposes such extension not later than three months before the end of each period.		
3. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.		
4. The delegation of powers referred to in Articles 5(2) and 6(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the <i>Official Journal of the European Union</i> or at a later date		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
specified therein. It shall not affect the validity of any delegated acts already in force.		
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.		
6. A delegated act adopted pursuant to Articles 5(2) and 6(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the		



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
initiative of the European Parliament or of the Council.		
Article 46		
<b>Committee procedure</b>		
1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.		
2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.		
	SE:  <u>Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act in respect of the implementing powers referred to in Article 17(3) of this Regulation, and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply</u>	SE:  As stated in relation to Article 17, we suggest that a no opinion clause is introduced in article 46.
4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
5. The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.		
The committee may furthermore examine any other matter concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.		
CHAPTER VIII		
CONFIDENTIALITY AND PENALTIES		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
Article 47		
<b>Confidentiality</b>		
1. All parties shall respect the confidentiality of the following information and data obtained in carrying out their tasks in accordance with this Regulation:		
(a) personal data;		
(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights, unless disclosure is in the public interest.		
2. Without prejudice to paragraph 1, information exchanged on a confidential basis		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
between the competent national authorities and between competent national authorities and the Commission shall not be disclosed without the prior agreement of the originating competent national authority.		
3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.		
4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
which they have concluded bilateral or multilateral confidentiality arrangements.		
Article 48		
<b>Penalties</b>		
1. Member States shall lay down the rules on penalties applicable to infringements by economic operators of this Regulation and shall take all measures necessary to ensure that they are enforced. The penalties provided for shall be effective, proportionate and dissuasive and may include criminal penalties for serious infringements.		
2. Member States shall notify those rules and those measures to the Commission by ...	SE:	SE:

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
[ <del>24</del> <b>29</b> months after the date of entry into force of this Regulation] and shall notify it without delay of any subsequent amendment affecting them.	Member States shall notify those rules <del>and those measures</del> to the Commission by ... [29 months after the date of entry into force of this Regulation] and shall notify it without delay of any subsequent amendment affecting them.	We do not see how a MS, one month before the date of the Regulation's application, can notify measures that it has done to ensure the enforcement of this Regulation. We furthermore don't understand the scope of the subsequent obligation to continuously notify amendments affecting enforcement measures, nor see the added value of having this obligation in parallel to the obligation to submit national market surveillance strategies according to article 13 of the Market Surveillance Regulation (an article whose applicability to Machinery can be put in question by this separate obligation and the Market Surveillance Regulation's <i>lex specialis</i> clause). We therefore suggest limiting the notification obligation so that it only relates to the rules on penalties laid down by MS, as is the case in for instance Regulations 2016/424 (cableways), 2016/425 (PPE) and 2016/426 (gas appliances).
CHAPTER IX		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
TRANSITIONAL AND FINAL PROVISIONS		
Article 49		
<b>Repeals</b>		
1. Directive 73/361/EEC is repealed.		
References to the repealed Directive 73/361/EEC shall be construed as references to this Regulation.		
2. Directive 2006/42/EC is repealed with effect from ... [30 months after the date of entry into force of this Regulation].	PT: Directive 2006/42/EC is repealed with effect from ... [ <del>30</del> <b>48</b> months after the date of entry into force of this Regulation].	PT: 30 months is not enough for the updating of the standards and the adaptation of the economic operators. We propose 48 months as the Draft Report from IMCO



<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
References to the repealed Directive 2006/42/EC shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex XI.		
Article 50		
<b>Transitional provisions</b>		
1. Member States shall not <del>until ... [42 months after the date of entry into force of this Regulation]</del> 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 <del>entry into force</del> <b>application</b> of this Regulation]. However, Chapter VI of this Regulation shall apply	SE:  Member States shall not impede the making available on the market of <b>machinery products covered by Directive 2006/42/EC</b> which <b>are in</b> <del>was placed on the market in</del> conformity with <b>that</b> Directive <b>2006/42/EC and which were placed on the market</b> before ... [12 months after the date of application of this Regulation]. However, Chapter VI of this Regulation shall	SE:  We would like the transitional provisions to refer to products covered by Directive 2006/42/EC rather than machinery, seeing as this term is used differently in this Regulation and it might wrongfully imply that related products and partly completed machinery is not covered by this article. As a drafting suggestion, we propose aligning the provision with the corresponding

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
<i>mutatis mutandis</i> 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 ... [ <i>the date of entry into force of this Regulation</i> ].	apply <i>mutatis mutandis</i> 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 ... [ <i>the date of entry into force of this Regulation</i> ].	provisions in the PPE regulation, so as not to unintentionally limit its applications to machinery as it is defined in the new Regulation.
2. EC type-examination certificates and approval decisions issued in accordance with Article <del>14</del> <b>12</b> of Directive 2006/42/EC shall remain valid until ... [ <del>42</del> <b>60</b> months after the date of <del>entry into force</del> <b>application</b> of this Regulation], unless they expire before that date.		
Article 51		
<b>Evaluation and review</b>		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
1. By ... [ <del>54</del> <b>48</b> months after the date of <del>entry into force</del> <b>application</b> 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.		
2. Taking account of technical progress and practical experience gained in Member States as indicated in Article 5, the Commission shall in its report include an evaluation on the following aspects of this Regulation:		
(a) the essential health and safety requirements set out in Annex III;		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
(b) the conformity assessment procedure applicable to <b><u>potentially</u></b> high-risk machinery <b><u>or related</u></b> products listed in Annex I.		
Where appropriate, the report shall be accompanied by a legislative proposal for amendment of the relevant provisions of this Regulation.		
Article 52		
<b>Entry into force and application</b>		
This Regulation shall enter into force on the twentieth day following that of its publication in the <i>Official Journal of the European Union</i> .		

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
It shall apply from ... [30 months after the date of entry into force of this Regulation]—, <b><u>with the exception of:</u></b>		
(a) <b><u>articles 24 to 40 and article 46, which shall apply from [6 months following the entry into force of this Regulation]</u></b>		
(b) <b><u>article 48(1) which shall apply from [29 months following the entry into force of this Regulation]</u></b>		
	PT:  <b><u>c) Chapter VI of this Regulation shall apply <i>mutatis mutandis</i> to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already</u></b>	PT:  Misses part of article 50.

<b>Presidency compromise:</b>	<b>Drafting Suggestions</b> CZ, DK, ES, FI, IT, MT, SE, PT	<b>Comments</b> CZ, DK, ES, FI, IT, MT, SE, PT
	<b><u>been initiated under Article 11 of Directive 2006/42/EC as from ... [the date of entry into force of this Regulation].</u></b>	
This Regulation shall be binding in its entirety and directly applicable in all Member States.		
Done at Brussels,		
For the European Parliament For the Council		