



## POSITION PAPER

Brussels, 13 October 2021

# CECE comments to the proposal for a Regulation on Machinery Products - COM(2021) 202

### Executive Summary

CECE welcomes the proposal on the Regulation on machinery products COM(2021) 202 which we hope will bring further legal clarity. We fully support the alignment with the **New Legislative Framework** (NLF) as it brings coherence with the other legislative acts and horizontal transparency. We also support the **conversion of the Directive into a Regulation** as it facilitates uniform application across all European Union Member States and therefore the free movement of goods.

On the **definition of Artificial Intelligence**, CECE believes that the definition as such will impact a larger number of products in its scope than was initially intended by the European Commission. CECE recognizes that the definition of artificial intelligence (AI) currently in the Machinery Regulation proposal is aligned with that of the AI Regulation proposal.

However, such definition must be adapted in order to focus only on systems with evolving behaviour and avoid any confusion with non-evolving systems that could incorporate technologies listed in Annex I of the AI Regulation proposal. For example, GNSS (Global Navigation Satellite Systems) use Kalman filtering, which is an algorithm that uses a series of measurements observed over time.

On **high-risk machinery and conformity assessment procedures**, the criteria to include machines under Annex I should be clearly defined and the process well-understood. In addition, we strongly disagree with the removal of the possibility for the manufacturer to self-assess its machine using harmonised standards. Not allowing self-assessment will impose the involvement of a notified body in the conformity assessment procedure, generating only extra burden for the manufacturer.

On the concept of **substantial modification**, CECE members believe that the text as proposed fails to bring the intended clarity to the subject that the EC consider to be lacking in the current Directive. Our members' intention is to cooperate with the co-legislators to improve the text.

On the EC proposal to use its mandate to create **delegated acts in order to draft Technical Specifications**, CECE believe that the development of technical specifications should not be used to substitute the process of development of harmonised standards. We want to ensure that the respect

for the current principles used in standardisation (e.g., a consensus-based text, a balanced representation of stakeholders and transparency, ensured with the public enquiry) will be applied also in the drafting of technical specifications.

On the **annexes** to the proposal, our understanding is that annex III became over-prescriptive and our members question the feasibility of some of these new requirements. For example, it is disproportionate to oblige manufacturers to supply each machinery product with test equipment to allow the user to test the safety functions. Also, some other requirements like data recording, some of the proposed changes on autonomous mobile machinery, assembly instructions and obligations for PCM manufacturers are overly burdensome. In general, requirements must have clear limits and balances to the responsibility of the original manufacturer, other economic operators and market surveillance authorities.

On the **transitional provisions**, CECE believes that article 50 is unclear and misleading. The 12 months granted for making available of products should be converted in a proper transitional period, allowing the placing on the market of Machinery products under the current Machinery Directive, as has always been the case with other legislations.

Considering the proposal and annexes of the Machinery Product Regulation (MPR) COM(2020) 202, CECE would like to raise the following concerns and points for improvement:

## I. MAIN TEXT OF THE PROPOSAL

### 1. Definition of Artificial Intelligence

The proposal on the Machinery Regulation references the one on Artificial Intelligence for the definition of AI. Taking into consideration the definition and annex I as presented in the AI proposal, CECE believes there will be a larger number of products in the scope than initially intended by the European Commission.

The AI proposal Annex I b) and c) are too general and we fear that they will enlarge the scope to products without learning capability into the scope of the regulation as collateral damage.

It implies a broad understanding of what can be classified as an AI system. For example, there are systems that use Bayesian estimation and optimisation, but do not learn from data.

Therefore, we believe that the definition of “artificial intelligence” in the AI proposal article 3 should explicitly refer to the evolving behaviour of software, rather than simply listing techniques that are also used outside the scope of AI systems.

For example, GNSS (Global Navigation Satellite Systems, e.g. GPS) use Kalman filtering, also known as linear quadratic estimation (LQE), which is an algorithm that uses a series of measurements observed over time, containing statistical noise and other inaccuracies. It produces estimates of unknown variables that tend to be more accurate than those based on a single measurement alone, by estimating a joint probability distribution over the variables for each timeframe. Our understanding is that the definition in the draft proposal for a Regulation on AI - Annex I (c) would lead to interpret GNSS as an AI system. A GPS system by itself should not be considered safety-related, but once the output is used to instruct the driver, this may be the case and once its output is used to control machinery movement<sup>1</sup>, this will be the case.

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<sup>1</sup> Autonomous machinery does not rely solely on GNSS for movement; there are typically multiple systems working together (GNSS + Object Detection + Lane Assist, LIDAR & RADAR, etc.)

Another example are object detection cameras using reinforced learning, as described in the AI proposal ANNEX I a) which classify object and estimate the distance to them. Alone they are not considered safety-related but depending on its use this interpretation may change.

Furthermore, according to recital 29: *where the machinery product integrates an artificial intelligence system, the risks identified during the risk assessment should include those risks that may appear during the machinery product’s lifecycle due to an **intended** evolution of its behaviour to operate with varying levels of autonomy.*

We believe that the European Parliament and Council should include the word “intended” whenever possible throughout the legislation. As such, industry and stakeholders would clearly understand the boundaries of the evolving behaviour, providing legal clarity to the manufacturer whenever identifying risks throughout the product lifecycle.

Reference: MPR proposal Art 3(15) & AI proposal Art 3(1) and Annex I

EC proposal on AI	Amendment proposal
Article 3.(1)	
<p>‘artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;</p>	<p>‘artificial intelligence system’ (AI system) means software <del>that</del> <i>intended to evolve during its lifetime by itself</i>, that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions <del>influencing</del> <i>impacting</i> the environments they interact with;</p>

## 2. High Risk Machinery and conformity assessment procedure

CECE understands the need to adapt equipment under Annex I outside the framework of the EU’s Ordinary Legislative procedure. We welcome the possibility to be able to also remove equipment from this annex in case there is enough proof that it does not represent high-risk.

We urge that the criteria to include machines under Annex I is clearly defined and that the process is understood timewise. Our members fear that any machinery can potentially be considered high-risk and sudden changes in this annex may unexpectedly include machines that until this day do not represent a high risk to end-users. Besides, a single non-compliant machinery product posing a risk could de facto lead to the inclusion in Annex I of all the same type of machinery products to the detriment of all manufacturers who do comply with the legislation.

Furthermore, we disagree with the changes proposed on conformity assessment procedures for such machines under Annex I. The removal of the possibility for the manufacturer to self-assess its machine when using harmonised standards will disrupt a system that has been functioning well for more than 15 years. Manufactures with products under Annex I will be obliged to involve a notified body in the conformity assessment procedure, generating costs and extra burden for the manufacturing process.

Removing this possibility questions not only the quality of harmonised standards but also weakens the process. Construction equipment manufacturers are keen developers and users of harmonised standards under different legislations.

Therefore, we urge the European Parliament and Council to amend article 21.2 and reintroduce the possibility for manufacturers to self-asses their machines whenever using harmonised standards.

References: Art 5 & Art 21.2 (a)

EC proposal	Amendment proposal
Article 5.2, 5.3 and 5.4	
<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 high-risk machinery products a new machinery product or withdrawing an existing machinery product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.</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 high-risk machinery products a new machinery product or withdrawing an existing machinery product from that list, pursuant to the criteria laid down in paragraphs <del>3 and 4</del>.</p>
<p>3. A machinery product shall be included in the list of high-risk machinery products in Annex I if it poses a risk to human health taking into account its design and intended purpose. A machinery product shall be withdrawn from the list of high-risk machinery products in Annex I if it no longer poses such risk. The risk posed by a certain machinery product shall be established based on the combination of the probability of occurrence of harm and the severity of that harm.</p> <p>In determining the probability and severity of harm, the following shall be taken into account:</p> <ul style="list-style-type: none"> <li>(a) the degree to which each affected person would be impacted by the harm;</li> <li>(b) the number of persons potentially affected;</li> <li>(c) the degree to which potentially affected parties are dependent on the outcome produced by the machinery product;</li> <li>(d) the degree to which potentially affected parties are in a vulnerable position vis-à-vis the user of the machinery product;</li> <li>(e) the degree of reversibility of the harm produced by the machinery product;</li> <li>(f) the degree to which the machinery product has been used for a specific purpose;</li> <li>(g) indications of harm that have been caused in the past by machinery products which have been used for a specific purpose.</li> </ul>	<p>3. A machinery product shall be included in the list of high-risk machinery products in Annex I if it poses a <b>high</b> risk to human health taking into account its design and intended purpose. A machinery product shall be withdrawn from the list of high-risk machinery products in Annex I if it no longer poses such risk. The risk posed by a certain machinery product <b>type</b> shall be established based on the combination of the probability of occurrence of harm and the severity of that harm.</p> <p><i>In determining <del>if the risk is high the probability and severity of harm</del>, the following shall be taken into account:</i></p> <ul style="list-style-type: none"> <li><i>(a) the degree to which each affected person would be impacted by the harm;</i></li> <li><i>(b) the number of persons potentially affected;</i></li> <li><i>(c) the degree to which potentially affected parties are dependent on the outcome produced by the machinery product <b>type</b>;</i></li> <li><i>(d) the degree to which potentially affected parties are in a vulnerable position vis-à-vis the user of the machinery product <b>type</b>;</i></li> <li><del><i>(e) the degree of reversibility of the harm produced by the machinery product;</i></del></li> <li><i>(f) the degree to which the machinery products have been operated used for a specific purpose for their intended use</i></li> <li><i>(g) indications of harm that have been caused in the past by machinery products which have been used <b>accordingly to their intended use for a specific purpose</b>.</i></li> </ul>

	<i>h) the level of training required to operate machinery product for professional use only</i>
4. The Commission shall thoroughly assess the criteria laid down in paragraph 3 on the basis of available information. In particular the following information shall be communicated to the Commission by the Member States when it becomes available to them in connection with market surveillance or as a result of the concerns referred to in the fifth paragraph: (...)	<del>4. The Commission shall thoroughly assess the criteria laid down in paragraph 3 on the basis of available information.</del> In particular the following information shall be communicated to the Commission by the Member States when it becomes available to them in connection with market surveillance or as a result of the concerns referred to in the fifth paragraph: (...)
Article 21.2	
2. Where the machinery product is a high-risk machinery product listed in Annex I, the manufacturer or the manufacturer’s authorised representative and the person who has carried out a substantial modification to the machinery product shall apply one of the following procedures:	<i>2. Where the machinery product is a high-risk machinery product listed in Annex I, and manufactured in accordance with the harmonised standards referred to in Article 7(2), and provided that those standards cover all of the relevant essential health and safety requirements the manufacturer or the manufacturer’s authorised representative and the person who has carried out a substantial modification to the machinery product shall apply one of the following procedures:</i>
New	<i>(a.1) internal production control procedure (module A) set out in Annex VI.</i>

### 3. Definition of “safety function”

In different parts of the proposal the EC chose to use the words “safety function” to classify, for example, AI systems responsible for a crucial function within the machine. CECE believes that it is necessary to have in the future MPR a clear and widely used definition of safety function. This would give manufacturers legal certainty when identifying systems, software and components that should fall under this category.

Therefore, we suggest amending article 3 to include a definition of safety function and use the well-accepted definition from EN ISO 12100:2010 Safety of machinery — General principles for design — Risk assessment and risk reduction, copied below:

*‘safety function’ function of a machine whose failure can result in an immediate increase of the risk(s)*

EC proposal	Amendment proposal
Article 3 new	
new	<i>‘safety function’ function of a machine whose failure can result in an immediate increase of the risk(s)</i>

### 4. Concept of Substantial Modification

CECE members believe that the concept of substantial modification as proposed by the EC brings an extra set of requirements and constraints to common practices of manufactures in different Member States.

CECE suggests a different proposal based on the reality of construction equipment industries, which includes an extra requirement before considering a modification as substantial. According to our suggestion, the cumulative criteria would be any alteration that *“results in a modification to the intended purpose for which the machinery product has been assessed”*.

This change of the intended purpose (i.e. change of specific application) is an objective criteria, easy to check, much more precise to illustrate a concept of transformation and preserve a good articulation between MPR and legislations related to the use of work equipment, especially the framework Directive 89/391/EEC on the safety and health of workers at work and Directive 2009/104/EC on the use of work equipment by workers at work.

Reference: Art 3.(16)

EC proposal	Amendment proposal
Article 3(16)	
(16) ‘substantial modification’ means a modification of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen by the manufacturer and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements may be affected;	(16) ‘substantial modification’ means a modification of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen by the manufacturer <b>of the original machinery product, and resulting in a change of its; specific application; and/or safety components as listed in Annex II;</b> and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements <b>is</b> affected;

### 5. Partly Completed Machinery (PCM)

The EC proposal for a Machinery Regulation amends the legislation in a way that it refers to the concepts of machinery and machinery product. Compared to the current Machinery Directive, it removes most of the references to Partly Completed Machinery (PCM).

CECE fears that changes of terminology may consequently change the current legal definition and obligations for PCM. Our members want to preserve the interpretation of the current Machinery Directive and distinguish PCM from a (complete) machinery product.

CECE wants the assurance that under the current Machinery Regulation proposal the concept of PCM and the obligations to PCM manufacturers remain legally separated from those of (complete) machinery products. This is a crucial point due to the specificities inherent to the products classified as PCM.

We remind the proposal’s recital 18, which states that *it is not necessary that all requirements of this Regulation apply to partly completed machinery but in order to ensure the safety of the machinery 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.*

Moreover, in Annex IV B, manufacturers are asked to include in their technical documentation the intended use of the PCM in question. Our members would like to remind the legislator that according to the definition of PCM, such incomplete machinery have no intended use.

In Annex X, we suggest amending the text in a way that the PCM manufacturer includes a statement in the instructions that *“the final machinery product shall not compromise health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment”*. The manufacturer of the PCM cannot describe the conditions which are to be met to ensure that the final machinery does not compromise health and safety. It is under the responsibility of the integrator by applying the machinery legislation to its machinery.

We suggest that the legislator amends text in a way that all the current exclusions for PCM remain the same under the new text.

References: Art 1, Art 3 (10), (12), Art 4.2, Annex IV B and Annex X

EC proposal	Amendment proposal
<b>Article 3(7)</b>	
‘partly completed machinery’ means an assembly which is machinery but for the fact that it cannot in itself function so as to perform a specific application and which is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming a machinery product;	‘partly completed machinery’ means an assembly which is machinery but for the fact that it cannot in itself function so as to perform a specific application and which is only intended to be incorporated into or assembled with machinery or other partly completed machinery or equipment, thereby forming a machinery <del>product</del> ;
<b>Annex III 1(b)</b>	
(b) determine the risks resulting from interactions between machinery in order to achieve the same end that are arranged and controlled so that they function as an integral whole, thus forming a machinery product as defined in Article 3, point (1), point (d);	(b) determine the risks resulting from interactions between machinery <del>and/or partly completed machinery</del> in order to achieve the same end that are arranged and controlled so that they function as an integral whole, thus forming a machinery product as defined in Article 3, point (1), point (d);
<b>Annex IV 3.2.2</b>	
(a) a complete description of the partly completed machinery and of its intended use;	(a) a complete description of the partly completed machinery and of <del>its intended use</del> ;

## 6. Obligations of economic operators and digitalisation

Our members fear that some additions in the proposal will represent new obligations to manufacturers without any clear benefit stemming from it. According to the proposal of article 10(6), the manufacturer would also need to include on the machinery product the email address.

We believe that making the email address an alternative to the postal address would be proportionate to the current obligations to economic operators and it would also be in line with the Commission’s idea to modernize the legislative text in view of digitalisation. We also suggest including wording to allow the manufacturer to include such information by physical or machine-readable means, such as a QR code.

Reference: Art 10

EC proposal	Amendment proposal
Article 10(6)	
6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address and the email address at which they can be contacted on the machinery product or, where that is not possible, on its packaging or in a document accompanying the machinery product. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.	6. Manufacturers shall indicate their name, registered trade name or registered trade mark, the postal address <del>and</del> or the email address at which they can be contacted <b>by physical or machine readable means</b> on the machinery product or, where that is not possible, on its packaging or in a document accompanying the machinery product. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

### 7. EC Implementing powers on Technical Specifications

The development of technical specifications should not be used to substitute the process of development of harmonised standards. CECE wants to ensure the respect for the current principles of development of harmonised standards, which are: a consensus-based text, a balanced representation of stakeholders and transparency, ensured with the public enquiry.

Many questions remain on the interplay between technical specifications and harmonised standards. For example, in case a harmonised standard is developed in the future, could the technical specifications be substituted? We firmly believe that the procedure should be determined before the new legislation is published.

Reference: Article 17.3

### 8. Transitional provisions: placing on the market and making available

CECE believes that article 50 is unclear and misleading. It limits the making available on the market of machinery placed on the market before the entry into force of this regulation, without saying nothing about machinery legally produced and placed on the market during the subsequent 30 months, i.e. before the repeal of current Machinery Directive.

The use of placing on the market instead of making available brings clarity and consistency with other pieces of legislation.

Reference: Art 50

EC proposal	Amendment proposal
Article 50	
1. Member States shall not until ... [42 months after the date of entry into force of this Regulation] impede the making available on the market of machinery which was placed on the market in conformity with Directive 2006/42/EC before ... [the date of entry into force of this Regulation]. However, Chapter VI	1. <i>Member States shall not until ... [42 months after the date of entry into force of this Regulation] impede <b>the placing making available</b> on the market of machinery products <del>which was placed on the market</del> in conformity with Directive 2006/42/EC before ... [the <b>date of entry</b></i>

<p>of this Regulation shall apply mutatis mutandis to such machinery instead of Article 11 of that Directive, including machinery for which a procedure has already been initiated under Article 11 of Directive 2006/42/EC as from ... [the date of entry into force of this Regulation].</p>	<p><del>into force of this Regulation</del> repealing of MD 2006/42/EC].</p>
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## II. ANNEXES

### 9. Clarifications on concepts related to New Technologies

Concepts related to new technologies are relatively new and clear-cut definitions are not always widely clearly understood. Throughout the MPR proposal, the European Commission includes concepts that are unclear to the engineers responsible for developing products under the scope of CECE.

Our members would like to ask the European Commission, European Parliament and Council to provide further explanations on some of the concepts included in the legislation prior to its final publication. We believe this would facilitate the understanding of both the scope and consequences of the new additions in the text.

Specifically, we call for clarifications to what the legislator understands by machinery product with **fully and partially evolving behaviour or logic** and **varying levels of autonomy**.

References: Annex III 1 (c), 1.1.6 (e) and (f)

### 10. Supply of test equipment

According to Annex III 1.1.2 (e), manufacturer would need to supply the machinery product with all the special equipment and accessories to allow the user to test the safety functions. The breadth of this requirement would put a disproportionate responsibility on the user to test a huge range of measures that are incorporated within highly complex machinery. Such tests are the responsibility of the OEM who has the required specialist skill and appropriate equipment and safety knowledge. Providing test equipment with each machine represents a disproportionate burden on the user.

We suggest reverting to the text of the current Machinery Directive with a minor editorial adaptation.

Reference: Annex III 1.1.2 (e)

EC proposal	Amendment proposal
Annex III 1.1.2 (e)	
<p>(e) A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions, and the machinery product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.</p>	<p><b>(e) Machinery product shall be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.</b></p>

## 11. Cybersecurity requirements

Our members propose to simplify the wording used in the EC's proposal as we believe this would bring more clarity to the text. Those include removing over prescriptive words such as legitimate or illegitimate, accidental, or intentional.

Reference: Annex III 1.1.9

EC proposal on AI	Amendment proposal
Annex III 1.1.9	
A hardware component for connection that is critical for the compliance of the machinery product with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption. The machinery product shall collect evidence of a legitimate or illegitimate intervention in the hardware component.	A hardware component for connection that is critical for the compliance of the machinery product with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption. The machinery product shall collect evidence of an <del>legitimate or illegitimate</del> intervention in the hardware component.
Software and data that are critical for the compliance of the machinery product with the relevant health and safety requirements shall be identified as such and shall be adequately protected against accidental or intentional corruption.	Software and data that are critical for the compliance of the machinery product with the relevant health and safety requirements shall be identified as such and shall be adequately protected against <del>accidental or intentional</del> corruption.
The machinery product shall identify the software installed on it that is necessary for it to operate safely, and shall be able to provide that information at all times in an easily accessible form.	The machinery product shall identify the software installed on it that is necessary for it to operate safely, and shall be able to provide that information at all times in an easily accessible form.
The machinery product shall collect evidence of a legitimate or illegitimate intervention in the software or a modification of the software installed on the machinery product or its configuration.	The machinery product shall collect evidence of an <del>legitimate or illegitimate</del> intervention in the software or a modification of the software installed on the machinery product or its configuration.

## 12. Recording of data

We question the feasibility of the requirement for manufactures to record data on the safety related decision-making process after the machinery product has been placed on the market or put into service. Depending on the quantity of the data being recorded and retained, the manufacturer would face difficulties with storage capacity. Furthermore, this proposal is unclear on what kind, where, how and how much data is to be recorded.

In addition, this requirement seems redundant when both looking at the risks already addressed under point (d) and the source code required at Annex IV A (n) and under the obligations for economic operators.

Reference: Annex III Article 1.2.1 g

## 13. Access to operating positions and servicing points

Already today, the manufacturer must consider any restrictions, the actual and foreseeable working conditions by describing the adjustment and maintenance operations. Moreover, the inclusion of the word “guarantee” is problematic because manufacturers cannot design the machine in a way to guarantee a timely rescue, this depends on many external factors, including the emergency services.

Reference: Annex III 1.6.2

EC proposal	Amendment proposal
Annex III 1.6.2	
In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses shall be dimensioned and adapted for the use of rescue equipment in such a way that a timely rescue of the persons is guaranteed.	In the case of machinery into which persons shall enter for operation, adjustment, maintenance or cleaning, the machinery accesses <del>shall be dimensioned and adapted for the use of rescue equipment in such a way that a timely rescue of the persons is guaranteed</del> shall be designed taking emergency rescue into consideration.

#### 14. Contents of the instructions

CECE disagrees with the additions of item w). The risk is already covered by EHSR 1.5.13. The proposal tends to impose a technology, which is not the purpose of Machinery Directive.

Technical solutions to a specific issue should be discussed in standardisation committees. Specifically, on portable machinery, the risk of exposure is also a duty for employers who must take appropriate measures on jobsites for the operators. This must be done by the provision of appropriate Personal Protective Equipment, organisational measures (staff turnover) or the provision of additional equipment intended to reduce this exposure (e.g. water spraying/sprinkling equipment).

We understand that point (w) as including requirements for engine emissions as well, the way it has been drafted would entail a second set of requirements that are already regulated under type approval legislation.

Reference: Annex III 1.7.4.2. (w)

#### 15. Exposure to vibrations and peak value

CECE believes that peak values are more related with the work site and therefore the measure provided by the manufacturer will not be representative or helpful. Also, our members do not believe that peak values are directly related to safety-related issues or work illness.

CECE wants to better understand the reason for this being included in the MPR proposal and what would be the added value of this requirement.

Reference: Annex III 2.2.1.1 (b) & 3.6.3.1. (b)

#### 16. Seating

Annex III 3.2.2 includes a requirement to provide a visual or audible signal at the driving position alerting the driver when the restraint system is not active. CECE believes that this only makes sense

when there is a mandatory requirement to install Roll-Over Protective Structures (ROPS). A restraint system in combination with the mandatory use of ROPS. Such signal shall not be provided if the use of the restrain system increases the risk.

Reference: Annex III 3.2.2

EC proposal	Amendment proposal
Annex III 3.2.2	
<p>Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the surroundings should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, the machinery shall be designed or equipped with a restraint system so as to keep the persons in their seats or in the protective structure, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats.</p> <p>Such restraint systems or provision shall not be fitted if they increase the risk.</p> <p><b>A visual or audible signal shall be provided at the driving position alerting the driver when the restraint system is not active.</b></p>	<p>Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and the surroundings should the machinery roll or tip over, in particular for machinery equipped with a protective structure referred to in section 3.4.3 or 3.4.4, the machinery shall be designed or equipped with a restraint system so as to keep the persons in their seats or in the protective structure, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats.</p> <p><b>A visual or audible signal shall be provided at the driving position alerting the driver when the restraint system is not active.</b></p> <p>Such restraint systems or provision shall not be fitted if they increase the risk.</p>

### 17. Supervisory Control Function

CECE believes that the European Parliament and Council should further clarify this clause. The deletion of the word “only” would clarify that other actions may be allowed through the supervisory control function, potentially becoming also a remote control function, provided that all other requirements of this regulation are fulfilled. Remote operations are becoming more and more common.

Furthermore, the use of the words “**driver**” and “**operator**” is not fully clear. We recommend avoiding using any designation in this text.

Reference: Annex III 3.2.4

EC proposal	Amendment proposal
Annex III 3.2.4	
<p>Autonomous mobile machinery products shall have a supervisory control function specific to the autonomous mode. This function shall allow the operator to remotely receive information from the machine. The supervisory control function shall only allow actions to stop and to start remotely the machine. It shall be designed and constructed to allow those actions only when the driver can see directly or indirectly the machine's movement and</p>	<p>Autonomous mobile machinery products shall have a supervisory control function specific to the autonomous mode. This function shall allow <del>the operator</del> to remotely receive information from the machine. The supervisory control function shall <b>only at least</b> allow actions to stop <del>and to start</del> the machine <b>remotely</b>. It shall be designed and constructed to allow those actions only when <del>the driver can see directly or indirectly the machine's movement</del> <b>the</b></p>

<p>working area and the protective devices are operational.</p> <p>The information the driver receives from the machine when the supervisory control function is active shall enable the driver to have a complete and accurate view of the operation, movement and safe positioning of the machine in its travel and working area.</p> <p>This information shall alert the driver of the occurrence of unforeseen or dangerous situations present or impending, which require driver’s intervention.</p>	<p>machine’s movement and working area can be monitored and the protective devices are operational.</p> <p>The information <del>the driver</del> received from the machine when the supervisory control function is active shall enable <del>the driver to have a complete and accurate view</del> monitoring of the operation, movement and safe positioning of the machine in its travel and working area.</p> <p>This information shall alert <del>the driver of to</del> the occurrence of unforeseen or dangerous situations present or impending, which require <del>driver’s</del> intervention.</p>
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### 18. Autonomous Mobile Machinery

The EC proposal states that for autonomous mobile machinery products, the control system shall be designed to perform the safety functions by itself (...), even when actions are ordered by using a remote supervisory function.

We suggest deleting this paragraph because the capability of performing safety functions is directly linked to the varying degrees of autonomy. And therefore, this requirement is too broad to be applied in practice. It does not consider safety functions initiated or performed by a supervisor.

Reference: Annex III 1.2.1 (h)

EC proposal	Amendment proposal
Annex III 1.2.1 (h)	
(h) the safety-related parts of the control system shall apply in a coherent way to the whole of an assembly of a machinery product.	(h) the safety-related parts of the control system shall apply in a coherent way to the whole of an assembly of a machinery product.
For wireless control, a failure of the communication or connection or a faulty connection shall not lead to a hazardous situation.	For wireless control, a failure of the communication or connection or a faulty connection shall not lead to a hazardous situation.
For autonomous mobile machinery products, the control system shall be designed to perform the safety functions by itself as set out in this section, even when actions are ordered by using a remote supervisory function.	<del>For autonomous mobile machinery products, the control system shall be designed to perform the safety functions by itself as set out in this section, even when actions are ordered by using a remote supervisory function.</del>

### 19. Assembly instructions

Due to the nature of PCM as an incomplete machine, the PCM manufacturer is not able to describe the conditions which are to be met to ensure that the final machinery does not compromise health and safety. The integrator is responsible to correctly apply the Machinery legislation when completing the machine.

CECE proposes to adapt the EC text so that the PCM manufacturer should include a statement about the final machinery product.

Reference: Annex X

EC proposal	Amendment proposal
Annex X	
The assembly instructions for partly completed machinery shall contain a description of the conditions, which are to be met to ensure that the partly completed machinery is correctly incorporated in the final machinery product, and that the final machinery product does not compromise health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.	The assembly instructions for partly completed machinery shall contain a description of the conditions, which are to be met to ensure that the partly completed machinery is correctly incorporated in the final machinery product, and <b>a statement</b> that the final machinery product <del>does</del> <b>shall</b> not compromise health and safety of persons and, where appropriate, domestic animals and property and, where applicable, the environment.

**20. Other amendments**

EC proposal	Amendment proposal
Article 3.(1)(d)	
(d) assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point (7) which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;	(d) assemblies of machinery referred to in points (a), (b), (c) or partly completed machinery referred to in point <del>(7)</del> <b>(10)</b> which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;
<u>Justification:</u> Editorial amendment to correct a reference.	
Article 3.(24)	
(24) ‘harmonised standard’ means a harmonised standard as defined in Article 2(1), point (c) of Regulation (EU) No 1025/2012;	(24) ‘harmonised standard’ means a <b>European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation;</b>
<u>Justification:</u> we suggest transcribing the entire definition text from Regulation (EU) No 1025/2012	
Article 7	
Machinery products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended purpose or under conditions which can reasonably be foreseen, they meet the essential health and safety requirements set out in Annex III	Machinery products shall only be made available <del>on the market or put into service</del> if, where properly installed and maintained and used for their intended purpose or under conditions which can reasonably be foreseen, they meet the essential health and safety requirements set out in Annex III
Article 14	
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 10 where that importer or distributor places a machinery product on the market under his or her name or trademark or carries out a substantial modification of a machinery	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 10 where that importer or distributor places a machinery product on the market under his or her name or trademark or carries out a substantial modification of a machinery

product that has already been placed on the market or put into service	product <del>that has already been placed on the market or put into service</del>
Article 10.4 second paragraph	
4. (...) When deemed appropriate with regard to the risks presented by machinery products, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of machinery products made available on the market or put into service, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery products and machinery product recalls, and shall keep distributors informed of any such monitoring.	4. (...) When deemed appropriate with regard to the risks presented by machinery products, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of machinery products made available on the market or put into service, investigate, and, if necessary, keep a register of complaints, of non-conforming machinery products and machinery product recalls, and <del>shall</del> keep distributors informed of any such monitoring.
<u>Justification:</u> The way the sentence is drafted, the information to distributors becomes mandatory in any case, when in reality manufacturers may keep distributors informed of any such monitoring only if necessary.	
Article 21	
1. In order to certify the conformity of a machinery product with this Regulation, the manufacturer or its authorised representative and the person who has carried out a substantial modification to the machinery product, shall apply one of the procedures for assessment of conformity referred to in paragraphs 2 and 3.	1. In order to certify the conformity of a machinery product with this Regulation, the manufacturer or its authorised representative <del>and the person who has carried 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.  (new) The same obligation under paragraph 1 applies to the person who has carried out a substantial modification to the machinery product.
2. Where the machinery product is a high-risk machinery product listed in Annex I, the manufacturer or the manufacturer’s authorised representative and the person who has carried out a substantial modification to the machinery product shall apply one of the following procedures:	2. Where the machinery product is a high-risk machinery product listed in Annex I, the manufacturer or the manufacturer’s authorised representative <del>and the person who has carried out a substantial modification to the machinery product</del> shall apply one of the following procedures:  (new) The same obligation under paragraph 2 applies to the person who has carried out a substantial modification to the machinery product.
3. Where the machinery product is not a high-risk machinery product listed in Annex I, the manufacturer or the manufacturer’s authorised representative and the person who has made a substantial modification to the machinery product shall apply the internal production	3. Where the machinery product is not a high-risk machinery product listed in Annex I, the manufacturer or the manufacturer’s authorised representative <del>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.	control procedure (module A) set out in Annex VI.  <b>(new) The same obligation under paragraph 3 applies to the person who has carried out a substantial modification to the machinery product.</b>
Annex III 3.3.3	
Autonomous mobile machinery products shall comply with any of the following conditions:	Autonomous mobile machinery products shall comply <b>with either or both</b> of the following conditions:
Annex IV B (d)	
(d) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the partly completed machinery;	(d) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point <del>(d)</del> (c) and of the operation of the partly completed machinery;

**CECE strongly believes that the future Regulation on machinery products should strive for the correct balance between the responsibilities of each economic operator and those of Member States' authorities. A future-proof machinery legislation should balance the level-playing field, foster the better conditions for innovation to flourish and continue ensuring the safe placing on the market of machinery products.**

## ANNEX – Extra amendments

### Denomination of Annex I as High-Risk machinery

We consider that the designation "High-Risk Machinery Products" risks creating confusion and impacting the position of European manufacturers. Such a designation suggests that machines covered by Article 5 and listed in Annex I would pose a high-risk during use. However, this is not the case, as the legislation forbids the making available of machinery that poses a high risk. According to the current legal provisions, which have been successfully applied in practice since 1 January 1993, only machines whose risks have been eliminated or reduced to the lowest possible level on the basis of the state of the art may be marketed.

We therefore find it problematic that some products would be labelled "High-Risk" under the draft Regulation. Such a designation would be misleading for customers and damaging to the reputation of European manufacturers. Furthermore, we believe a clear definition of the machinery designated in Article 5 is necessary. This is especially important as the Commission will have the power to amend Annex I in view of technical progress. Clear criteria are necessary to better understand the process by which new machinery types will be added, and to foster transparency and stakeholder involvement in this process.

Therefore, we propose to change the title of Article 5 to "Categories of machinery products to which one of the procedures referred to in Articles 5 and 21 must be applied" since this is the same wording that is used in the existing Machinery Directive (2006/42/EC) with only the references to the specific Articles being changed, and to add clear criteria to identify the types of machines that this article refers to. We also suggest deleting the words high-risk in all the articles of the proposal where they reference Annex I.

Related articles: art 5, Annex I and all other articles where the reference to Annex I as High-Risk appears.

EC proposal	Amendment proposal
<b>Article 5</b>	
High-risk machinery products	<b>Categories of machinery products to which one of the procedures referred to in Articles 5 and 21 must be applied</b>
1. High-risk machinery products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Article 21(2).	1. <del>High-risk</del> Machinery products listed in Annex I shall be subject to a specific conformity assessment procedure, as referred to in Article 21(2).
2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I in view of technical progress and knowledge or new scientific evidence by including in the list of high-risk machinery products a new machinery product or withdrawing an existing machinery product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.	2. The Commission is empowered to adopt delegated acts in accordance with Article 45 to amend Annex I in view of technical progress and knowledge or new scientific evidence by including in the list of <del>high-risk</del> machinery products a new machinery product or withdrawing an existing machinery product from that list, pursuant to the criteria laid down in paragraphs 3 and 4.

<p>3. A machinery product shall be included in the list of high-risk machinery products in Annex I if it poses a risk to human health taking into account its design and intended purpose. A machinery product shall be withdrawn from the list of high-risk machinery products in Annex I if it no longer poses such risk. (...)</p>	<p>3. A machinery product shall be included in the list of <del>high-risk</del> machinery products in Annex I if it poses a risk to human health taking into account its design and intended purpose. A machinery product shall be withdrawn from the list of <del>high-risk</del> machinery products in Annex I if it no longer poses such risk. (...)</p>
<p>Annex I - title</p>	
<p>Annex I - High-risk machinery products</p>	<p><b>Annex I - Categories of machinery products to which one of the procedures referred to in Articles 5 and 21 must be applied</b></p>

**Conformity assessment when multiple legislations apply**

The Machinery Product Regulation is considered a vertical EU legislation. As such, it covers specific aspect of machinery products. There are other EU legislations that may address specific subjects not directly dealt with by this legislation. The goal of this proposal should be to avoid creating any inconsistencies between different legislations.

The proposal also states that to avoid incoherence about the type of conformity assessment and to avoid introducing requirements to perform two conformity assessments, those specific safety requirements should be checked as part of the conformity assessment procedure set out in this Regulation. This should be reflected in Article 8.

The situation is clear and specified in the legal text also when it comes to the link between Low Voltage Directive (LVD) 2014/35/EU and Machinery Regulation (for example Annex III, point 1.5): requirements of both legislations have to be applied (as appropriate), but the conformity assessment procedure has to be made just once, according to the Machinery Regulation only.

However, the situation remains unsolved for other applicable directives such as the RED and PED. Therefore, this amendment would clarify and apply the same approach to the other relevant legislations.

Reference: Art 8.

EC proposal	Amendment proposal
<p>Article 8</p>	
<p>Where, for a certain machinery product, 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 harmonisation legislation, this Regulation shall not apply to that machinery product to the extent that that specific Union legislation covers such risks.</p>	<p>Where, for a certain machinery product, 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 harmonisation legislation, this Regulation shall not apply to that machinery product to the extent that that specific Union legislation covers such risks.</p> <p><b>Without prejudice to the provisions set out by the Directive 2000/14/EC on noise emission in the environment by equipment for use</b></p>

	<p>outdoors, for all Union legislation referred to in the first subparagraph the conformity assessment module and the placing on the market and/or putting into service are governed solely according to this Regulation.</p>
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**Overhead power lines**

CECE disagrees with that addition because this risk is already covered in in clause 1.1.7 Operating positions where it is stated:

*1.1.7 Operating positions*

....

*If the machinery is intended to be used in a hazardous environment presenting risks to the health and safety of the operator or if the machinery itself gives rise to a hazardous environment, adequate means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.*

Such risks may include, for example, exposure to hot and cold atmospheres, to risks due to noise, radiation, humidity, adverse weather conditions or atmospheres polluted by hazardous substances. This section also covers the risk of electric shock due to overhead lines in the operating area. The manufacturer must therefore take account of the intended and foreseeable conditions of use of the machinery.

Reference: MPR proposal Annex III 3.5.4

EC proposal	Amendment proposal
Annex III 3.5.4	
<p>Depending on the height of the machinery products, mobile machinery product shall, where relevant, be designed, constructed and equipped, so as to prevent the risk of contact with an energised overhead power line or the risk of creating an electric arc between any part of the machinery or an operator driving the machinery and an energised overhead power line.</p> <p>When the risk of contact or electric arc with an energised overhead power line cannot be fully avoided, mobile machinery products shall be designed, constructed and equipped in such a way that all hazards of an electrical nature are prevented or can be prevented in the event of contact or electrical arc with an energized power line.</p>	<p><del>Depending on the height of the machinery products, mobile machinery product shall, where relevant, be designed, constructed and equipped, so as to prevent the risk of contact with an energised overhead power line or the risk of creating an electric arc between any part of the machinery or an operator driving the machinery and an energised overhead power line.</del></p> <p><del>When the risk of contact or electric arc with an energised overhead power line cannot be fully avoided, mobile machinery products shall be designed, constructed and equipped in such a way that all hazards of an electrical nature are prevented or can be prevented in the event of contact or electrical arc with an energized power line.</del></p>