Revision of the Machinery Directive 2006/42/EC

# Position Paper

## CECE table of comments on the Member States' proposals for the revision of Directive 2006/42/EC on machinery

May 2020


EXECUTIVE SUMMARY

- CECE comments on the differet topics currently being discussed in the framework of the revision of the Machinery Direcrive.
- The document includes main messages from our members on topics such as new technologies (for example "Artificial Intelligence"), cybersecurity/security requirements, Partly Completed Machinery (PCM), harmonised standards and format and availability of instructions.
- We provide a table where you may find in the second column proposals from Member States and other stakeholders and in the third column our comments.


# Introduction

CECE, the Committee of European Construction Equipment, is the recognised organisation representing the European construction equipment manufacturers and related industries. CECE is a European network consisting of national associations in 13 different European countries and the industry behind CECE comprises 1,200 companies.

We welcome the opportunity to provide comments and react to the Member States' and other stakeholders' proposals to the revision of the Machinery Directive.

Our main messages include:

- **A machinery does what the designer has programmed the machine to do,** by using software, automation and eventually Artificial Intelligence. The type of AI being used and developed today constitutes what is known as narrow AI, whereby a machine can only perform an action assigned from the outset by human – whether a designer, computer specialist or manufacturer.
- **The Machinery Directive covers safety aspects and should remain as such**. Cyberattacks are not considered a foreseeable misuse but a malicious use of the product. Any future cybersecurity/security requirements have to be considered under a separate horizontal legislation and not under the Machinery Directive.
- **Stakeholders should better understand the reality of the industries in the scope of the Machinery Directive.** For example, CECE considers that the concept of Partly Completed Machinery (PCM) is well understood and provides an important role for our industry in setting out fundamental procedures for supply of products that will undergo further interventions before a completed Machinery can be placed on the market or put into service.
- **The Machinery Directive Guidelines should be adapted whenever necessary**. We remain open to further discuss any Member States' proposals in the framework of the update of the Machinery Directive Guidelines. We believe this would solve any potential point of concern quicker without having to wait for a new Machinery Directive.
- **Some proposals should be discussed in the framework of the development to harmonised standards under the Machinery Directive**. Our impression is that some proposals question the available "state of the art" technology or would end up imposing a specific technology to the Machinery Directive. The participation of stakeholders in the standardisation process is the most effective way to address such issues.
- **Format and availability of instructions should allow for flexibility.** Each manufacturer has the responsibility to choose which format of instructions is better for the machines they are placing on the market. Level of knowledge and accessibility of users with the format(s) shall be taken into account.

Furthermore, we ask the European Commission to carefully analyse the social and economic impacts of any future changes in the Machinery Directive taking into consideration the consequences of the COVID-19 crisis and the economic recovery of the construction equipment sector.

We provide a table in this document where you may find our detailed comments. In the first column the slide number in the European Commission's presentation[1], in the second column you have the proposals from Member States and other stakeholders and in the third column our comments.

[1] Document reference on CIRCAC WG-2020.03

| Slide | WG-2020.03 - Proposals for the revision of the MD rev2 | CECE comments |
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| 4 | Annex I - 1.1.1. Definitions and 1.1.6. Ergonomics | |
| | Proposal 1<br>**France:** Add a definition in point 1.1.1 relating to different work situations implementing a robotic application, specifying that the preventive measures must be adapted to the different situations, avoiding any dangerous contact *EHSR 1.3.7 Risks related to moving parts:*<br>- Situation of human-robot coexistence in a shared space without direct collaboration,<br>- Work situation in human-robot interaction (simultaneous or alternating work on a piece). | CECE considers the definitions of Machinery quite clear both in the legal text and in the Machinery Guidelines<br><br>**Proposal 1**<br>CECE disagrees with this amendment proposal from France for the following reasons:<br>1. This is not the purpose of the Machinery Directive to list all possible work configurations. Those work configurations are part of the information needed to make the risk assessment. In a general way, the work configurations are machine type oriented, that is why they are taken into account when drafting EN standards dealing with the safety of a specific machine family.<br>2. In addition, in terms of consistency, why such specific amendment proposal should be only focused on EHSR 1.3.7? Such work configurations have also to be taken into account during the risk assessment for all other relevant EHSR (e.g. EHSR related to ergonomics, ejection of pieces, contact with thermal parts, etc.). Consequently, if we start drafting work configurations in the legal text, we will increase a lot the content of the legal act without adding any value.<br>3. We believe there is no reason to focus on human-robot coexistence in a shared space without direct collaboration for EHSR related to moving parts, while in a more general way, there are work configurations of operator-machine coexistence in a shared space without direct collaboration (e.g. operators on a jobsite in |

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| | Proposal 2<br>**Netherlands (TNO Report)**: Add new EHSRs for control system ergonomics to be included in the Machinery Directive (supplementary to Section 1.1.6, Annex I MD):<br>a. Machines equipped with machine learning technology must be able to respond to people adequately and appropriately.<br>b. Machines equipped with machine learning technology must indicate which actions they are about to perform and must provide details of the information on which these actions are based. | the vicinity of mobile machinery). Regarding work situation in human-robot interaction, there are some standardisation works in order to address the relevant EHSR for such situations (e.g. requirements dealing with the maximum forces and frequencies of contact between an operator and a collaborative robot).<br>Any further clarification may be included in the revision of the current Machinery Directive Guidelines.<br><br>**Proposal 2**<br>CECE disagrees with this amendment proposal from Netherlands because the machine learning in itself does not create new risks. For machines with specific functions (e.g. mobility, lifting of persons), it is relevant to have a set of EHSR in order to address the relevant safety issues for the risks related to these functions. Machine learning is not a function, but a technology and the Machinery Directive must remain technology neutral. |
| **5** | **Annex I –1.1.2. Principles of safety integration** | |
| | Proposal- **France**<br>New EHSR or addition in Guide as follows:<br><br>1.1.2 Principles of safety integration (continued) . . .<br>(e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and | CECE disagrees. The maintenance phase is already well taken into consideration in the MD, through specific EHSRs in clause 1.6 and through the chapter “content of instructions”, especially in sub-clauses 1.7.4.2.e), r) or s)<br>Those EHSR already require providing information and instructions. |

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| | used safely. The manufacturer shall provide test procedures and / or test devices for the maintenance and adjustment of machinery using AI. | Besides, AI is not a function, but a technology and it is important to remind that the Machinery Directive is technology neutral. |
| **6** | **Annex I –1.2.1. Safety and reliability of control systems** | |
| | **Proposal 1 – the Netherlands**<br>*1.2.1. Safety and reliability of control systems*<br>*Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that: — they can withstand the intended operating stresses and undesirable external influences,*<br>*— a fault in the hardware or the software of the control system does not lead to hazardous situations,*<br>*— errors in the control system logic do not lead to hazardous situations,*<br>*— reasonably foreseeable human error during operation does not lead to hazardous situations,*<br>*— if any errors or unforeseen conditions should occur in the control system, the machine should immediately revert to a safe state*<br>*(……)*<br>*For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.*<br><br>*With regard to the safety and reliability of the control systems:* | CECE disagrees with the introduction of "*undesirable*". This term is too much subjective and the new formulation could be interpreted in different ways.<br>We also assume that this new formulation could justify that cyberattacks are risks covered by the MD, while this is not the case and must remain out of the MD scope.<br>Cybersecurity requirements cannot be under the MD because the MD is a safety directive while Cybersecurity/security has to be considered under a separate horizontal legislation covering malicious use.<br><br>We do not see the value of adding the paragraph below:<br>*— if any errors or unforeseen conditions should occur in the control system, the machine should immediately revert to a safe state*<br>We believe that the existing two EHSRs just above achieve the same result:<br>*— a fault in the hardware or the software of the control system does not lead to hazardous situations,* |

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| | *— Machines equipped with machine learning are not permitted to make decisions or assessments in relation to injury to people or damage to the surroundings,*<br><br>*— Machine learning must not cause the machine to exhibit new actions that exceed its defined task and movement space,*<br><br>*— If they take incorrect decisions, machines equipped with machine learning technology must be retrospectively correctable, to prevent any future recurrences of that particular error,*<br><br>*— The actions of a machine equipped with machine learning technology must be traceable in advance and retrospectively, based on transparency of the datasets used, as well as of the test environments and of the decision frameworks or assessment criteria for algorithm-based decisions,*<br><br>*— The decision-making process of a machine equipped with machine learning technology must be logged and retained in such a way that this information remains available for a minimum period of time and can then be checked, for instance during audits or incident analyses.* | *— errors in the control system logic do not lead to hazardous situations,*<br><br>CECE disagrees with the new clause, because a machinery cannot make any decision outside the boundaries previously set by the original manufacturer. The type of AI being used and developed today constitutes what is known as narrow AI, whereby a machine can only perform an action assigned from the outset by human – whether a designer, computer specialist or manufacturer.<br>A machinery does what the designer has programmed the machine to do, by using software, automation and eventually AI. Moreover, AI module is not necessarily safety related. There may have AI modules only designed to adapt the task intended to be done by the machine.<br>In any case, a machine with AI still works under the limits of a "safety envelope" which has been developed at the design stage by the OEM. This "safety envelope" takes into consideration all relevant risks of that machine and the environment (outdoor, indoor, with/without operators in the vicinity, etc.) where the machine is intended to be used. |
| **7** | **Annex I –1.2.1. Safety and reliability of control systems** | |

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| | Proposal 2 - **France**<br>2.a - *Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that:*<br>*— they can withstand the intended operating stresses and external influences,*<br>*— a fault in the hardware or the ~~software~~ logic of the control system does not lead to hazardous situations,*<br>*— errors in the control system logic do not lead to hazardous situations,reasonably foreseeable human error during operation does not lead to hazardous situations,*<br>*— The safety functions cannot change outside the limits of the manufacturer's defined scope. This scope is validated and guaranteed by the machine manufacturer, regardless of any modifications to the settings or rules generated either by artificial intelligence or by operators in charge of the learning phases.*<br><br>OR 2.b – Update Chapter 86 of the Guide<br>The machinery may need to be tested as part of the installation and commissioning process for a short and limited period under the full control of the manufacturer, which includes the control of the persons involved in the testing.<br>The learning phase which is essential to the machinery using AI to be useable must be carried out, under the responsibility of the manufacturer, before the machine is placed on the market and the | CECE believes the Machinery Directive already covers the risk of the changing of safety functions. Those can be found in the Annex I - Essential Health and Safety Requirements under General principles 1st indent, below:<br>*By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:*<br>*— determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,*<br><br>Generally, CECE agrees with the adaptation of the Machinery Directive Guidelines. We remain open to further discuss this proposal in the framework of the update of the Machinery Directive Guidelines. |

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| | EU declaration of conformity is issued. This learning phase must be carried out without generating risks.<br><br>AND<br>(!) Terms and notions used in MD should be updated. Notion of Control systems (EHSR 1.2) used in the MD as means for risk reduction will not be useable if a machinery is using vocal detection device and/or visual detection device and/or non-physical device (e.g. neural piloting of the machinery). How to ensure the same level of safety with those new technologic means in the MD?<br>(!) There are no Specific requirement for mobile machinery which are not driven by a human operator in EHSR 3. It is typically necessary to have those kind of requirement for outdoor activities (e.g Agriculture machinery used in fields). | |
| **8** | **Annex I - 1.2.3. Starting -& 1.2.4.3. Emergency stop** | |
| | Proposal - **Robotics Association**<br>Define 'automatic' and autonomy' in: *1.2.3. Starting*<br>*…….*<br>*For machinery functioning in automatic mode, the starting of the machinery, restarting after a stoppage, or a change in operating conditions may be possible without intervention, provided this does not lead to a hazardous situation.*<br>Reasoning: The text make reference to 'automatic' mode' without defining 'automatic'. When developing robotics solutions and autonomous machines, it is more convenient to use 'autonomy' to describe the ability of the machine to take decisions in order to | CECE disagrees because the proposal is not clear enough and for sure, not relevant in this section. |

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| | adapt its motion for achieving its goal. Defining both terms could provide a better guidance for standard writing and risk assessment.<br><br>Add an additional exception for situations where machinery is doing its job autonomously and the human supervisor (especially in remote situations) may have only partial contextual data, which are not suited for a proper evaluation of hazard occurrence:<br><br>*1.2.4.3. Emergency stop*<br>*Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.*<br>*The following exceptions apply:*<br>*— machinery in which an emergency stop device would not lessen the risk, either because it would not reduce the stopping time or because it would not enable the special measures required to deal with the risk to be taken,*<br>*— portable hand-held and/or hand-guided machinery. …….*<br>Reasoning: The emergency stop for a remote supervisory station – when the operator does not have the direct command of the actuators – does not seem suited and could lead to additional hazards. | The definition of "emergency stop" is that it must not introduce new hazards in its activation. The machine operation is already considered when designing the emergency stop. |
| **9** | Annex I - 3.1.1. Definitions & 3.2.1 Driving position | |
| | Proposal - **Robotics Association:**<br>Clarify the notion of 'driver' with a more appropriate wording for robotics solutions, such as replacing it with 'supervisor': | CECE disagrees with the changes of the definition of "driver" nor extend it. This should be addressed in a separate part of the definitions. |

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| | *3.1.1. Definitions ……*<br>*(b) 'Driver' means an operator responsible for the movement of a machine. The driver may be transported by the machinery or may be on foot, accompanying the machinery, or may guide the machinery by remote control.*<br><br>Reasoning: The driver is defined as an operator responsible for the movement. For autonomous work, a natural person is still responsible for the autonomous operation to be safely done, but the notion of 'driver' may not be the most accurate way to describe his function.<br>In relation to the proposal above, to define 'supervisory station', either as a part of the driving station or as a whole new position:<br><br>*3.2.1. Driving position*<br>*Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use.*<br>*Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.*<br>*Machinery on which the driver is transported must be designed and constructed in such a way that, from the driving positions, there is no risk to the driver from inadvertent contact with the wheels and tracks.*<br>*The driving position of ride-on drivers must be designed and constructed in such a way that a driver's cab may be fitted, provided* | |

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| | *this does not increase the risk and there is room for it. The cab must incorporate a place for the instructions needed for the driver.*<br><br>Reasoning: The driving position is clearly defined. For autonomous machinery, the driver could manually operate the machine through control or launch autonomous work. The supervised task could be resumed by a start/stop device to authorize or terminate the autonomous work. | |
| **10** | **Annexes IV & V (software)** | |
| | Proposal - France<br>When the component using AI to provide a safety function (and integrated into the machinery) has been placed independently on the market, then components using this kind of AI should be considered as "safety component under Annex V"<br>When the component using AI to provide a safety function (and integrated into the machinery) *has not been placed independently on the market*, i.e. the component is directly designed by the machinery manufacturer, then the assessment of the overall machinery provided in Article 12 point(3) of the Directive is necessary (list of machines in Annex IV), and an item 24 should be added to the list of Annex IV: 24) machinery using AI which manages a safety function(s) when the AI is not integrated into a safety component.<br><br>Reasoning: AI replacing conventional systems that perform a safety function (whether they are safety components independently | CECE does not support the proposal. We believe that such type of software is already included under the Machinery Directive Annex V – 4 – Logic units to ensure safety functions.<br>By definition AI is coded software where requirements are laid down in the Machinery Directive. If AI interacts with safety function, it needs to adhere to requirements for safety-related software. |

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| | placed on the market or devices directly designed by the machinery manufacturer) cannot be yet assessed. Conventional programming evaluation tools are not useable for AI technology, hence explicability of AI algorithms not yet possible<br>Those solutions will emerge in future, so they have to be taken into account in MD. | |
| **12** | **New Article - Removal of PED exclusion on Cat. I machinery** | |
| | Proposal<br>Addition of a NEW article in MD to amend PED in order to eliminate the below exclusion: *DIRECTIVE 2014/68/EU on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment.*<br><br>*Article 1 Scope*<br>*2. This Directive shall not apply to:*<br>*(f) equipment classified as no higher than category I under Article 13 of this Directive and covered by one of the following Directives:*<br>~~*(i) Directive 2006/42/EC of the European Parliament and of the Council;*~~ | CECE does not support this proposal. This does not bring any improvement regarding to safety: we are talking here about components or sub-assemblies that will be integrated in a bigger assembly. Machinery manufacturers always carry out a conformity assessment procedure according to Article 5(1) of the Machinery Directive for the entire machine. This includes a risk assessment which takes into account the elements that work under pressure.<br>Based on the final destination and integration of this equipment (or sub-assembly), the machinery manufacturer shall define the appropriate protective means in order to address any risk that could occur in case of failure of the pressure equipment.<br>The protective means will depend on the way such equipment is integrated in a machine and the relevant risk to be addressed (e.g. enclosing the pressure equipment, fitting a safety valve,…).<br>Up to the knowledge of CECE, there is no significance concerning safety. |
| **14** | **Article 1.2 (c) nuclear purposes** | |
| | Proposals | CECE agrees with the principle to not make any exclusion but this new proposal is not clear enough. Proposal suggested: |

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| | *Article 1.2 The following are excluded from the scope of this Directive:*<br>*(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;*<br>to be reworded as:<br><br>Option 1 [France]:*Art 1.2(c) machinery specially designed for use within or used in a nuclear installation and whose conformity with the Machinery Directive may affect (undermining) nuclear safety*<br>Reasoning: Replace the notion of "nuclear use" with that of "nuclear installation" which is the one used by Directive 2013/59/ Euratom; and use the notion of "undermining" also derived from the Euratom Directive.<br><br>Option 2 [COM]: *Art 1.2(c) 'machinery specially designed for use within or used in a nuclear installation, which, in the event of failure, may affect (undermining) nuclear safety;*<br>Reasoning: Art 1.2.(h) of PED matches the current text in MD: *This Directive shall not apply to: items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;* | *Art 1.2(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in **a direct** emission of radioactivity* |
| **19** | **Article 2 Definitions - Machinery** | |
| | Proposal - **France**<br>Current definition: 'machinery' means<br>— an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, | We believe the addition of the sentence regarding energy storage adds no clarity and creates confusion. |

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| | consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application.<br><br>**France:** '— 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 and for a use as defined by the manufacturer. The energy stored in the equipment must be greater than the energy generated by a single human or animal action for it to be considered machinery.'<br><br>Reasoning: according to exiting definition the notion of machinery and PCM overlaps; If the *specific application* is deemed to be the basic function of machinery, there are very few items of partly completed machinery. Regarding the notion of specific application in the updated Guide, version 2.1 of July 2017 Machinery must be useable for a specific application as applying to the complete machine and its intended use. | Both proposals 19 and 20 are intended to address what is considered to be an ambiguity regarding the relationship between Machinery and PCM.<br><br>CECE considers that the concept of PCM is well understood and provides an important role for our industry in setting out fundamental procedures for supply of products that will undergo further interventions before a completed Machinery can be placed on the market or put into service.<br><br>Where clarification is necessary it is already adequately provided for in the MD Guidance e.g.<br><br>*§35 The basic definition*<br>*Machinery must be useable for a specific application as applying to the complete machine and its intended use. Typical machinery specific applications include, for example, the processing, treatment, or packaging of materials, or the moving of materials.....*<br><br>this links the concept of a Specific Application with that of the Intended use and provides examples thereof. The concept of Intended use is unambiguous it appears in the text of the Directive as early as the General Principles and is the subject of an explicit definition;<br><br>*1.1.1 Definitions (continued)*<br>*. . .* |

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| | | *(h) 'intended use' means the use of machinery in accordance with the information provided in the instructions for use;*<br>. . .<br><br>As result the manufacturer who must consider the intended use as a core principle of the risk assessment can easily recognise where the requested delivery conditions of his product would prevent it from being considered as a Machinery.<br>Furthermore, the person completing the PCM and hence conferring the possibility to carry out the intended use can be clear regarding their obligations before placing on the market of a finished Machine.<br><br>Despite finding no practical problems with the current legal text CECE would be open to assist in providing further expansion or examples for a future iteration of the guidance. |
| **20** | **Article 2 Definitions - PCM Proposal** | |
| | Current definition:<br>'Partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application.<br><br>Proposal 1<br>Removal of PCM<br><br>Proposal 2<br><br>Clarification of PCM - **France: 2 alternatives**: | Please refer to CECE comment under point 19 |

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| | 1) clarify by introducing the relative differences between PCMs and interchangeable equipment: '*an assembly which is almost machinery but which cannot in itself perform a specific application.* Any device installed after the machinery on which it is assembled has been put into service is not deemed partly completed machinery.<br><br>2) in an Annex or in the Guide, define a restrictive list of equipment that may be deemed partly completed machinery. | |
| **21** | **Annex II Declarations - PCM in connection to Proposal 2** | |
| | France: Annex II B. DECLARATION OF INCORPORATION OF PARTLY COMPLETED MACHINERY This declaration and translations thereof must be drawn up under the same conditions as the instructions (see Annex 1, section 1.7.4.1(a) and (b)), and must be typewritten or else handwritten in capital letters.<br>The declaration of incorporation must contain the following particulars:<br><br>4. a sentence declaring which essential requirements of this Directive are applied and fulfilled and that the relevant technical documentation is compiled in accordance with part B of Annex VII, and, where appropriate, a sentence declaring the conformity of the partly completed machinery with other relevant Directives. These references must be those of the texts published in the Official Journal of the European Union. Partly completed machinery cannot | CECE fully disagrees because a PCM is only intended to be integrated into a machinery or an assembly of machinery. This is the reason why the fulfilment of an EHSR at the PCM stage does not necessarily presuppose fulfilment of that requirement at machine level.<br>This specific legal status in the MD has been created for partly completed machinery because PCM have no specific application while it is not the case of a machinery. PCM are only intended to be incorporated into a machinery or an assembly of machinery, so a PCM cannot be considered like machinery.<br><br>It makes no sense to ask a manufacturer of partly completed machinery to apply the whole Annex 1 because this partly completed machinery is intended to be integrated into machinery for which there will be an overall risk analysis. |

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| | claim to meet the requirements of this Directive without satisfying any essential requirements;<br><br>**KAN/NB:** The following should be specified in the directive:<br>The manufacturer of partly completed machinery shall fulfil all the applicable essential health and safety requirements. | This does not mean that the manufacturer of a PCM will not address any EHSR. Why a manufacturer of a conveyor intended to be incorporated in an asphalt mixing plant shall address risks related to means of access if he does not know how its conveyor will be integrated in the plant? At the machine level stage, the manufacturer (integrator of the PM) will analyse the risk of falling and for example, depending on the height of the conveyor from the ground, he will provide (or not) lateral means of access along the conveyor. |
| **22** | **Article 2 Definitions - Assembly** | |
| | Proposal<br>Addition of a NEW definition in Art. 2: 'Assembly'<br><br>Stakeholders participating in the OPC most frequently mentioned that the concept of assembly is complicated to understand. Some proposals received:<br><br>**Industry association (DE):** Article 2(a), fourth indent should be deleted. This part of the definition has led to numerous discussions in practice, to claims, to conformity assessments of complex industrial plans and a CE mark for the complete system to install. In Germany, the ministry responsible had published the BMAS interpretative paper. Already in the first indent it becomes clear that a machine is an entity of interconnected parts or devices and this includes both individual parts of a machine as well as the | CECE does not see the need to change the wording for assemblies in the Machinery Directive.<br>We are open to further discuss this point in the framework of guidelines if necessary. |

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| | assembly composed of several machines, if they are linked together in terms of safety.<br><br>**Machinery safety consultant (NL):** '*A unit consisting of components that have been fitted together to perform a specific function, and that can be disassembled without destruction'.* Manufacturer (DE): If any machinery are interlinked as a unit from a safety point of view, it should be considered as an "assembly of machinery." This assembly of machinery is to be considered as new machine placed on the market. However, if several machinery with individual functions on a handling process are installed and can be used independently, they are rather to be considered as a "group of machinery". If an emergency stop affects this machinery when activated, and this is not required from a safety viewpoint, it is not an "assembly of machinery" but a "group of machinery".<br><br>**Machinery safety consultant (IT):** "Assembly of machinery should specify if it applies also to temporary installation of machinery and control systems, potentially interchangeable and if - in this case - a specific DoC of the assembly of machinery is required for every possible configuration. An example of this are hundreds of chain hoists combined with controllers, integrated for rigging installations and controlled with a unique control device". | |
| **23** | **Article 2 Definitions - Installer** | |
| | Proposal<br><br>Addition of a NEW definition in Art. 2: 'Installer' | In line with our previous comment under slide 22 – Assembly, we do not see the need to add the concept of "Installer" in the Machinery Directive. |

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| | Should the role of an installer can be added similarly as it is arranged in the Lifts Directive? According to some, the Guide to the MD already covers the activity of an installer in 2 sections *(§36 Machinery supplied without connection components* and *§264 Assembly, installation and connection).*<br><br>**Spain:** suggested it would be useful to include the role of an installer. They face issues with the installation of assemblies such as slow speed lifts; they think the directive should extend certain obligations to installers, similarly to what is done in the lifts directive. Spain to provide concrete suggestion and data.<br><br>**Proposal from a manufacturer:** "No, an installer would have to follow the instruction of the OEM and all required instructions are sufficiently covered by the current MD. Spain faces issues with the installation of assemblies such as slow speed lifts; they think the directive should extend certain obligations to installers, similarly to what is done in the lifts directive. Special roles for installer leads to splitting of responsibility and finally to confusion. One additional remark to this question: Full adoption of the New Legislative Framework will help the alignment of definitions".<br><br>**Proposal from workers and employers' representatives:**<br>"Yes, but only for some limited cases, i.e. not just for an installer who only places a complete machine on a floor and may just bolt it down. However, where the installation is critical for safety, then | |

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| | this would make sense. In general, we consider this is only needed for a small sub-set of machinery such as platform lifts".<br><br>**COM:** Lifts Directive deals only with one type of product. | |
| **24** | **Article 2 Definitions - Safety function** | |
| | Proposal - France Addition of a NEW definition in Art. 2: 'Safety function'<br>(x) 'safety function' means a function which has an active effect on the risk, such that its failure may immediately result in a heightened risk. A simple warning system does not perform a safety function under this definition; | CECE does not see the need and the added value in including a definition for "safety function" under the Machinery Directive. |
| **25** | **Article 2 Definitions – Substantial modification** | |
| | **Proposal**<br>Addition of a NEW definition in Art. 2: 'Substantial modification'<br>**Opinions**<br>**Poland:** YES - The inclusion of criteria relating to machinery in the Directive will make it possible to avoid differences of interpretation in this respect.<br><br>**Denmark:** There should be flexibility in managing this, because 1) the vast majority of these machines are being modified in production companies and 2) these machines are in use (hence not placed on the market). It is very burdensome for a user undertaking to re-label the entire machine as it is not possible to make the change only. | CECE disagrees to add a definition of substantial modification in the Machinery Directive. |

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| | **Germany:** This does not need to be regulated in the Directive or in the guide. Since most of the changes are made to machines in use and not in view of their placing on the market, the impact on the European single market is therefore low. A list of possible items could only be exemplary and would not be able to answer all the questions. It seems preferable to provide an appropriate analysis of the risks and risks arising from the change and of the measures to be taken. It is sufficient for the individual Member States to make their own interpretations.<br><br>**France:** NO – France is not in favour of this option. There are no operating criteria unless the rebuilding is considered to be a substantial change. The Directive also applies in the case of re-building: this concept corresponds to the intention to design a new machinery for a shorter application. Each function of the machinery is specified by the designer. For example, designing a machine for spraying water on work by using the existing chassis of a dumper truck.<br><br>**Switzerland:** the amendments should be made or included in the Guide rather than in the Directive - If a change is made to a machine, a risk assessment is required. If the risk assessment shows that new or higher risks arise as a result of the change, corresponding mitigating measures shall be ordered and taken and the amended product shall be considered to be a new one. | |

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| | **Suggestions to solve this issue:**<br>**1) re-introduce the whole annex** (at least the extract given above) **of the old version of MD guidelines which was very helpful in terms of general principles <u>AND</u>**<br>**2) considering accidents data, as a first priority, define the notion of "modification" which is a notion that belongs to the user's legislation**<br>Indeed, there are accidents occurring in the field because of modifications of machinery which are done without any correct risk assessment. This is typically the case for attachment fitted to a base machinery by a user without any consideration of the instructions given by OEMs of the base machinery and attachment. There are frequent initiatives and discussions to deal with the adequation of base machinery and attachment that illustrates that aspect which takes its origin in the result of "bad" modifications coming from the field.<br>This is why we strongly believe that it would be much more useful for health and safety of workers to have a definition of a "modification of a machine in service" in the legislation applicable to the use of work equipment, i.e. the Directives 2009/104/EC of 16 September 2009 and the Health and Safety at Work Directive framework 89/391/EEC | |
| **26** | **Article 2 Definitions – State of the art** | |
| | **<u>Proposal</u>**<br>Addition of a NEW definition in Art. 2: 'State of the art'<br>The concept of "the state of the art" is crucial as it implies that EHSRs are not absolute, hence a manufacturer must strive to | CECE does not support a definition of the state of the art in the Machinery Directive. We consider that the concept of "state of the art" has a clear common-sense understanding. |

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| | achieve the EHSRs' objectives to the furthest extent possible according to the current technical and economic status.<br>The technical solutions adopted to fulfil the EHSRs must employ the most effective technical means that are available at the time for a cost that is reasonable taking in account the total cost of the category of machinery concerned, the seriousness of harm machinery can entail and the risk reduction required to address it.<br>This also means "the state of the art" considered for the machinery when it was built might no longer be valid in the future.<br>Does 'state of the art' require a definition / an "economic" definition? | |
| **27** | **Article 2 Definitions – Specific application** | |
| | Proposal - **France**<br>Addition of a NEW definition in Art. 2: 'Specific application'<br><br>**France:** The current definition of application is set out in the guide for the application of the Machinery Directive (comment 35 of the Guide version 2.1 July 2017): machinery must be able for a specific application as applying to the complete machine and its intended use. Specific applications include, for example, the processing, treatment, or packaging of materials, or the moving of materials, objects or objects. It is a very broad definition of the machine which treats it as its basic function; the concept is therefore identical to that of quasi-machinery.<br>The French proposal gives a more restrictive definition which introduces the concept of use defined by the manufacturer: fitted | Please refer to CECE comment under point 19 |

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| | or intended to be fitted with a drive system, other than directly applied human or animal force, consisting of linked parts or components of which at least one is mobile and which are jointly and severally bound for its application defined for a purpose defined by the manufacturer. | |
| **30** | **Annex I - 1.1.6. Ergonomics** | |
| | Proposal - **ETUI**<br>1.1.6. Ergonomics<br>Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic, human factors, and usability knowledge and principles such as:<br>— allowing for the variability of the operator's physical dimensions, strength and stamina, — providing enough space for movements of the parts of the operator's body,<br>— avoiding a machine-determined work rate,<br>— avoiding monitoring that requires lengthy concentration,<br>— adapting the man/machinery interface to the foreseeable characteristics of the operators,<br>— involving users during machinery design and development. | CECE disagrees with the proposal and does not see the need for any additions in this section.<br>Usability knowledge, as we understand it, and the relevant human factors are already covered in the text of the MD under 1.1.6.<br><br>Concerning the 2nd proposal, the feedback from users shall be organized in such a way that we can capture in a consolidated way the different areas of progress and their priorities at national or European level. This feedback shall also be analysed by standard makers who are close to engineering teams of manufacturers. This is the reason why we believe that the European standardisation process is the most relevant platform able to address this challenge. And this is already a practice today, for example in the construction machinery sector where users are regularly invited to take part to the standardisation process, at national level, European level and sometimes international level, in order to get their feedback, |

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| | | because concrete safety issues coming from the field are always interesting to take into account.<br>In addition, this feedback is also organized in each manufacturing company in order who all wants to improve the development of their future machinery. |
| **31** | **Annex I - 1.1.2. Principles of safety integration** | |
| | Proposal 1 - France<br>1.1.2. Principles of safety integration<br>(a) Machinery must be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.<br>The aim of measures taken must be to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping. (….)<br>(e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.<br>(f) the machinery must be designed taking account of actual feedback from users on previous models or similar machinery.<br><br>Proposal 2 - ETUI<br>1.1.2. Principles of safety integration | **Please refer to our previous comment on slide 30.**<br><br>**Please refer to our previous comment on slide 30.** |

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| | (a) Machinery must be designed and constructed according to human-centred principles so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen but also taking into account any reasonably foreseeable misuse thereof.<br><br>The aim of measures taken must be to achieve productive, safe, usable machinery, and to eliminate any risk throughout the foreseeable lifetime of the machinery including the phases of transport, assembly, dismantling, disabling and scrapping. | |
| **32** | **Annex I - 1.5.10 Radiation** | |
| | Proposal - **France**<br>Update of EHSRs as per Directive No. 2013/35/EU of 26/06/13 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields).<br>*1.5.10 Radiation*<br>*"Each notice must contain, where applicable, at least the following information: (….)*<br>*(w) where the machinery is likely to emit functional electromagnetic fields or low-frequency electromagnetic fields which may cause an adverse or harmful effect on persons, in particular persons with active or non-active implantable medical devices, information on the level of electrical, magnetic or electromagnetic fields in a form* | CECE does not support this inclusion. Directive 2013/35/EU on electromagnetic fields is a jobsite Directive, where the employer is responsible to implement the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents. Furthermore, in the Machinery Directive under Annex I point 1.7.3 – Warning of residual risks, it is stated that<br>*Where risks remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted, the necessary warnings, including warning devices, must be provided.* |

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| | *to assist the user in conducting the risk assessment pursuant to Directive 2013/35/EC.* | |
| **33** | **Annex I - 1.7.4 Instructions - paper and/or digital (part 1)** | |
| | Proposals<br>▪ Always a printed user manual<br>▪ Printed manual should be available on demand only<br>▪ Access to a digital user manual (online or displayed by the product)<br>▪ A short printed Quick-Start Guide and an access to a more in-depth online user manual<br><br>**Costs and Benefits**<br>In case of digital format for instructions:<br><br>**Manufacturers:**<br>(+) economic operators would have lower paper, printing and shipping costs in relation to the user manuals. These cost savings, however, might be balanced out through the costs of developing the relevant digital tools for the manuals and the maintenance of the access. Positive environmental impact, reduced burden and costs and facility to provide instruction updates.<br>(-) Main risk remaining is the availability of the online manual if a manufacturer ceases to exist during the lifetime of the machinery, and how to make sure the user manual available is the right version. | CECE reinforces its position of a flexible approach in the Machinery Directive Guidelines. Each manufacturer has the responsibility to choose which format of instructions is better for the machines they are placing on the market.<br>The manufacturer shall take into account foreseeable circumstances and conditions of use of the product when selecting the format(s) in which instructions are presented. Level of knowledge and accessibility of users with the format(s) shall be taken into account. At the time of placing on the market, instructions in hardcopy should, upon request, be made available free of charge. |

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| | **Users and workers:**<br>(+) Digital versions of the manual might be easier to read such as through the search function or the manufacturer's possibility to enhance the format or provide additional information.<br>(-) Digital documentation would provide additional burden to access the information, which could lead to less reading of the manuals and thus increase the safety risks. Certain groups such as less digitally savvy users or workers without internet access in certain environments could have difficulty to access the manuals. Allowing printed user manuals on demand would cover these risks. | |
| **34** | **Annex I - 1.7.4 Instructions - paper and/or digital (part 2)** | |
| | **Opinions**<br>**Czech Republic, Denmark, Finland, Netherlands, Poland, Portugal, Romania, Slovenia:** Short printed Quick-Start Guide + access to a more in-depth online user manual.<br><br>**Belgium, Cyprus:** Access to a digital user manual (online or displayed by the product). France, Poland and Sweden: Access to manual on external device such as DVD/USB stick Germany: This should be left open depending on the type of machinery and its use. It must be ensured that a purchaser of a machine is provided with the printed user manual of the last supply chain (manufacturer, distributor) without additional effort. An obligation should therefore be included so that a paper user manual shall be supplied at the end user's request at no additional cost. | **Please refer to the comment above on slide 33** |

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| | **Denmark:** If a Quick Start Guide in paper form delivered with the machine is agreed, then the Quick Start Guide should as a minimum contain the following information:<br><br>▪ The business name and full address of the manufacturer and of his authorized representative;<br>▪ The designation of the machinery as marked on the machinery itself;<br>▪ A description of the intended use of the machinery;<br>▪ Warnings concerning ways in which the machinery must not be used that experience has shown might occur;<br>▪ Safety information (to be further specified in the guide);<br>▪ Instructions for transport, assembly and installation, depending on a risk assessment;<br>▪ Technical data (weight, power etc.);<br>▪ Noise and vibration information;<br>▪ The contents of the EC declaration of conformity;<br>▪ Unique link to download access of the hole instruction manual, if the manual is not supplied in electronic form together with the machine;<br>▪ A paper version should always be available free of charge for the consumers who request it.<br><br>**Switzerland:** The form of the instructions must be user-specific. Useful to introduce more flexible forms of flexibility. | |
| **35** | **Annex I - Chemical risks Proposal - France** | |

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| | 1.7.4.2 Content of the instructions<br>(r) the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed taking account of the restrictions and actual and foreseeable working conditions, the description of the adjustment and maintenance operations that the user must perform and the preventive measures that must be observed"<br><br>(s) instructions and operational methods designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations.<br>(w) the following information on emissions of hazardous substances from the machinery:<br>the characteristics of the capturing, filtration or discharge device when not provided with the machinery, and the flow rate for the emission of hazardous materials and substances from the machinery, or the concentration of hazardous materials or substances around the machinery, or the effectiveness of the capturing or filtration device and the conditions to be observed to maintain its effectiveness over time. These values are either actually measured for the machinery in question or established based on measurements taken from machinery that is technically comparable, which is representative of the machinery to be produced. | CECE does not support the proposal**.** The amendment does not introduce new aspects, see also §272 of the guide. Already today, the manufacturer has to take the restrictions and the actual and foreseeable working condition into account by describing the adjustment and maintenance operations. Moreover, the amendment makes things unclear.<br><br>This new requirement seems to be too broad and does not concern only the machinery itself. Requirements for the devices should be part of their respective legislation and not be part of the MD.<br><br>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.<br><br>Specifically, on portable machinery, the risk of exposure is also a duty for employers who have to take appropriate measures on jobsites for the operators. This must be done by the provision of appropriate PPE, organisational measures (staff turnover) or the |

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| | 2.2 Portable hand-held and/or hand-guided machinery, 2.2.1. General<br>Portable hand-held and/or hand-guided machinery must: …… The handles of portable machinery must be designed and constructed in such a way as to make starting and stopping straightforward. The portable machinery must have a device to capture emissions of hazardous substances at the source, if required.<br><br>3.5.3. Emissions of hazardous substances<br>The second and third paragraphs of section 1.5.13 do not apply where the main function of the machinery is the spraying of products. However, the operator must be protected against the risk of exposure to such hazardous emissions.<br>Mobile machinery designed for spraying or likely to be used for spraying chemicals must be equipped with filter cabins. | provision of additional equipment intended to reduce this exposure (e.g. water spraying/sprinkling equipment).<br><br>On mobile machinery, there is only an annex dealing with hazards due to mobility of machinery. The MD shall provide the Essential Health and Safety requirements while remaining technology neutral. |
| **37** | **Annex I - Electrical risks - Overhead power lines** | |
| | Proposal - **France**:<br><br>Additional EHSR<br>3.5.4 *Overhead power lines*<br>Mobile *machinery is designed and manufactured so as to prevent the risk of contact with live overhead power lines or the risk of electrical arcing between any part of the machinery or an operator driving the machinery and an energized overhead power line under normal operating conditions and foreseeable misuse.* | CECE disagrees with that addition because this risk is already covered in a more general way in clause 1.1.7 Operating positions where it is stated:<br><br>*1.1.7 Operating positions*<br>*….*<br>*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* |

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| | When *the risk of contact cannot be fully avoided, the machinery shall be designed and constructed so as to prevent any electrical hazards in the event of contact with an energized power line.*<br>Mobile *machinery especially designed to perform work under power shall be designed and manufactured so as to prevent any electrical hazards in the event of contact with an energized power line under normal operating conditions and foreseeable misuse.* | *means must be provided to ensure that the operator has good working conditions and is protected against any foreseeable hazards.*<br><br>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. |
| **38** | **Annex I - 3.2.1. Driving position & 3.2.2 Seating** | |
| | Proposal - France<br>*3.2.1. Driving position*<br>*Visibility from the driving position must be such that the driver can, in complete safety for himself and the exposed persons, operate the machinery and its tools in their foreseeable conditions of use.*<br>*Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.*<br>*Machinery on which the driver is transported must be designed and constructed in such a way that there is no risk of driver ejection from the driving position and there is no risk to the driver from inadvertent contact with the wheels and tracks.*<br><br>*3.2.2 Seating*<br>*Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and* | Proposal on 3.2.1 Driving position<br>CECE disagrees with the French proposal. The manufacturer already takes into consideration during its risk assessment the risk of driver ejection from the driving position on a case by case basis. Moreover, it is technologically challenging to include a restraint system for “non-seated” operators and increases the risk for the evacuation in case there is not a ROPS.<br><br>Proposal on 3.2.2 Seating<br>We agree with the replacement of “their seats” by “the machinery”.<br>We disagree with the inclusion of “and in the protective structure”. We believe the inclusion is redundant because when there is a |

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| | *the ground 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 ~~their seats~~ must be designed or equipped with a restraint system so as to keep the persons in their seats and in the protective structure, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems should not be fitted if they increase the risk.*<br><br>*It must not be possible for the machinery to move if the restraint system is not active.* | restraint system in place keeping the person in the seat, it is implied that the person is in a protective structure.<br>We suggest substituting it for "deflection-limiting volume", as already mentioned in 3.4.3 and 3.4.4.<br><br>A restraint system disabling the movement of a machine when not active, would hamper the operation of the machine due to a high risk of detection errors.<br>In cars such systems are not present either despite higher numbers of accidents. An alternative is to show an alarm message, if the operator did not wear the belt instead of forcing the machine to stop. The proposed text is design-restrictive and does not reflect the established State of the Art<br>**This topic should be considered in the framework of the standardisation process. Preventing a machine from moving in case a restraint system is not active should be analysed by a risk assessment on a case by case basis in the development of product specific harmonised standards.** |
| **42** | **Annex IV (part 1) Proposal - France** | |
| | Removing the self-assessment procedure based on harmonized standards for Annex IV type of machinery, for which conformity assessments remain difficult to do.<br><br>3. Where the machinery is referred to in Annex IV and manufactured in accordance with the harmonised standards referred to in Article 7(2), and provided that those standards cover | CECE disagrees with the French proposal for the following reasons: Annex IV of the Directive sets out a strict list of categories of machinery which may be subject to a conformity assessment procedure involving a Notified Body (EC type-examination or full quality assurance) or to self-assessment by the manufacturer when they are manufactured in accordance with harmonised standards which cover all the relevant EHSR. |

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| | all of the relevant essential health and safety requirements, the manufacturer or his authorised representative shall apply one of the following procedures:<br>~~(a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII;~~<br>(b) the EC type-examination procedure provided for in Annex IX, plus the internal checks on the manufacture of machinery provided for in Annex VIII, point 3;<br>(c) the full quality assurance procedure provided for in Annex X." | There is no evidence that the safety level is compromised by the use of self-assessment. All the stakeholders have been applying this approach for more than 20 years without any specific concern and the removal of this possibility would have a significant impact on costs for the manufacturers and the users. |
| **43** | **Annex IV (part 2)** | |
| | Update Annex IV<br>**France:**<br>i) Add some machinery to Annex IV. In this context, there is some farming machinery to propose (chippers, spreaders and balers in particular).<br><br>Add a new point to the machinery of Annex IV: "24. Combination or assembly of machinery containing at least one item of machinery from points 1 to 23, if the composed assembly does not eliminate the risky component associated with this machinery (for example manual loading or unloading)." | CECE believes that any additions to the list of machinery under Annex IV should be justified, including accident data linked with the residual risk of the specific machine. |

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| | ii) Establish cross-cutting machinery categories with certain risks and propose that a European group be set up (see next slide).<br><br>**MD NB (VG8 Vehicles servicing lifts VG9 Lifting persons device):**<br><br>**i)** Add Escalators and moving walks. These are machines with similar or greater high risk factor and potential for danger than comparable other machines, such as stairlifts for disabled persons. They have unrestricted, public access and are intended to be used by unskilled persons/laypersons without instructed personnel. They have crushing and shearing points. There are high risks in case of failure of the controls.<br><br>**ii)** Add Cranes with a load moment >150 kNm. In Germany in 2016 there were 1180 accidents at work with cranes, winches, loading arms on carrier vehicles. With loads on cranes this hazard potential there were also a four-digit number of accidents. | |
| **44** | **Annex IV (part 3)** | |
| | Proposal from **France** - Option ii)<br>1. Machinery for cutting and working wood or meat. (replaces points 1 to 8)<br>2. Machinery with a risk of crushing/compression related to manual loading/unloading. (replaces p. 9 to 11 and 13)<br>3. Machinery for underground working of the following types: (identical to point 12) 3.1. locomotives and brake-vans;<br>3.2. hydraulic-powered roof supports. | **Item 2 and 6**. CECE disagrees with this proposal because the wording is so wide that it may concern some of machines that were not initially targeted by the French proposal. This list must be machine type oriented and not formulated as a list of risks. On item 6, "Vehicle servicing lifts" seemed to be more precise compared to the new formulation which may be relevant for a lot of lifting machinery (e.g. cranes) |

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| | 4. Removable mechanical transmission devices including their guards. (identical to point 14) 5. Guards for removable mechanical transmission devices. (identical to point 15)<br>6. Machinery used to perform operations under a load or a vehicle. (replaces point 16)<br>7. Machinery for the lifting of persons or of persons and goods involving a hazard of falling from a vertical height of more than three metres (identical to point 17)<br>8. Portable cartridge-operated fixing and other impact machinery. (identical to point 18)<br>9. Protective devices designed to detect the presence of persons. (identical to point 19)<br>10. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in section 2. (identical to point 20)<br>11. Logic units to ensure safety functions. (identical to point 21) 12. Roll-over protective structures (ROPS). (identical to point 22)<br>13. Falling-object protective structures (FOPS). (identical to point 22)<br>14. Mobile machinery or machinery on carrying vehicles. | **Item 14.** CECE fully disagrees with the adding of mobile machinery or machinery on carrying vehicles. Such matter has not been raised until now, including during the public consultation. We believe there is no justification, including accident data, to raise suddenly this item and propose to amend the MD to include mobile machinery under Annex IV.<br>We remain available to discuss this issue once France provides further clarification on their proposal. |
| **45** | **Annex IV (part 4)** | |
| | Proposal from Finland<br>- Category I: could be placed on the market under the current manufacturer's internal control procedure.<br>- Category II: would contain machines with higher risks and e.g. machines requiring type approval procedure and | CECE disagrees with the proposal. We do not see any safety benefit from the categorization and the manufacturers is the responsible for the safety of the machinery based on the conformity assessment options under the MD article 12. |

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| | - Category III: having highest risk and belonging to scope of type examination should have in addition also obligation of the manufacturing quality assurance.<br>It might not be necessary to have 3 categories, 2 might be enough. In general, there is no need for use of third parties before placing on the market to such type of machinery to which type examination would not improve safety. A great deal of machinery types should be possible to be placed on the market without type examination | |
| **47** | **Annex V** | |
| | Proposal – **NB** (VG8 Vehicles servicing lifts & VG9 Lifting persons device) Amend 17 g):<br><br>(g) electric safety devices in the form of safety switches containing electronic components, functional safety equipment including hardware and software.<br><br>Reasoning: To meet EHSR considering the fast moving technical developments in the fields of functional safety and security there is a need for the extension and modification of the non-exhaustive list of safety components to include safety-related machine control engineering equipment, functional safety equipment including hardware and software (includes mobile and desktop applications or web applications). | CECE does not support the proposal. Because we believe that such type of hardware and software are already included under the Machinery Directive Annex V – 4 – Logic units to ensure safety functions.<br>See also CECE comment under point/slide 10 |
| **48** | **Annexes VII & VIII** | |

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| | Proposal - **France**<br><br>Annex VII, part A, section 1, point (b)<br><br>For series-manufactured machinery: Introduce a production monitoring procedure for the machinery in Annex IV to make sure there are no deviations in the production of machinery that has undergone a conformity assessment. Certain examples showed deviations between initially certified machinery and associated types of machinery placed on the market. In addition, this type of procedure (associated with module C.2, or more restrictive module F in the Blue Guide) is used in other regulations for products for which failure may result in a permanent or fatal injury to its users (PPE regulation)<br><br>Annex VIII point 3: define the notion of an internal check to specify the manufacturer's obligations regarding the manufacturing process. Non-formalized and/or unsatisfactory procedure, traceability | CECE disagrees with the introduction of a production monitoring procedure.<br>If there is such deviation, this means that the manufacturer has failed to fulfil its obligation. The MD is not guilty for that. |