



**MESSAGE EVOLIS:**

Ce document recense les derniers sujets qui étaient en discussion au niveau européen et pour lesquels il était attendu que les différentes parties prenantes se positionnent pour le mois de mai 2020. Ce travail a été finalisé vendredi 20 mars 2020 et transmis à différents Comités européens, au moment de premières mesures de confinement prises en France à cause de l'arrivée du virus COVID-19.

# **Proposals for the Revision of Directive 2006/42/EC on machinery**

## **Machinery Working Group**

**Brussels, 19-20 January 2020**

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1	<b>Intro</b>	
	Directive 2006/42/EC Machinery Working Group Doc. WG-2020.03 Proposals for the Revision of Directive 2006/42/EC on machinery Machinery Working Group Brussels, 19-20 January 2020	<b>Please insert your comments and concrete suggestions for a reformulation of the existing text of the directive in this column</b> 
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	List of areas: <ul style="list-style-type: none"> <li>o New technologies</li> <li>o Scope and borderlines with other directives</li> <li>o Definitions</li> <li>o Annex I Essential Health and safety requirements</li> <li>o Annex IV</li> <li>o Annex V, VI, VII, VIII</li> </ul> Per each area, information is provided on: <ul style="list-style-type: none"> <li>o Inputs received from stakeholders</li> <li>o Outcomes of the on-going Impact Assessment</li> <li>o Commission comments based on the above</li> </ul>	
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4	Annex I - 1.1.1. Definitions and 1.1.6. Ergonomics	

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	<p style="text-align: center;"><b>Proposal 1</b></p> <p>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 <i>EHSR 1.3.7 Risks related to moving parts</i>:</p> <ul style="list-style-type: none"> <li>- Situation of human-robot coexistence in a shared space without direct collaboration,</li> <li>- Work situation in human-robot interaction (simultaneous or alternating work on a piece).</li> </ul> <p style="text-align: center;"><b>Proposal 2</b></p> <p>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):</p> <ul style="list-style-type: none"> <li>a. Machines equipped with machine learning technology must be able to respond to people adequately and appropriately.</li> <li>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.</li> </ul> <p style="text-align: center;"><b>Opinions</b></p> <p>Denmark: The MD already covers machines with machine learning in a sufficient way. The MD guide should be updated in order to explain this, and technical requirements should be specified in a standard. However if a majority of stakeholders wants requirements related to machine learning to be added to the MD, Denmark is not against this.</p> <p>NB: Essential health and safety requirements should be adapted to take into account humans and robots sharing a given space. Necessary distances, existing speeds of approach from person to robot, the resulting threats must be set out.</p> <p>Manufacturers: Most industry associations is of the opinion that the MD already covers machines with machine learning in a sufficient way.</p>	<p style="text-align: center;"><b>Proposal 1</b></p> <p><b>[EVOLIS] Disagree</b> with this amendment proposal from France for the following reasons:</p> <ol style="list-style-type: none"> <li>1. Firstly, 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's why they are taken into account when drafting EN standards dealing with the safety of a specific machine family.</li> <li>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.</li> <li>3. Thirdly, we don't see any 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 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).</li> </ol> <p style="text-align: center;"><b>Proposal 2</b></p> <p><b>[EVOLIS] Disagree</b> with this amendment proposal from Netherlands because the machine learning in itself doesn't 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. If we have to take into account existing technologies when revising the machinery directive, this legal text will become voluminous and which won't make it any easier to read.</p>
5	Annex I –1.1.2. Principles of safety integration	

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	<p>Proposal - France New EHSR or addition in Guide as follows:            1.1.2 Principles of safety integration (continued) . . .            (e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely. <b>The manufacturer shall provide test procedures and / or test devices for the maintenance and adjustment of machinery using AI.</b></p>	<p><b>[EVOLIS] Disagree</b>            First, we don't understand the need of such new legal requirement. What is the goal? What kind of maintenance or adjustment of machinery using AI would require such provision of test procedures and/or test devices? what are test devices ?</p> <p>Secondly, 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)            Those EHSR already requires to provide information and instructions.</p> <p>Moreover, there may have maintenance operations intended to be done exclusively by specialised personnel mandated by the manufacturer or his authorised representative. In such case, the manufacturer has to provide instructions for these specialised personnel, and we have some doubt about the ability of users to maintain and adjust the AI related part of a machine, taking into account that this AI related part of a machine belongs to the know-how of the OEM.</p> <p>Finally, this requirement proposal is inserted in a very general clause related to "Principle of safety integration" which is not relevant with a new requirement related to the provision of test procedures and/or test devices.</p>
6	Annex I –1.2.1. Safety and reliability of control systems	

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	<p><b>Proposal 1 – the Netherlands</b></p> <p><i>1.2.1. Safety and reliability of control systems</i></p> <p><i>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 <b>undesirable</b> external influences,</i></p> <ul style="list-style-type: none"> <li><i>— a fault in the hardware or the software of the control system does not lead to hazardous situations,</i></li> <li><i>— errors in the control system logic do not lead to hazardous situations,</i></li> <li><i>— reasonably foreseeable human error during operation does not lead to hazardous situations, — if any errors or unforeseen conditions should occur in the control system, the machine should immediately revert to a safe state</i></li> </ul> <p><i>(.....)</i></p> <p><i>For cable-less control, an automatic stop must be activated when correct control signals are not received, including loss of communication.</i></p> <p><i>With regard to the safety and reliability of the control systems:</i></p> <ul style="list-style-type: none"> <li><i>— Machines equipped with machine learning are not permitted to make decisions or assessments in relation to injury to people or damage to the surroundings,</i></li> <li><i>— Machine learning must not cause the machine to exhibit new actions that exceed its defined task and movement space,</i></li> <li><i>— If they take incorrect decisions, machines equipped with machine learning technology must be retrospectively correctable, to prevent any future recurrences of that particular error,</i></li> <li><i>— 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,</i></li> <li><i>— 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.</i></li> </ul>	<p><b>[EVOLIS] Disagree</b> with the introduction of “<i>undesirable</i>”. This term is too much subjective and the new formulation could be interpreted in different ways. We also assume that this new formulation could justify that cyberattacks are risks covered by the MD, while this is not the case.</p> <p><b>[EVOLIS] We don’t see the value of adding</b></p> <p><i>— if any errors or unforeseen conditions should occur in the control system, the machine should immediately revert to a safe state</i></p> <p>while there are already two EHSRs just above aiming at achieving the same result:</p> <ul style="list-style-type: none"> <li><i>— a fault in the hardware or the software of the control system does not lead to hazardous situations,</i></li> <li><i>— errors in the control system logic do not lead to hazardous situations,</i></li> </ul> <p><b>[EVOLIS] Disagree with the new clause, because a machinery cannot make any decision !</b></p> <p>A machinery does what the designer has programmed the machine to do, by using software, automatism 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.</p> <p>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.</p>
7	Annex I –1.2.1. Safety and reliability of control systems	

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	<p style="text-align: center;">Proposal 2 - France</p> <p>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:</p> <ul style="list-style-type: none"> <li>— they can withstand the intended operating stresses and external influences,</li> <li>— a fault in the hardware or the <i>software-logic</i> of the control system does not lead to hazardous situations,</li> <li>— errors in the control system logic do not lead to hazardous situations, reasonably foreseeable human error during operation does not lead to hazardous situations, — <i>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.</i></li> </ul> <p style="text-align: center;">OR 2.b – Update Chapter 86 of the Guide</p> <p>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. <i>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 EU declaration of conformity is issued. This learning phase must be carried out without generating risks.</i></p> <p style="text-align: center;">AND</p> <p>(!) 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 ?</p> <p>(!) 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).</p>	<p><b>[EVOLIS]</b> Would it be possible to understand the reason for such change “<i>software-logic</i>” ?</p> <p><b>[EVOLIS]</b> Agrees with Proposal 2.b</p> <p><b>[EVOLIS]</b> Don’t agree with a revision of the term “control system” because there is still a control system. Whatever the means used to activate a control (voice, visual detection), there is still an information pick-up device, i.e. sensor, which will actuate a control itself being part of a control system.</p>
8	Annex I - 1.2.3. Starting -& 1.2.4.3. Emergency stop	

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	<p>Proposal - Robotics Association  Define 'automatic' and autonomy' in: 1.2.3. Starting  .....  <i>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.</i>  <u>Reasoning:</u> 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 adapt its motion for achieving its goal. <u>Defining both terms could provide a better guidance for standard writing and risk assessment.</u>  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:  1.2.4.3. <i>Emergency stop</i>  <i>Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted.</i>  <i>The following exceptions apply:</i>  — <i>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,</i>  — <i>portable hand-held and/or hand-guided machinery. ....</i>  <u>Reasoning:</u> 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.</p>	<p><b>[EVOLIS] Disagree</b>, because the proposal is not clear enough and for sure, not relevant in this section.  First of all, a machine cannot take any decision ! There is a difference between automatic and autonomous machines  The definition of machinery in Art. 2 is broad enough to include automatic or autonomous machines. Annex I, 1.2.3 deals with all machines (stationary and mobile ones). There is no reason to introduce "autonomous machines" in general requirements.</p> <p><b>[EVOLIS]</b>  → TBD</p>
9	Annex I - 3.1.1. Definitions & 3.2.1 Driving position	

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	<p style="text-align: center;">Proposal - Robotics Association:</p> <p>Clarify the notion of ‘driver’ with a more appropriate wording for robotics solutions, such as replacing it with ‘supervisor’:</p> <p>3.1.1. Definitions .....</p> <p>(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.</p> <p><u>Reasoning:</u> 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.</p> <p>In relation to the proposal above, to define ‘supervisory station’, either as a part of the driving station or as a whole new position:</p> <p>3.2.1. Driving position</p> <p><i>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. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.</i></p> <p><i>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.</i></p> <p><i>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 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.</i></p> <p><u>Reasoning:</u> 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.</p>	<p>[EVOLIS] For autonomous machines, the concept of driver is not relevant because there is no driver.          → TBD</p> <p>[EVOLIS] For autonomous machines, there is no driving position because there is no driver.          → TBD</p>
10	Annexes IV & V (software)	

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	<p>Proposal - France</p> <p><u>When the <b>component using AI to provide a safety function</b> (and integrated into the machinery) has been placed independently on the market, then components using this kind of AI should be considered as “<b>safety component under Annex V</b>”</u></p> <p><u>When the component using AI to provide a safety function (and integrated into the machinery) <i>has not been placed independently on the market</i>, 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: <b>24) machinery using AI which manages a safety function(s) when the AI is not integrated into a safety component.</b></u></p> <p><u>Reasoning:</u> AI replacing conventional systems that perform a safety function (whether they are safety components independently 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</p> <p>Those solutions will emerge in future, so they have to be taken into account in MD.</p> <p>Opinions</p> <p>Netherlands: When safety features are built into the software, we need to have EHSR about keeping it safe (e.g. who can change or which change is allowed to the robot programming). Software updates should be treated as part of the machinery. However the machinery should always be safe without updates and should also continue to function safely without updates. If not then it is reasonably foreseeable that users will try to get the machinery working themselves.</p> <p>NB: Safety-related software must be considered as a safety device and be included in Annex V.</p>	<p><b>[EVOLIS]</b> Internal question to manufacturers:</p> <ol style="list-style-type: none"> <li>1) Are there some components <ul style="list-style-type: none"> <li>- placed independently or not on the market</li> <li>- using AI and</li> <li>- where AI provides a safety function ?</li> </ul> </li> <li>2) Taking into account that safety functions of a machinery are being part of the risk assessment of the whole machinery, is it possible to envisage that a component with AI providing a safety function and <b><u>being placed independently on the EU market</u></b> ?</li> <li>3) Do we know a machinery with AI and where AI is intended to manage safety functions ?</li> <li>4) Don't we consider the AI as part of the know-how of the OEM ?</li> <li>5) If we consider AI as part of the know-how of the OEM, how a third party will be able to verify the management of a safety function by AI ?</li> </ol>
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	<p>List of areas:</p> <ul style="list-style-type: none"> <li>o New technologies</li> <li>o Scope and borderlines with other directives</li> <li>o Definitions</li> <li>o Annex I Essential Health and safety requirements</li> <li>o Annex IV</li> <li>o Annex V, VI, VII, VIII</li> <li>• Per each area, information is provided on: <ul style="list-style-type: none"> <li>o Inputs received from stakeholders</li> <li>o Outcomes of the on-going Impact Assessment</li> <li>o Commission comments based on the above</li> </ul> </li> </ul>	

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12	<p><b>New Article - Removal of PED exclusion on Cat. I machinery</b></p>	
	<p style="text-align: center;">Proposal</p> <p>Addition of a NEW article in MD to amend PED in order to eliminate the below exclusion:  <i>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.</i>  <i>Article 1 Scope</i>  <i>2. This Directive shall not apply to:</i>  <i>(f) equipment classified as no higher than category I under Article 13 of this Directive and covered by one of the following Directives:</i>  <i>(i) Directive 2006/42/EC of the European Parliament and of the Council;</i></p> <p style="text-align: center;">Opinions</p> <p>MSA: To the question “Would it be beneficial for the safety of the machinery if, in addition to the Machinery Directive, the Pressure Equipment Directive also applied even if the items of pressure equipment are classified no higher than category I under the Pressure Equipment Directive?” a majority of MS authorities replied ‘yes’.  NB: the exclusion of pressure equipment category I from the PED does lead to safety concerns (50%).  Manufacturers: Most manufacturers indicated no safety concerns from the exclusion.  Workers and employers’ associations: support the inclusion of the pressure equipment Cat.1 in the PED.</p> <p style="text-align: center;">Impacts</p> <p>Costs: If the exclusion is removed, increased costs are expected by manufacturers of pressure equipment, and as a consequence, by manufacturers of machinery using this equipment. No quantification has been provided.  Benefits: Improved safety. Improve competitiveness of EU industry outside the EU.</p>	<p><b>[EVOLIS] This proposal aims at changing the scope of PED. It has nothing to do with the revision of MD.</b></p> <p>The impact of such proposal would mean that an equipment classified as no higher than category I under article 13 of PED and covered only by MD, would not be excluded anymore from PED.</p> <p><b>We don’t agree with this removal proposal for the following reasons.</b></p> <p>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.</p> <p>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.</p> <p>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,...).</p> <p>In addition, there is <b>no accident data</b> that would justify such a change.</p>

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13	<p><b>Article 1.2 (b) fairgrounds</b></p>	
	<p>Proposal 1 Removal of the exclusion <i>The following are excluded from the scope of this Directive:</i> <del>(b) specific equipment for use in fairgrounds and/or amusement parks;</del></p> <p>Proposal 2 Clarification of the exclusion Finland: There are continuously emerging new type of equipment that are not designed to be used in a fairground or amusement park, but are highly comparable to such equipment. This exclusion should be clarified, if kept in the new legislation. Finland to provide concrete suggestion.</p> <p>Opinions All stakeholder types: the exclusion requires clarification or should be removed. Consumer organisations: this remains an important issue, since currently there is no EU legislative framework covering this type of equipment. COM: Need to consider both 'fixed location amusement parks' and 'travelling fairs'. NB: According to one NB, it is possible to shift the amusement parks into the MD under the condition that additional dedicated EHSRs (G-Forces etc.) are clearly defined. <u>NB to provide concrete suggestion.</u></p> <p>Impacts Costs: additional costs for manufacturers to comply with MD. No quantification provided. Benefits: Improved safety. <i>IAAPA (International Association of Amusement Parks and Attractions) Ride Safety Report 2017 on fixed location amusement parks – EMEA</i> shows 570 injuries for the EU27, EEA, Switzerland, Turkey and UK, of which 27 were serious: 10 when getting in/out and 17 when ride in motion.</p>	<p>[EVOLIS] No opinion.</p>

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14	<p><b>Article 1.2 (c) nuclear purposes</b></p>	
	<p style="text-align: center;">Proposals</p> <p><i>Article 1.2 The following are excluded from the scope of this Directive:</i>  <i>(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity;</i>  to be reworded as:  Option 1 [France]: <i>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</i>  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.  Option 2 [COM]: <i>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;</i>  Reasoning: Art 1.2.(h) of PED matches the current text in MD: <i>This Directive shall not apply to: items specifically designed for nuclear use, failure of which may cause an emission of radioactivity;</i></p> <p style="text-align: center;">Opinions</p> <p>All stakeholder types: the majority of respondents had no opinion (70%). Manufacturers: About half of the respondents that manufacture nuclear machinery (50%) indicated rather disapproval to the exclusion.</p> <p style="text-align: center;">Impacts</p> <p>Costs: Manufacturers of nuclear machinery interviewed were split between expecting costs to increase with changes in the MD and no costs expected. No estimates were provided. Benefits: Improved safety.</p>	<p>[EVOLIS] Agree with the principle to not make any exclusion but this new proposal is not clear enough. Proposal suggested:  Art 1.2(c) machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in <del>a</del> direct emission of radioactivity</p>

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15	<p><b>Article 1.2 (f) seagoing vessels</b></p>	
	<p style="text-align: center;">Proposal</p> <p><i>Article 1.2 The following are excluded from the scope of this Directive:</i>  <i>(f) seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units;</i></p> <p>Proposal [France] – Art 1.2 (f) ‘seagoing vessels and mobile offshore units and machinery installed on board such vessels and/or units <i>which is intended for the safety of life at sea;</i>’</p> <p><u>Reasoning:</u> The machinery directive guidelines (§ 58) specify that seagoing vessels are covered by the conventions of the International Maritime Organisation (IMO). However IMO covers only international activity, and not coastal fishing. France provided examples of serious injuries to workers operating machinery on board of seagoing vessels.</p> <p style="text-align: center;">Opinions</p> <p>Austria: Difficulty to deal with vessels from a third country approaching EU ports with non-CE marked machinery was a reason for having set up this exclusion in the first place.  COM: Are requirements in MD adequate for a marine environment (atmospheric salinity and humidity, etc.)?</p> <p style="text-align: center;">Impacts</p> <p>Costs: No quantification provided.  Benefit: Increase the safety of workers using machinery on board of seagoing vessels (such as machinery for handling and processing fishing products).</p>	<p>[EVOLIS] No opinion</p>

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16	<p><b>Article 1.2 (k) LVD (Part 1) Proposal 1</b></p>	
	<p>Remove the exclusion Article 1.2 The following are excluded from the scope of this Directive: (k) electrical and electronic products falling within the following areas, insofar as they are covered by Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits (3):</p> <ul style="list-style-type: none"> <li>— household appliances intended for domestic use, — audio and video equipment,</li> <li>— information technology equipment, — ordinary office machinery,</li> <li>— low-voltage switchgear and control gear, — electric motors;</li> </ul> <p>Opinions</p> <p>Netherlands: In favour of removing the exclusion of low-voltage equipment from the scope of the Directive in Article 1 (2) (k), so that all machines, regardless of risk, are subject only to the MD. This would allow a clear separation between both product groups:</p> <ul style="list-style-type: none"> <li>- Everything which is by definition a machine falls under the Machinery Directive.</li> <li>- All other electrical products that do not meet the definition of a machine, e.g. cable, plug, installation material... etc. are covered by the Low Voltage Directive.</li> </ul> <p>In addition, the distinction between consumer and professional use is a grey area as many times professional products are being used in the consumer domain and vice versa.</p> <p>Germany: In the case of requests to our authority, in about half of all cases it is not clear which harmonisation legislation applies to the product requested (MD or LVD).</p> <p>Industry: the majority of industry associations, importers, distributors and machinery manufacturers did not experience any problems of compliance due to exclusion of LVD products.</p> <p>Impacts</p> <p>Costs: The costs of removing the exclusion could not be reliably quantified.</p> <p>Benefits: improved safety. Best is to let all machinery fall under the MD since it is a very elaborate directive. The LVD needs to apply ONLY when some product is NOT machinery.</p>	<p><b>[EVOLIS]</b> By removing this precise list of electrical products from the list of exclusions of the MD, this would lead to the consequence that all machinery connected to the low voltage network would not have to fulfil anymore the LVD.</p> <p>As far as we know, this would change the practice for a lot of machinery (e.g. tower cranes, aggregate processing plant, intralogistics plant,..)</p> <p><b>Need feedback from OEM to evaluate this change !!</b></p>

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17	<p><b>Article 1.2 (k) LVD (Part 2) Proposal 2</b></p>	
	<p>Update the list of electrical and electronic products in the exclusion: <i>Article 1.2(k) — household appliances intended for domestic use,</i></p> <ul style="list-style-type: none"> <li>— <i>audio and video equipment,</i></li> <li>— <i>information technology equipment, — ordinary office machinery,</i></li> <li>— <i>low-voltage switchgear and control gear, — electric motors;</i></li> </ul> <p>Opinions</p> <p>Most authorities: difficulties in enforcing the MD by differentiating between consumer and professional products (58%).</p> <p>Finland: the list of electrical appliances in the scope of the LVD that are excluded from the MD does not consider new type of appliances that do not fit in the groups of the list as such, but are comparable to them. The list should be updated so that new type of products may be included continuously, when needed. <u>Finland to provide concrete suggestion.</u></p> <p>Denmark: There is no need to change the scope related to LVD. Changes mean new uncertainty and the need for revision of standards. The proposal to clarify the issue concerning chargers embedded or supplied separately could be clarified in the guide.</p> <p>Overall: more respondents indicated that changes in general would facilitate the enforcement of the Machinery Directive or the standardisation process (45%) rather than not being beneficial (21%), but they could be made in the Guide (as done in version 2.2).</p> <p>Impacts</p> <p>Costs: The costs of changing the list of products under Art.1.2(k) could not be reliably quantified. Benefits: improved safety. Looking into the RAPEX list of alerts from the past ten years, a total of 1,844 products related to electrical appliances were found. Of these products, eight did not comply with the requirements of the Machinery Directive, all of which were originating from China, and included: generators (2), a 3D printer for home use</p>	<p><b>[EVOLIS] No opinion at that time.</b> Wait and see Finland proposals</p>
18	<p><b>Index</b></p>	
	<p>List of areas:</p> <ul style="list-style-type: none"> <li>o New technologies</li> <li>o Scope and borderlines with other directives</li> <li>o Definitions</li> <li>o Annex I Essential Health and safety requirements</li> <li>o Annex IV</li> <li>o Annex V, VI, VII, VIII</li> <li>• Per each area, information is provided on: <ul style="list-style-type: none"> <li>o Inputs received from stakeholders</li> <li>o Outcomes of the on-going Impact Assessment</li> <li>o Commission comments based on the above</li> </ul> </li> </ul>	

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19	<p><b>Article 2 Definitions - Machinery</b></p>	
	<p>Proposal - France</p> <p>Current definition: ‘machinery’ means — 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.</p> <p>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 <b>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.</b>’</p> <p><u>Reasoning:</u> according to exiting definition the notion of machinery and PCM overlaps; If the <i>specific application</i> 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.</p>	<p><b>[EVOLIS] We understand the concern of French authorities as a wish of defining the notion of ‘specific application’ in order to clarify the borderline between PCM and Machinery.</b></p> <p>Indeed, the ‘<i>specific application</i>’ is one of the criteria to distinguish a machinery from a PCM and that notion is not defined today, <b>but we don’t see the added value of this amendment proposal.</b> Moreover, we don’t understand the link between the energy stored in the equipment and the reasoning for such amendment proposal ?</p> <p>We believe that there is a large consensus on the fact that the specific application refers to an intended use of a machine as defined by the manufacturer at the design stage. This intended use corresponds to the final use of a machine. A PCM only brings a function to machinery (or to an assembly of machinery), but a PCM doesn’t have any final use, because it is only intended to be integrated in a bigger assembly.</p> <p><b>Taking also into consideration the comment given in item 20 by most of respondents (“Most respondents would prefer a more clearly defined term of “specific application”), we agree that it could helpful to clarify the notion of ‘specific application’ in the interpretation guidelines of the MD. For this, see our suggestion related to item 27.</b></p>

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20	<p><b>Article 2 Definitions - PCM Proposal</b></p>	
	<p>Current definition: ‘Partly completed machinery’ means an assembly which is almost machinery but which cannot in itself perform a specific application.</p> <p>Proposal 1 Removal of PCM</p> <p>Proposal 2 Clarification of PCM - France: 2 alternatives: 1) clarify by introducing the relative differences between PCMs and interchangeable equipment: <i>‘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.</i> 2) in an Annex or in the Guide, define a restrictive list of equipment that may be deemed partly completed machinery.</p> <p>Opinions Netherlands: Agree to Proposal 1. Germany: Agree to both proposals - either delete the definition or, if no deletion is made, the requirements for incomplete machines to be equated to those of the complete machine. Denmark: Agree to Proposal 1. NB: Agree to Proposal 2 - for machinery such as pumps, compressors, centrifuges, HVAC systems and hydraulic power units placed on the market as PCM, the obligations to complete the conformity assessment procedure are transferred to the employer/ operator who is often unaware of this matter. Most respondents would prefer a more clearly defined term of “specific application”, e.g. machine suitable for its intended use able to perform its function actively and safely.</p> <p>Impacts Benefits: saving of administrative costs by changes in documentation and additional agreements with clients or customers, estimated EUR 5,000 to 10,000.</p>	<p><b>[EVOLIS]</b> As a general statement, we would like to underline the fact that such discussions related to definitions of some terms in the MD are not safety related but more helpful to clarify the responsibility of some stakeholders, e.g. is a supplier of an equipment (e.g. conveyor, motorized valve), a supplier of a PCM or a manufacturer of a machine ? Indeed, we have never heard about any accident occurring in the field which is the result of a misinterpretation of the concept of PCM versus interchangeable equipment of PCM versus machinery. The definitions given in the MD are not guilty of accidents occurring in the field. That’s why we would prefer to clarify the borderline by adding some general principles and concrete example in the MD guidelines, instead of changing some definitions that are suitable for a great majority of cases.</p> <p><b>[EVOLIS]</b> We fully disagree with that both proposals. Regarding proposal 1, the removal of PCM will disturb a lot the market which is used to use this notion. This proposal doesn’t bring added value in terms of safety. This will not clarify also some specific cases of equipment which are still controversial at European level regarding their legal status i.e. PCM or machinery.</p> <p>Regarding proposal 2, there is no need to clarify the differences between PCMs and Interchangeable equipment. The definitions are sufficiently clear enough. Moreover, the 1<sup>st</sup> alternative proposed is not correct. Indeed, it is possible to install a new PCM (e.g. conveyor) into an assembly of machinery (e.g. intralogistics installation, aggregate processing plant) already put into service. This is called a modification of an assembly of machinery in service, by addition of a new PCM. This is up to each industrial sector to develop its guidelines for illustrating by some examples the different equipment placed on the market and their respective legal status in the sense of the MD. This is not up to the MD guidelines to compile all this information. MD guidelines should concentrate on the general principles and can use few examples, aiming at understanding the principles. As a reminder, obligations for PCM are</p> <ul style="list-style-type: none"> <li>➤ only procedural and informative</li> <li>➤ There is no conformity assesment procedure and annex I doesn’t apply</li> <li>➤ But there is an obligation to declare the EHSRs applied and fulfilled</li> </ul>

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		<p>This obligation to deliver a set of documents (relevant technical documentation as described in Annex VII, part B, assembly instructions acc. to Annex VI and a declaration of incorporation acc. to Annex II, part 1, Section B) is very important because:</p> <ul style="list-style-type: none"> <li>- it defines a minimum legal framework between the supplier of PCM and the integrator of the PCM</li> <li>- this information given by manufacturer of PCM, is intended to be part of the technical file of the final machine</li> <li>- this minimum legal framework can also help to stimulate the exchange of information during contractual discussions between the PCM supplier and the integrator and to clarify at an early stage all the technical specifications expected by the future PCM.</li> </ul> <p>The <b>PCM concept is <u>very important</u> especially for assemblies of machinery.</b></p>
21	Annex II Declarations - PCM In connection to Proposal 2	

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	<p>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.</p> <p>The declaration of incorporation must contain the following particulars:</p> <p>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. <b>Partly completed machinery cannot claim to meet the requirements of this Directive without satisfying any essential requirements;</b></p> <p>KAN/NB: The following should be specified in the directive:  <b>The manufacturer of partly completed machinery shall fulfil all the applicable essential health and safety requirements.</b></p> <p style="text-align: center;">Opinions</p> <p>PCM for machines intended to be inserted into production lines is expected to increase in the future. The manufacturer of the sub-assembly should provide information on which EHSR the PCM complies with, what hazards the PCM cannot comply with, and how to build the product together with other sub-assemblies.</p> <p>Costs and Benefits Benefits: Increased safety and legal clarity.</p>	<p><b>[EVOLIS] Fully disagree</b> 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.</p> <p>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.</p> <p>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.</p> <p>This doesn't 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 doesn't 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.</p>
22	Article 2 Definitions - Assembly	

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	<p style="text-align: center;">Proposal</p> <p>Addition of a NEW definition in Art. 2: ‘Assembly’ Stakeholders participating in the OPC most frequently mentioned that the concept of assembly is complicated to understand. Some proposals received: 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 assembly composed of several machines, if they are linked together in terms of safety.</p> <p>Machinery safety consultant (NL): <i>‘A unit consisting of components that have been fitted together to perform a specific function, and that can be disassembled without destruction’.</i></p> <p>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”.</p> <p>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”.</p>	<p><b>[EVOLIS] Disagree with the deletion of the notion of assemblies of machinery.</b></p> <p>If we delete this notion, very soon some other stakeholders will ask to create a new term describing the concept of assemblies of machinery. We will not solve any difficulties related to the implementation of the legislation by a removal of this notion.</p> <p>If there are some discussions in practice or claims related to the conformity assessment of industrial plant and CE mark, it is up to the industrial sectors to develop guidelines. In France, the main issues we have with assemblies of machinery are related :</p> <ul style="list-style-type: none"> <li>- either to the legal status given (e.g. PCM of Machinery) to some sub-units of the assembly</li> <li>- or the affixing of a new CE mark on an existing assembly, in case of adding a new machinery connected to this assembly or replacing a sub-unit by a new one</li> </ul> <p>In the first case, the issue must be solved by the drafting of guidelines in the industrial sector.</p> <p>In the second case, the issue is related to modification of machinery and assembly of machinery in service which is out of the scope of the MD, but part of the implementation of the user’s legislation.</p>
23	Article 2 Definitions - Installer	

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	<p>Proposal</p> <p>Addition of a NEW definition in Art. 2: ‘Installer’ 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).</p> <p>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. <a href="#">Spain to provide concrete suggestion and data.</a></p> <p>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”.</p> <p>Proposal from workers and employers’ representatives: “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 this would make sense. In general, we consider this is only needed for a small sub-set of machinery such as platform lifts”.</p> <p>COM: Lifts Directive deals only with one type of product.</p>	<p><b>[EVOLIS]</b> We don’t see the need for such definition in the MD. Moreover, the adoption of the New Legislative Framework should help the alignment of definitions and clarify responsibilities of stakeholders.</p>
24	<p><b>Article 2 Definitions - Safety function</b></p>	
	<p>Proposal - France Addition of a NEW definition in Art. 2: ‘Safety function’ (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;</p>	<p><b>[EVOLIS]</b> We don’t see the added value of that proposal because the notion of safety function is already defined in EN ISO 12100-1 as following: « <b>safety function</b> function of the machine whose failure can result in an immediate increase of the risk(s) ».</p> <p>With the current existing definition, it is clear that a simple warning system does not perform a safety function.</p>

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25	Article 2 Definitions – Substantial modification	

### Proposal

Addition of a NEW definition in Art. 2: ‘Substantial modification’

### Opinions

Poland: YES - The inclusion of criteria relating to machinery in the Directive will make it possible to avoid differences of interpretation in this respect.

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.

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. 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. 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.

### Suggestions to solve this issue:

- 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 AND**
- 2) **considering accidents data, as a first priority, define the notion of “modification” which is a notion that belongs to the user’s legislation**

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.

- ➔ 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

### [EVOLIS] Fully disagree for the following reasons:

#### 1) About the concept of substantial modification and the practices in the field

There are some discussions since several years now at EU level on this matter and despite the frequent request to get some concrete example, we still don't have any real case to illustrate this concept.

- ➔ Since the beginning, we believe that ‘*substantial modification*’ is a theoretical concept which has no link with the real life. This is the reason why we don't expect to obtain any concrete example to illustrate it.

We must also remind that it may happen sometimes that a modified machinery is subject to a new CE marking. It is true that this practice may exist more or less in some countries, but we must be very clear on the fact that this practice is a strong misuse of the CE marking which is reserved exclusively for new machinery intended to be placed for the first time on the EU market.

This bad practice consisting of affixing a new CE mark on machinery in service is the result of a lack of requirements and guidelines in the user's legislation.

- ➔ So this bad practice cannot be used as an example to justify the need to create a new definition related to substantial modification

#### 2) If this concept really exists and if it is introduced in the MD, it could only lead to a market for new machines competing unfairly with a market for fake new machines (second-hand machines “CE” re-marked) with as a final outcome, a total destruction of the market of new machinery

3) **“No re-invent the wheel”**. Indeed, the 1<sup>st</sup> version of the application guide of the MD 98/37/EC had already investigated this concept, which was called "reconstruction" or "transformation" (see extract below in italic font).

#### **Concept of “reconditioned” machinery (i.e. remanufacturing)**

*In most languages spoken in the European Union, the words describing reconditioned machinery start with a prefix which indicates the repetition of an action of the return to a prior situation (retro). Reconditioned machinery, is existing machinery which has undergone technical work designed to modify its condition, its performance, its safety, etc. This work may consist of modifying the machinery to a greater or lesser extent.*

*Superficial reconditioning consists of modifying certain parts of the machinery and of changing worn parts.*

#### **Concept of “reconstructed” or “rebuilt” machinery**

*“Reconstructed” or “rebuilt” machinery is new machinery consisting entirely or in part, of parts taken from old machinery.*

#### **Can European technical regulations be applied to second-hand or reconditioned machinery ?**

*“New approach” Directives were designed exclusively for new products or for products regarded as new. Application of “new approach” Directives to second-hand products might result in a loss of credibility for the “CE” marking.*

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26	<p><b>Article 2 Definitions – State of the art</b></p>	
	<p>Proposal</p> <p>Addition of a NEW definition in Art. 2: ‘State of the art’</p> <p>The concept of “the state of the art” is crucial as it implies that EHSRs are not absolute, hence a manufacturer must strive to achieve the EHSRs’ objectives to the furthest extent possible according to the current technical and economic status.</p> <p>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.</p> <p>This also means “the state of the art” considered for the machinery when it was built might no longer be valid in the future.</p> <p>Does ‘state of the art’ require a definition / an “economic” definition?</p> <p>Opinions</p> <p>Most respondents do not consider necessary to include a definition in the legal text.</p> <p>Denmark: It can be explained in the MD guide.</p>	<p>[EVOLIS] Regarding a proposal for a definition of “state of the art”, <b><u>if it is really needed</u></b>, we believe that it would be sufficient to define the state of the art <b>in the MD guidelines</b>.</p>

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27	<p><b>Article 2 Definitions – Specific application</b></p>	
	<p>Proposal - France</p> <p>Addition of a NEW definition in Art. 2: 'Specific application'</p> <p>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.</p> <p>The French proposal gives a more restrictive definition which introduces the concept of use defined by the manufacturer: fitted 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.</p> <p>Opinions</p> <p>NB: Definition of 'Specific application': Process that transforms a product as a result of operations performed by the machine. Lifting of persons and/or goods.</p> <p>Denmark: it is not necessary to define the concept. Guidance should be adequate. In our view, if the machine is designed to function autonomously, i.e. it can function without being part of a machine or assembly of machines, it has a defined use.</p> <p>Germany: It is considered difficult to find a generally valid definition. The term should not be defined in the Directive. There should be an interpretation of the term in the guide.</p>	<p><b>[EVOLIS]</b> We believe that the guidelines of the machinery directive 98/37/EC titled “Comments on Directives 98/37/EC » was clear enough to understand this concept and we <b>propose to reintroduce</b> (see extract below in italic font) the text related to the example of motors and motorized valves, in a new version of the MD guidelines:</p> <p>“</p> <p><i>64. It is not always easy to apply the definition of “machinery” in practice. An internal combustion engine, for example, supplied to be built into a machine, is not “machinery” within the meaning of the Directive since it has no definite application before it is built in. An outboard motor, with its propeller, sold direct to the user, on the other hand, has a definite function of propelling a vessel, without modification or other operation by a specialist. Outboard motors are covered by the Directive whereas in-board motors for propelling boats are not! “Machinery with heat engines for use in underground working” referred to in Annex IV of the Directive is the only exception to this rule. These motors have been included in the Directive pending the Directive on equipment intended for use in an explosive atmosphere.</i></p> <p><i>65. The issue is even more ambiguous with products such as motorized valves since it is the intended end use of the product which determines whether or not it is covered by the Directive. This use is sometimes laid down by the manufacturer of the motorised valve where it is a separate whole machine.</i></p> <p><i>66. In most cases the manufacturer of the motorised valve does not stipulate a particular use, and thus the following rule can apply. If a motorised valve, such as a lock gate valve sold as such, is installed in isolation, it is covered by the Directive because it has a definite application as supplied. It is the principal part of the lock gate and guarantees correct operating. If a motorised valve intended to be incorporated in a machine or an assembly is sold to a manufacturer of machinery or more complex assemblies where “CE” marking is required under the “machinery” Directive, it should not be regarded as machinery within the meaning of the Directive but rather an ordinary component. Where necessary it will be accompanied by a manufacturer’s declaration as referred to in Annexe II.B</i></p> <p>”.</p>

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	<p>List of areas:</p> <ul style="list-style-type: none"> <li>o New technologies</li> <li>o Scope and borderlines with other directives</li> <li>o Definitions</li> <li>o Annex I Essential Health and safety requirements</li> <li>o Annex IV</li> <li>o Annex V, VI, VII, VIII</li> </ul> <ul style="list-style-type: none"> <li>• Per each area, information is provided on: <ul style="list-style-type: none"> <li>o Inputs received from stakeholders</li> <li>o Outcomes of the on-going Impact Assessment</li> <li>o Commission comments based on the above</li> </ul> </li> </ul>	
29	<b>Annex I – General Principles</b>	
	<p style="text-align: center;">Proposal – Notified Bodies</p> <p>NB MD VG8 - Vehicles servicing lifts &amp; VG9 - Lifting persons device:  The verifiability of safety-related parts/components and functions must be a product requirement. GENERAL PRINCIPLES</p> <p>1. The manufacturer of machinery or his authorised representative must ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. The machinery must then be designed and constructed taking into account the results of the risk assessment.</p> <p>By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:</p> <ul style="list-style-type: none"> <li>— determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof,</li> <li>— identify the hazards that can be generated by the machinery and the associated hazardous situations,</li> <li>— estimate the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,</li> <li>— evaluate the risks, with a view to determining whether risk reduction is required, in accordance with the objective of this Directive,</li> <li>— eliminate the hazards or reduce the risks associated with these hazards by application of protective measures, in the order of priority established in section 1.1.2(b),</li> <li>— <b>design safety-related parts/components and functions of a machine testable and verifiable</b></li> </ul>	<p>[EVOLIS]  Not evaluated.</p>

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30	<b>Annex I - 1.1.6. Ergonomics</b>	
	<p style="text-align: center;">Proposal - ETUI</p> <p>1.1.6. Ergonomics 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, <b>human factors, and usability knowledge</b> and principles such as:</p> <ul style="list-style-type: none"> <li>— allowing for the variability of the operator's physical dimensions, strength and stamina,</li> <li>— providing enough space for movements of the parts of the operator's body,</li> <li>— avoiding a machine-determined work rate,</li> <li>— avoiding monitoring that requires lengthy concentration,</li> <li>— adapting the man/machinery interface to the foreseeable characteristics of the operators, — <b>involving users during machinery design and development.</b></li> </ul>	<p><b>[EVOLIS]</b> Regarding 1<sup>st</sup> proposal, would it be possible to clarify the background for such change ? what means “<i>usability knowledge</i>” ?</p> <p><b>[EVOLIS]</b> Concerning the 2<sup>nd</sup> 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 <b>construction</b> 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, because concrete safety issues coming from the field are always interesting to take into account.</p> <p>For this reason, we <b><u>agree in principle with this idea, but this is up to the standardisation process</u></b> (at least at national level) to involve users in discussions related to the design of future machines.</p> <p>In addition, this feedback is also organized in each manufacturing company in order who all wants to improve the development of their future machinery. <b>We don't believe</b> that such adding in the principles of safety integration of the MD will help at involving users.</p> <p><b>The real challenge is more a fieldwork sector by industrial sector to explain and motivate users in European standardization.</b></p>
31	<b>Annex I - 1.1.2. Principles of safety integration</b>	

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	<p style="text-align: center;">Proposal 1 - France</p> <p>1.1.2. Principles of safety integration  (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.  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. (...)  (e) Machinery must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.  (f) the machinery must be designed taking account of actual feedback from users on previous models or similar machinery.</p> <p style="text-align: center;">Proposal 2 - ETUI</p> <p>1.1.2. Principles of safety integration  (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.  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.</p>	<p>[EVOLIS] Proposal 1  We don't see any added value in MD (same explanation as given in item 30).</p> <p>[EVOLIS] Proposal 2  No opinion.</p>
32	Annex I - 1.5.10 Radiation	

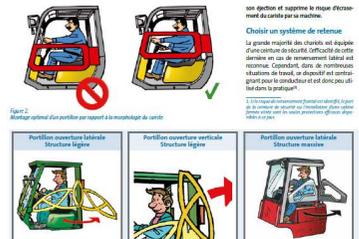
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	<p style="text-align: center;">Proposal - France</p> <p>Update of EHSRs as per Directive No. 2013/35/EU of 26/06/13 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields).</p> <p>1.5.10 Radiation</p> <p>"Each notice must contain, where applicable, at least the following information: (...)</p> <p><i>(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 to assist the user in conducting the risk assessment pursuant to Directive 2013/35/EC.</i></p>	<p><b>[EVOLIS]</b> As a remark, the amendment proposal is not as it appears in the left column. Considering the existing text of MD, the real amendment should be:</p> <p>"Each notice must contain, where applicable, at least the following information: (...)</p> <p><i>(w) where the machinery is likely to emit functional electromagnetic fields or low-frequency electromagnetic fields non-ionising radiation which may cause an adverse or harmful effect on persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons on the level of electrical, magnetic or electromagnetic fields in a form to assist the user in conducting the risk assessment pursuant to Directive 2013/35/EC.</i></p>
33	Annex I - 1.7.4 Instructions - paper and/or digital (part 1)	

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	<p>Proposals</p> <p>Always a printed user manual  Printed manual should be available on demand only  Access to a digital user manual (online or displayed by the product)  A short printed Quick-Start Guide and an access to a more in-depth online user manual</p> <p>Costs and Benefits</p> <p>In case of digital format for instructions:  Manufacturers:  (+) 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.  (-) 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.  Users and workers:  (+) 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.  (-) 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.</p>	<p><b>[EVOLIS] - Just some considerations</b></p> <p>Today, paper manuals are almost never present in machines and rarely read in their entirety. An electronic version of the instructions detailed manuals could suffice and would avoid printing all these manuals. Especially since the state of the art is changing and operators are now more comfortable with reading on a screen than on a printed document e.g. using a search engine. The use of means of communication such as smartphones has become widely democratized in companies, it would therefore be more coherent to facilitate access by more modern means. This would also reduce costs for manufacturers and the impact on the environment, by a reduction in paper consumption. It should be pointed out that in the field of non-road mobile machinery, they are now often with on-board screens at the driver's station. The development of man-machine interfaces Ergonomic cabin design allows for digital storage of instructions and the use of a digital display guides or quick start checklist.</p> <p>In general, the more machines are complex, the more the content of the instructions is huge/voluminous. However, operators only take the time to read the instruction manual, only if it's simple and concise. The Quick Start Guide falls within these criteria. This guide could refer to the full notice with a means to access it. The advantage of the digital manual is that it remains available in case of loss or poor condition of the printed version. The paper format could nevertheless remain indispensable in certain situations where operators would not have access to a computer on board the machine or to wifi access. It should also be taken into account that in some places, internet access is blocked for security reasons (military, nuclear sites, etc.).</p>
34	<p><b>Annex I - 1.7.4 Instructions - paper and/or digital (part 2)</b></p>	
	<p>Opinions</p> <p>Czech Republic, Denmark, Finland, Netherlands, Poland, Portugal, Romania, Slovenia: Short printed <u>Quick-Start Guide + access to a more in-depth online user manual</u>.  Belgium, Cyprus: <u>Access to a digital user manual (online or displayed by the product)</u>.  France, Poland and Sweden: <u>Access to manual on external device such as DVD/USB stick</u>  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. <u>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.</u></p>	<p><b>[EVOLIS]</b> See above</p>

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

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	<p>1.7.4.2 Content of the instructions</p> <p>(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 <b>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</b></p> <p>(s) instructions <b>and operational methods</b> designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations. <b>(w) the following information on emissions of hazardous substances from the machinery:</b></p> <p><b>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.</b></p> <p>2.2 Portable hand-held and/or hand-guided machinery, 2.2.1. General 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. <b>The portable machinery must have a device to capture emissions of hazardous substances at the source, if required.</b></p> <p>3.5.3. Emissions of hazardous substances 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. <b>Mobile machinery designed for spraying or likely to be used for spraying chemicals must be equipped with filter cabins.</b></p>	<p><b>[EVOLIS] Disagree</b> because we don't see the added value of that adding <b>"taking account of the restrictions and actual and foreseeable working conditions"</b> because, restrictions of use, foreseeable working conditions are part of the risk assessment and everything described in the instructions is the result of this risk assessment and the adding <b>"the description of the adjustment and maintenance operations"</b> is a repetition of the existing requirement".</p> <p><b>[EVOLIS] Disagree with the adding of new item w),.</b></p> <p><b>[EVOLIS] Disagree with that proposal on portable machinery.</b> This adding creates a very huge impact in terms of design and manufacturing of portable machinery which are small machinery that are expected to fulfil important ergonomics requirements, in terms of weight and manoeuvrability for example. The exposure of operators to dust or hazardous substances may be reduced by design on larger machinery, where it is possible to fit additional protective measures, but not on very small machinery. It is also a duty for the OEM to remind and give some recommendations in their instructions. But, this 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 provision of additional equipment intended to reduce this exposure (e.g. water spraying/sprinkling equipment). It is not technically possible to eliminate or reduce all risks by design. Some risks are inherent to the process itself and cannot be considered only in the light of the machinery directive. <b>[EVOLIS] Disagree with 2<sup>nd</sup> proposal on mobile machinery.</b> First of all, mobile machinery don't exist legally speaking because there is no definition. There is only an annex dealing with hazards due to mobility of machinery. It is technology oriented while the MD shall be written in a neutral way.</p>

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36	<b>Annex I - Vibrations</b>	
	<p style="text-align: center;">Proposal - Sweden</p> <p>2.2.1.1. Instructions  <i>The instructions must give the following information concerning vibrations transmitted by portable handheld and hand-guided machinery:</i></p> <ul style="list-style-type: none"> <li>— the vibration total value to which the hand-arm system is subjected, if it exceeds 2,5 m/s<sup>2</sup>. Where this value does not exceed 2,5 m/s<sup>2</sup>, this must be mentioned,</li> <li>— the uncertainty of measurement.</li> </ul> <p>9.6.2006L 157/50 Official Journal of the European Union EN  <i>These values must be either those actually measured for the machinery in question or those established on the basis of measurements taken for technically comparable machinery which is representative of the machinery to be produced.</i></p> <p><i>If harmonised standards are not applied, the vibration data must be measured using the most appropriate measurement code for the machinery.</i></p> <p><i>The operating conditions during measurement and the methods used for measurement, or the reference of the harmonised standard applied, must be specified.</i></p> <p>Sweden: there is a need to provide requirement for measuring and declaring peak value vibrations from percussive tools, or tools that have both rotating and percussive action. The value of 2.5 m/s<sup>2</sup> is assumed to be valid for all types of vibrating machinery. <u>Sweden to provide concrete proposal.</u></p>	<p>[EVOLIS] No opinion at this stage</p>
37	<b>Annex I - Electrical risks - Overhead power lines</b>	

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	<p>Proposal - France France: Additional EHSR                      3.5.4 <i>Overhead power lines</i>  <i>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.</i>                      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.                      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.</p>	<p><b>[EVOLIS] Disagree</b> with that adding because this risk is already covered in a more general way 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.</p>
38	<p><b>Annex I - 3.2.1. Driving position &amp; 3.2.2 Seating</b></p>	
	<p>Proposal - France                      3.2.1. <i>Driving position</i>                      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. Where necessary, appropriate devices must be provided to remedy hazards due to inadequate direct vision.                      Machinery on which the driver is transported must be designed and constructed in such a way that <b>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.</b>                      3.2.2 <i>Seating</i>                      Where there is a risk that operators or other persons transported by the machinery may be crushed between parts of the machinery and 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, <b>the machinery their seats</b> must be designed or equipped with a restraint system so as to keep the persons in their seats <b>and in the protective structure</b>, 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.                      It must not be possible for the machinery to move if the restraint system is not active.</p>	<p><b>[EVOLIS] - TBD</b>  <b>Internal remark :</b> We believe that this proposal is fork-lift truck oriented but it may cover other type of mobile machinery with ride on operator. We know that there are frequent accidents occurring after tipping over of fork-lift trucks and where the operators are crushed between the machinery and the ground, because of not use of the seat belts. The challenge is to keep the operator inside the envelope space in the cab, in case of tipping over. That's why another protective means considered as more efficient in some situations to achieve this goal is the use of a gate. Such gate is also a restraint system and it is recognised by INRS and social insurance organisms in France to be efficient.</p>  <p>See INRS documentation ED 125</p>

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39	<p><b>Annex I - 6.2. Control Devices (part 1)</b></p>	
	<p>Proposal – Germany (BAuA)</p> <p><b>6.2. CONTROL DEVICES</b></p> <p><i>Where safety requirements do not impose other solutions, the carrier must, as a general rule, be designed and constructed in such a way that persons in the carrier have means of controlling upward and downward movements and, if appropriate, other movements of the carrier.</i></p> <p><i>In operation, those control devices must override any other devices controlling the same movement with the exception of emergency stop devices.</i></p> <p><i>The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed.</i></p> <p>Either to delete the last sentence of 6.2 or to change it:</p> <p>a) <del>The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed.</del></p> <p><u>Reasoning:</u> This limits the technologies to be used to either a completely enclosed carrier or to hold-to-run devices. This was state of the art at the time when the Machinery Directive came into force. But with this requirement modern safety sensors are excluded.</p> <p>b) The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed. <del>If there is no risk of the persons on the carrier colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.</del></p> <p>[As in: 4.2.1. Control of movements</p> <p><i>Hold-to-run control devices must be used to control the movements of the machinery or its equipment. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by control devices authorising automatic stops at pre-selected positions without the operator holding a hold-to-run control device.]</i></p>	<p>[EVOLIS] Not evaluated</p>

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40	<b>Annex I - 6.2. Control Devices (part 2)</b>	
	<p>Opinions</p> <p>Netherlands: Rules should not prescribe the pressing of a button. Also the pressing of the button is not the benchmark. The ESHR should be that falling from the platform should be prevented. In addition, hold-to-run are often easy 'to manipulate' or overrule. A new innovation may be probably safer.</p> <p>Outcome from the consultations: The effects of redefining the requirements for completely enclosed carriers and hold to run controls for slow speed lifts were considered to be difficult to assess as it was indicated to be different depending on the type of product. While certain slow speed lifts might be provided with alternative control systems reaching the same or higher levels of safety, it was considered that these innovative systems might not suffice to prevent a falling of persons or goods. In the latter case, the effectiveness of the MD to ensure health and safety of users would decrease. <u>Adjusting the requirements might improve the use of innovative technologies for lifting products but it was considered beneficial to make a distinction between product types, having those intended for the general public and the lifting of persons in particular, be always subject to third-party conformity assessment.</u></p> <p>NB: The possibility of a support that is not completely closed must only be left to the machines for professional use (goods lift) and not for lifts with <math>v &lt; 0.15</math> m/s which are known to be used by everyone, including children and animals.</p> <p>The intervention times of the photoelectric barriers (and in general of the associated safety functions) must be equivalent to those of the safety buttons. Possible openings can cause independent variation of speed of ascent / descent of the load support.</p>	<p>[EVOLIS] Not evaluated</p>
41	<b>Index</b>	
	<p>List of areas:</p> <ul style="list-style-type: none"> <li>o New technologies</li> <li>o Scope and borderlines with other directives</li> <li>o Definitions</li> <li>o Annex I Essential Health and safety requirements</li> <li>o Annex IV</li> <li>o Annex V, VI, VII, VIII</li> <li>• Per each area, information is provided on: <ul style="list-style-type: none"> <li>o Inputs received from stakeholders</li> <li>o Outcomes of the on-going Impact Assessment</li> <li>o Commission comments based on the above</li> </ul> </li> </ul>	

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42	<p><b>Annex IV (part 1) Proposal - France</b></p>	
	<p>Removing the self-assessment procedure based on harmonized standards for Annex IV type of machinery, for which conformity assessments remain difficult to do.</p> <p>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 all of the relevant essential health and safety requirements, the manufacturer or his authorised representative shall apply one of the following procedures:</p> <p><del>(a) the procedure for assessment of conformity with internal checks on the manufacture of machinery, provided for in Annex VIII;</del></p> <p>(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;</p> <p>(c) the full quality assurance procedure provided for in Annex X."</p> <p>Opinions</p> <p>Finland and Romania: YES. Self-assessment increases the workload of public authorities.</p> <p>Netherlands: YES. Standards do not describe all hazards involved with the design of machinery. Poland: YES. There have been cases where the manufacturer has made conformity assessments based on standards which did not contain all the relevant safety requirements for the group of machinery concerned.</p> <p>Germany: NO. Standards must contain the same safety requirements as otherwise assessed by a notified body. If existing standards consider all relevant hazards and the manufacturer implements the recommended protection measures, there are no concerns.</p> <p>Denmark: NO. Have no basis to say that self-assessment according to harmonised standards provides a lower level of security.</p> <p>Sweden: NO.</p> <p><i>Impact Assessment: Lack of accident data backing up the change.</i></p>	<p><b>[EVOLIS]</b></p> <p>As a first remark, this amendment proposal deals with article 12 and not the annex IV itself.</p> <p><b>Disagree</b> with that proposal for the following reasons:</p> <p>Annex IV of the Directive sets out a strict list of categories of machinery which may be subject to one of two conformity assessment procedures 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.</p> <p>Where machinery listed in Annex IV is manufactured in accordance with harmonised standards which cover all the EHSR, the possibility of self-assessment by the manufacturer does not give rise to safety concerns and the removal of this possibility would have an impact on costs.</p>
43	<p><b>Annex IV (part 2)</b></p>	

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	<p style="text-align: center;">Update Annex IV</p> <p>France:</p> <p>i) Add some machinery to Annex IV. In this context, there is some farming machinery to propose (<b>chippers, spreaders and balers</b> in particular). Add a new point to the machinery of Annex IV: <b>“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).”</b></p> <p>ii) Establish cross-cutting machinery categories with certain risks and propose that a European group be set up (<b>see next slide</b>).</p> <p>Netherlands: Annex IV to be changed in hazard categories instead of a limited list of machinery. Finland: Approach similar to PPE Regulation: replace the current Annex IV with the classification of machinery into categories according to risk and/or function of the machine. The conformity assessment procedures are done for each category separately (<b>see next slide</b>).</p> <p>Lifts NB: <b>Lift appliances</b> to be added to Annex IV. A significant difference between lifting appliances according to the Machinery Directive and lifts according to the Lifts Directive is, beside the speed, the design of the load carrier. While a fully closed load carrier is mandatory for lifts (according to the Lifts Directive), a load carrier for lifting appliances (according to the Machinery Directive) can be a platform without any wall, door or ceiling.</p> <p>MD NB (VG8 Vehicles servicing lifts VG9 Lifting persons device):</p> <p>i) Add <b>Escalators and moving walks</b>. 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/layers without instructed personnel. They have crushing and shearing points. There are high risks in case of failure of the controls. ii) Add <b>Cranes with a load moment &gt;150 kNm</b>. 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.</p> <p>Germany: Deleting or adding categories of machinery, depending on the risk. A complete deletion of Annex IV is still possible.</p> <p>Denmark: Annex IV should remain unchanged. Deletion could lead to more dangerous machines on the market. Expanding the scope will be costly for the industry.</p> <p><i>Impact Assessment: Lack of accident data backing up the changes.</i></p>	<p><b>[EVOLIS]</b> Not directly concerned, except if the motivation is linked with a risk due to mobility.</p> <p>What means lift appliances ? <b>Need feedback from OEM</b></p> <p>What means escalators and moving walks ? <b>Need feedback from OEM</b></p> <p>Which type of cranes are concerned ? <b>Need feedback from OEM</b></p>
44	<b>Annex IV (part 3)</b>	

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	<p style="text-align: center;">Proposal from France - Option ii)</p> <ol style="list-style-type: none"> <li>1. Machinery for cutting and working wood or meat. (replaces points 1 to 8)</li> <li>2. Machinery with a risk of crushing/compression related to manual loading/unloading. (replaces p. 9 to 11 and 13)</li> <li>3. Machinery for underground working of the following types: (identical to point 12) 3.1. locomotives and brake-vans; 3.2. hydraulic-powered roof supports.</li> <li>4. Removable mechanical transmission devices including their guards. (identical to point 14)</li> <li>5. Guards for removable mechanical transmission devices. (identical to point 15)</li> <li>6. Machinery used to perform operations under a load or a vehicle. (replaces point 16)</li> <li>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)</li> <li>8. Portable cartridge-operated fixing and other impact machinery. (identical to point 18)</li> <li>9. Protective devices designed to detect the presence of persons. (identical to point 19)</li> <li>10. Power-operated interlocking movable guards designed to be used as safeguards in machinery referred to in section 2. (identical to point 20)</li> <li>11. Logic units to ensure safety functions. (identical to point 21)</li> <li>12. Roll-over protective structures (ROPS). (identical to point 22)</li> <li>13. Falling-object protective structures (FOPS). (identical to point 22)</li> <li>14. Mobile machinery or machinery on carrying vehicles.</li> </ol>	<p><b>[EVOLIS] Item 1. Not concerned</b></p> <p><b>[EVOLIS] Item 2. Disagree</b> with this proposal because the wording is so wide that it may concern a lot of machinery. This list must be machine type oriented and not formulated as a list of risks</p> <p><b>[EVOLIS] Item 6. Disagree</b> with this proposal because the wording is so wide that it may concern a lot of machinery. The wording for machinery shall be formulated in terms of specific application. "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)</p> <p><b>[EVOLIS] Item 14. Fully disagree</b> with the adding of mobile machinery or machinery on carrying vehicles. Such matter has not been raised until now, including during the public consultation. Is there any justification to raise suddenly this item and propose an amendment in the MD for such mobile machinery ? What is the reason for that inclusion? Do we have accident data justifying that inclusion in annex IV ? Anyway, whatever the risky situations behind this proposal, we don't believe that a third party certification would suddenly solve safety issues that may occur in the field ?</p>

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45	<b>Annex IV (part 4)</b>	
	<p>Proposal from Finland</p> <ul style="list-style-type: none"> <li>- Category I: could be placed on the market under the current manufacturer's internal control procedure.</li> <li>- Category II: would contain machines with higher risks and e.g. machines requiring type approval procedure and</li> <li>- Category III: having highest risk and belonging to scope of type examination should have in addition also obligation of the manufacturing quality assurance.</li> </ul> <p>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.</p>	<b>[EVOLIS] TBD</b>
46	<b>Index</b>	
	<p>List of areas:</p> <ul style="list-style-type: none"> <li>o New technologies</li> <li>o Scope and borderlines with other directives</li> <li>o Definitions</li> <li>o Annex I Essential Health and safety requirements</li> <li>o Annex IV</li> <li>o Annex V, VI, VII, VIII <ul style="list-style-type: none"> <li>• Per each area, information is provided on: <ul style="list-style-type: none"> <li>o Inputs received from stakeholders</li> </ul> </li> </ul> </li> <li>o Outcomes of the on-going Impact Assessment</li> <li>o Commission comments based on the above</li> </ul>	
47	<b>Annex V</b>	
	<p>Proposal – NB (VG8 Vehicles servicing lifts &amp; VG9 Lifting persons device) Amend 17 g):</p>	<b>[EVOLIS] General remark:</b> Annex V is not an identified item listed in different policy options for the revision of the MD and it has not been part of neither the public consultation nor the VVA interviews conducted last year.

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	<p>(g) electric safety devices in the form of safety switches containing electronic components, <b>functional safety equipment including hardware and software.</b></p> <p><u>Reasoning:</u> 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).</p>	<p><b>[EVOLIS] Disagree.</b> The inclusion of functional safety equipment including hardware and software shall not be part of the annex V. This will increase the cost without improving safety without increasing safety. What is the rationale behind this proposal ?</p>
<b>48</b>	<b>Annexes VII &amp; VIII</b>	
	<p>Proposal - France</p> <p>Annex VII, part A, section 1, point (b)</p> <p>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)</p> <p>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</p>	<p><b>[EVOLIS] Disagree with the introduction of a production monitoring procedure.</b></p> <p>If there is such deviation, this means that the manufacturer has failed to fulfil its obligation. The MD is not guilty for that.</p>