



Revision of the Machinery Directive 2006/42/EC

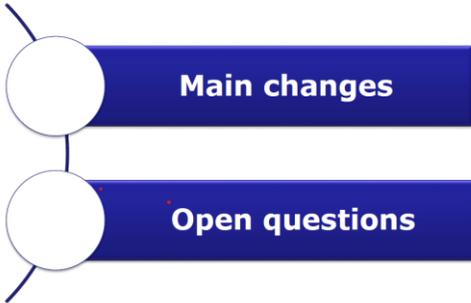


**Revision of the
Machinery Directive 2006/42/EC**

Machinery Working Group

Brussels, 9-10 November 2020

Machinery Regulation



- Main changes
- Open questions

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FIEC welcomes the opportunity to provide comments on the commission proposals for the revision of Machinery Directive 2006/42/CE

NLF INPUT

- Set the **obligations** and requirements for **economic operators**
- Set the level of **competence of the third party conformity assessment bodies** who assess products or quality management systems, and the **control mechanisms for these bodies** (notification and accreditation)
- Determine which are the **appropriate conformity assessment processes** (modules which also include the manufacturer's declaration of conformity) to be applied
- Impose the **appropriate market surveillance mechanisms** (internal and external) to ensure that the whole legislative instrument operates in an effective and seamless manner

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Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p><i>General principles – risk assessment</i></p> <p><i>By the iterative process of risk assessment and risk reduction referred to above, the manufacturer or his authorised representative shall:</i></p> <p><i>– identify the hazards that can be generated by the machinery and the associated hazardous situations, including new hazards that can be generated during the whole machinery lifecycle as an evolution of its behaviour due to the machinery design.</i></p> <p style="text-align: right;">  </p> <p>9</p>		<p><i>FIEC appreciates the technology neutrality of the Machinery Directive (MD) with the RA and RR principles.</i></p> <p><i>All the risks must be assessed, and all the changes and machine learning capabilities must be anticipated and predicted by the manufacturer before placing into the market.</i></p> <p>FIEC agrees with this proposal with respect to the enhancement of machinery capabilities due to machine learning.</p> <p><i>Machine learning phase is up to the manufacturer control and must be covered in the RA of the manufacturer.</i></p>



Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p>1.1.6. Ergonomics <i>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 principles such as:</i></p> <p>...</p> <p>— adapting the man/machinery interface to the foreseeable characteristics of the operators including with respect to machinery with fully or partially evolving behaviour or logic,</p> <p>10 </p>		<p>FIEC supports this proposal.</p> <p><i>Ergonomic principles must include machine learning capabilities, not adding new risks not addressed by the manufacturer.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p>1.1.9 Protection against corruption</p> <ul style="list-style-type: none"> – The machinery must be designed and constructed so that the connection to it of another device, by any feature of the connected device itself or by any remote device that communicates with the machinery does not lead to a hazardous situation. – A hardware component that is critical for the machinery compliance with the relevant health and safety requirements shall be designed so that it can be secured. Security measures foreseen shall provide for evidence of an intervention. – Software that is critical for the machinery compliance with the relevant health and safety requirements shall be identified as such and shall be secured. – Software identification shall be easily provided by the machinery. – Evidence of an intervention shall be available for a reasonable period of time. – Machinery data, software that is critical for the machinery compliance with the relevant health and safety requirements shall be adequately protected against accidental or intentional corruption. <p>11 </p>	<p>New technologies –Annex I</p> <p>1.1.9 Protection against corruption</p> <p>- (...)</p> <p>- <u>Software that is critical for the machinery compliance with the relevant health and safety requirements shall be identified as such and shall be secured by the manufacturer and/the third-party involved in the machinery supply chain, during the whole lifecycle of the machinery, in all operating modes.</u></p> <p>- (...)</p> <p>- <u>Machinery data, software that is critical for the machinery compliance with the relevant health and safety requirements shall be adequately protected against accidental or intentional corruption and shall fulfil the cybersecurity legislation.</u></p>	<p><i>FIEC supports this proposal, including the proposed rewording.</i></p> <p><i>Moreover, this software security must include all updates in its lifecycle, in all operating modes.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p><i>1.2. CONTROL SYSTEMS</i></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:</i></p> <p><i>— they can withstand the intended operating stresses and intended and unintended external influences, including those coming from malicious third parties leading to a hazardous situation,</i></p> <p>12 </p>		<p><i>FIEC supports this proposal.</i></p> <p><i>All the existing requirements are intended to protect the safety of the machinery. This is more a clarification and it doesn't really represent a new requirement.</i></p>



Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p>1.2. CONTROL SYSTEMS</p> <p>1.2.1. Safety and reliability of control systems</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:</i></p> <p>– the safety functions cannot change outside the limits of the machinery as defined by the manufacturer in the risk assessment. This must be guaranteed in the risk assessment by the machine manufacturer, regardless of any modifications to the settings or rules generated by the machinery or by operators in charge of the learning phases.</p> <p>13 </p>		<p>FIEC supports this proposal and the wording: <i>“safety functions must be guaranteed in the RA by the machine manufacturer.”</i></p> <p><i>Limits, settings, and scope must be defined by the manufacturer.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p>1.2. CONTROL SYSTEMS</p> <p>1.2.1. Safety and reliability of control systems</p> <p><i>Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. They must be designed and constructed in such a way that:</i></p> <p>...</p> <p>– machinery with fully or partially evolving behaviour or logic:</p> <p>a) must be intrinsic safe and must under all circumstances not be permitted to make decisions concerning life, injury and death of persons and damage to material and surroundings,</p> <p>b) must not cause the machine to perform actions that exceed its defined task and movement space,</p> <p>c) if taking incorrect decisions, the machinery placed on the market and new machinery to be placed on the market, must be correctable, to prevent any future recurrences of that particular error,</p> <p>14 </p>		<p><i>FIEC supports this proposal.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p><i>1.2. CONTROL SYSTEMS</i></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. They must be designed and constructed in such a way that:</i></p> <p>...</p> <p><i>– machinery with fully or partially evolving behaviour or logic:</i></p> <p><i>d) the actions 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 for conformity assessment and market surveillance purposes,</i></p> <p><i>e) the decision-making process must be logged and retained for conformity assessment and market surveillance purposes.</i></p> <p>15 </p>		<p><i>FIEC supports this proposal.</i></p>



Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p>1.2. CONTROL SYSTEMS</p> <p>1.2.1. Safety and reliability of control systems <i>Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. They must be designed and constructed in such a way that:</i></p> <p>– for autonomous mobile machinery, the control system must be designed to perform all of the above safety functions by itself.</p> <p>16 </p>		<p><i>FIEC supports this proposal.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p><i>1.2. CONTROL SYSTEMS</i></p> <p><i>1.2.1. Safety and reliability of control systems</i></p> <p><i>Particular attention must be given to the following points:</i></p> <ul style="list-style-type: none"> <i>– the safety-related parts of the control system must apply in a coherent way to the whole of an assembly of machinery and/or partly completed machinery. For cable-less control, a failure of the connection or a faulty connection must not lead to a hazardous situation.</i> <p>17 </p>		<p><i>FIEC supports this proposal.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p><i>1.2. CONTROL SYSTEMS</i></p> <p><i>1.2.6. Failure of the power supply and network connection</i></p> <p><i>The interruption, the re-establishment after an interruption or the fluctuation in whatever manner of the power supply and network connection to the machinery must not lead to dangerous situations.</i></p> <p>18 </p>		<p><i>FIEC supports this proposal.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p><i>1.3. PROTECTION AGAINST MECHANICAL RISKS</i></p> <p><i>1.3.7. Risks related to moving parts</i></p> <p>The prevention of risks of contact leading to hazard situations must be also adapted to:</p> <ul style="list-style-type: none"> - human-robot coexistence in a shared space without direct collaboration - human-robot interaction (simultaneous or alternating work on a piece) <p>Machinery with fully or partially evolving behaviour or logic must indicate which actions they are about to perform.</p> <p>19 </p>	<p style="text-align: center;">New technologies –Annex I</p> <p>1.3. PROTECTION AGAINST MECHANICAL RISKS</p> <p>1.3.7. Risks related to moving parts</p> <p>The prevention of risks (...)</p> <p>Machinery with fully or partially evolving behaviour or logic must indicate which <u>action</u> they are about to perform. <u>This indication must be ensured for machinery with no network connection or with an issue of power supply.</u></p>	<p><i>FIEC welcomes this new wording, incorporating coexistence and interaction, and including the proposed wording.</i></p> <p><i>The technology neutral formulation “must indicate which actions they are about to perform” must be related to the type of machineries, its use conditions and environment and must be clarified regarding the type of signalisation.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</p> <p>3.1.1 Definitions</p> <p><i>(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 or may remotely supervise the autonomous mobile machinery regardless of the distance and/or the means of communication.</i></p> <p><i>(c) 'Autonomous mobile machinery' means mobile machinery provided with an autonomous mode ensuring the permanent control of its travel and its operations.</i></p> <p><i>(d) 'Autonomous mode' means operating mode without permanent interaction of an operator, in which mobile machinery ensures all the essential functions for the safety in the travel and working area.</i></p> <p>20 </p>		<p><i>FIEC supports these new definitions.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</p> <p>3.2.4 Supervisory control station</p> <p><i>Autonomous machinery has a supervision station specific to the autonomous mode located remotely from the machinery which only authorizes actions to stop, start or restart the machine. It is designed and built to authorize starting or restarting only when the driver has a direct or indirect view of the machine's movement and working area and the protective devices are operational.</i></p> <p><i>The information available at this station must enable the driver to receive useful information on the operation, movement and safe positioning of the machine in the travel and working area.</i></p> <p><i>This information enables the driver of the autonomous machine to be alerted to the occurrence of unforeseen or dangerous situations actual or impending, which requires intervention.</i></p> <p>21 </p>	<p>New technologies –Annex I</p> <p>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</p> <p>3.2.4 Supervisory control station (...)</p> <p><i>This information enables the driver of the autonomous machine to be alerted to the occurrence of unforeseen or dangerous situations actual or impending, which requires intervention.</i></p> <p><u><i>The supervisor of the autonomous machinery must have the possibility to see the danger zones around the machine during the movements of the machine, if necessary with additional detection devices.</i></u></p>	<p><i>FIEC supports this proposal and proposes to add an element regarding the supervisor of the autonomous machinery.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p style="text-align: center;"><i>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</i></p> <p style="text-align: center;">3.3.2 Starting/ moving</p> <p style="text-align: center;"><i>The movement of an autonomous mobile machinery must take into account the risks related to the environment where intended to move and work.</i></p> <p style="text-align: right;">22 </p>	<p style="text-align: center;">New technologies –Annex I</p> <p style="text-align: center;">3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</p> <p style="text-align: center;">3.3.2 Starting/ moving</p> <p style="text-align: center;"><i>The movement of an autonomous mobile machinery must take into account the risks related to the <u>configuration (area, conditions, surroundings) of the environment where intended to move and work.</u></i></p>	<p><i>FIEC welcomes this proposal but the wording “environment” must be clarified.</i></p> <p><i>FIEC suggests replacing “environment” by “the configuration (area, conditions, surroundings) of the environment”.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p><i>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</i></p> <p><i>3.3.3 Travelling function</i></p> <p><i>Autonomous mobile machinery must move and operate in an enclosed zone fitted with a peripheral protection system comprising guards and protective devices or must be equipped with protective devices intended to detect any human or animal presence in the surrounding of the machinery.</i></p> <p><i>Autonomous mobile machinery shall be equipped with a guiding or navigation system designed for locating and positioning the machinery according to the relevant operations while preventing the unexpected movements beyond the intended limits of his travel and working area.</i></p> <p><i>The protective devices and control system of autonomous mobile machinery must be designed to stop automatically its movements and operations to prevent the risks in the following situations:</i></p> <ul style="list-style-type: none"> <i>• where a person or an animal is detected in the travel and working area;</i> <i>• where a person or an animal is crossing the peripheral protection system and enters in the travel and working zone of the autonomous mobile machinery.</i> <p>23 </p>	<p style="text-align: center;">New technologies –Annex I</p> <p>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</p> <p>3.3.3 Travelling function</p> <p><i>(...) The protective devices and control system of autonomous mobile machinery must be designed to stop automatically its movements and operations to prevent the risks in the following situations:</i></p> <ul style="list-style-type: none"> <i>• where a person or an animal is detected in the travel and working area danger zone;</i> <i>• where a person or an animal is crossing the peripheral protection system and enters in the travel and working danger zone of the autonomous mobile machinery.</i> <p><u>The danger zone of the machinery must be defined by the manufacturer.</u></p>	<p><i>FIEC supports this proposal and proposes to add an element regarding the danger zone (instead of working area).</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p><i>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</i></p> <p><i>3.3.5. Control circuit failure</i></p> <p><i>A failure in the power supply to the power-assisted steering, where fitted, must not prevent machinery from being steered during the time required to stop it.</i></p> <p><i>For autonomous mobile machines, a failure in the steering system shall stop any movements of the machinery.</i></p> <p>24 </p>		<p><i>FIEC supports this proposal.</i></p>

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<p style="text-align: center;">New technologies – Annex I</p> <p><i>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</i></p> <p><i>3.4.2. Moving transmission parts</i></p> <p><i>By way of exception to section 1.3.8.1, in the case of engines, moveable guards preventing access to the moving parts in the engine compartment need not have interlocking devices if they have to be opened either by the use of a tool or key or by a control located in the driving position, providing the latter is in a fully enclosed cab with a lock to prevent unauthorised access.</i></p> <p><i>This exemption is not relevant for autonomous mobile machinery.</i></p> <p>25 </p>	<p style="text-align: center;">New technologies –Annex I</p> <p>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</p> <p>3.4.2. Moving transmission parts</p> <p><i>(...) This exemption is not relevant for autonomous mobile machinery <u>in an autonomous mode.</u></i></p>	<p><i>FIEC supports this proposal and proposes to add an element regarding the autonomous mode.</i></p>

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<p style="text-align: center;">New technologies – Annex I</p> <p><i>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</i></p> <p>3.4.8 Autonomous mobile machinery</p> <p><i>For autonomous mobile machinery associated with one or more trailers or towed equipment, their movements shall not generate any risks for persons and animals in the vicinity of the travel and working zone of the machinery. In addition, for this machinery, the approach manoeuvres to the charging stations or other fuel delivery system shall not create risks.</i></p> <p>26 </p>		<p><i>FIEC supports this proposal.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex I</p> <p><i>3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY</i></p> <p><i>3.5.1 Batteries</i></p> <p><i>The automatic charging of batteries in particular for autonomous mobile machinery shall be performed without creating risks according to sections 15.1 and 1.3.8.2.</i></p> <p><i>3.6.3. Instructions</i></p> <p><i>3.6.3.3 Autonomous mobile machinery</i></p> <p><i>The instructions for use shall specify the travel and working zones including the operating limits.</i></p> <p>27 </p>		<p><i>FIEC supports this proposal.</i></p> <p><i>With respect to RA and RR made by the manufacturer, these risks are already covered.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex V</p> <p style="text-align: center;"><i>INDICATIVE LIST OF THE SAFETY COMPONENTS</i></p> <p style="text-align: center;">...</p> <p style="text-align: center;">(h) software with safety functions</p> <p style="text-align: center;">(i) artificial intelligence with safety functions</p> <div style="display: flex; justify-content: space-between; align-items: flex-end; margin-top: 20px;"> 28  </div>	<p style="text-align: center;">New technologies –Annex V</p> <p style="text-align: center;">INDICATIVE LIST OF THE SAFETY COMPONENTS</p> <p style="text-align: center;">...</p> <p style="text-align: center;">(h) software with safety functions</p> <p style="text-align: center;">(i) artificial intelligence with safety functions</p> <p style="text-align: center;"><u>(j) safety component with artificial intelligence safety function</u></p>	<p><i>FIEC supports this proposal.</i></p> <p><i>As it concerns all equipment with an AI safety function incorporated component (not AI applications for example), FIEC suggests adding an aspect regarding the safety component with artificial intelligence safety function.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex VII</p> <p>A. TECHNICAL FILE FOR MACHINERY <i>The technical documentation shall include at least the following elements:</i></p> <p><i>(n) during the use of specify machinery categories with sensor-fed, remotely-driven, autonomous, AI with learning capability, if the operations are alimented by (sensorial) data, or if the software can evolve by itself, the trace log of all relevant elements – both the data and the versions of software - should be collected and kept synchronized for an eventual ex-post inspection.</i></p> <p>29 </p>		<p>No comment.</p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">New technologies – Annex VII</p> <p><i>B. TECHNICAL FILE FOR PCM</i></p> <p><i>The technical documentation shall include at least the following elements:</i></p> <p><i>(m) where appropriate, the source code or programmed logic that are safety-related, together with the relevant data, should be collected and kept synchronized to allow failure analysis or in case of inspection.</i></p> <p style="text-align: right;">  </p> <p>30</p>		<p><i>No comment.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<div data-bbox="206 395 548 655" style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p style="text-align: center;">Scope exclusions</p> </div> <div data-bbox="206 660 972 1232" style="border: 1px solid black; padding: 10px;"> <p style="text-align: center;">Scope exclusions</p> <p><i>Article 1 - Subject matter</i> <i>This Regulation lays down requirements for the design and manufacture of machinery, which is to be made available on the market, in order to ensure protection of the health and safety of users, domestic animals and property and establish rules on the free movement of machinery in the Union.</i></p> <p><i>The road circulation risks of machinery are not part of this Regulation.</i></p> </div>		<p><i>FIEC supports this proposal.</i> Only safety aspects are included in the machinery regulation.</p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">Scope exclusions</p> <p style="text-align: center;">Low Voltage Directive products</p> <p><i>(k) electrical and electronic products falling within the following areas, insofar as they are covered by Directive 2014/35/EU of 26 February 2014 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits or by Directive 2014/53/EU of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC:</i></p> <ul style="list-style-type: none"> – household appliances intended for domestic use, – audio and video equipment, – information technology equipment, – ordinary office machinery, – low-voltage switchgear and control gear, – electric motors; <p>33 </p>		<p><i>No comment.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">Definitions</p> <p style="text-align: center;">Safety component</p> <p><i>'safety component' means a component:</i></p> <ul style="list-style-type: none"> – having any support, physical or digital, including a software – <i>which serves to fulfil a safety function,</i> – <i>which is independently placed on the market,</i> – <i>the failure and/or malfunction of which endangers the safety of persons, and</i> – <i>which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.</i> <p>35 </p>		<p><i>FIEC supports this additional precision for the definition of a safety component.</i></p>



Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">Definitions</p> <p style="text-align: center;">Partly completed machinery</p> <p><i>'Partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application which is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Regulation applies, other than an assembly that only lacks the upload or modification of a software. Any device installed after the machinery on which it is assembled has been put into service is not deemed partly completed machinery.</i></p> <p>36 </p>	<p style="text-align: center;">Definitions</p> <p style="text-align: center;">Partly completed machinery</p> <p><i>'Partly completed machinery' means an assembly which is almost machinery but <u>which cannot in itself perform a specific application</u> which is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery to which this Regulation applies, other than an assembly that only lacks the upload or modification of a software. Any device installed after the machinery on which it is assembled has been put into service is not deemed partly completed machinery.</i></p>	<p>FIEC does not support this proposal.</p> <p><i>The last sentence "Any device installed after the machinery on which it is assembled has been put into service is not deemed partly completed machinery" creates confusion on how to understand the PCM concept and needs clarification.</i></p> <p><i>FIEC suggests keeping the text as it is. FIEC suggests deleting the last sentence.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">Definitions Others</p> <ul style="list-style-type: none"> • <i>'instruction manual' means user manual in digital or paper format.</i> • <i>'safety manual' means safety instructions in printed format.</i> • <i>'data', 'software' (to be defined)</i> <p style="font-size: small;">37 </p>	<p style="text-align: center;">Definitions Others</p> <ul style="list-style-type: none"> • <i>'instruction manual' means user manual in digital or paper format.</i> • <i>'safety manual' means safety instructions <u>as an extracted version from the instruction manual, provided in printed format.</u></i> • <i>'data', 'software' (to be defined)</i> 	<p><i>There is a confusion with these 2 first definitions because safety manual (=safety instructions) is part of the instruction manual.</i></p> <p><i>FIEC suggests 2 main recommendations:</i></p> <ul style="list-style-type: none"> - <i>we must use the same wording for the same document: only one document called "instructions for use" is provided by the manufacturer</i> - <i>we need to be clear that "safety manual" is not a second new document: it is a printed format with only safety instruction (=Quick Start Guide), extracted from the instruction manual</i> <p><i>(Whatever the terminology, it is important to make sure that users are not confused or think that one part of the manual is not relevant for them).</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">Obligations of third parties involved in the machinery supply chain</p> <ol style="list-style-type: none"> 1. <i>Third parties who do not qualify as manufacturers, importers or distributors of machinery shall ensure that the terms and conditions of sale and supply of software, components, data and other services in relation to the safety functions of the machinery do not prevent meeting any compliance obligation under this Regulation.</i> 2. <i>Third parties involved in the supply chain under paragraph 1 shall cooperate with the manufacturers of machinery to ensure compliance with this Regulation within their capacities and responsibilities.</i> <p style="text-align: right;">  </p> <p>39</p>		<p><i>FIEC supports this proposal because supply chain is more and more complex and welcomes the explicit mention of “cooperation” between third parties (e.g.: AI software developers) and manufacturers.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">Presumption of conformity of machinery</p> <p><i>The Commission shall be empowered to adopt implementing acts establishing technical specifications that meet the essential health and safety requirements of this Regulation where the following conditions have been fulfilled:</i></p> <p><i>(a) no reference to harmonised standards is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012; or</i></p> <p><i>(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard and there are undue delays in the standardisation procedure or the request has not been accepted by any European standardisation organisations;</i></p> <p>...</p> <p><i>Machinery which is in conformity with the technical specifications or parts thereof shall be presumed to be in conformity with the essential health and safety requirements of this Regulation in so far as those technical or parts thereof cover those requirements.</i></p> <p>41 </p>	<p style="text-align: center;">Presumption of conformity of machinery</p> <p><i>The Commission shall be empowered to adopt implementing acts establishing technical specifications that meet the essential health and safety requirements of this Regulation where the following conditions have been fulfilled:</i></p> <p><i>(a) no reference to harmonised standards is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012; or and</i></p> <p><i>(b) the Commission has requested one or more European standardisation organisations to draft a harmonised standard and there are undue delays in the standardisation procedure or the request has not been accepted by any European standardisation organisations;</i></p> <p>...</p> <p><i>(...)</i></p>	<p>FIEC supports this proposal.</p> <p><i>Today, the system is based on a new approach directive and harmonised standards.</i></p> <p><i>If (a) and (b) are cumulative conditions, FIEC will suggest replacing “or” by “and”.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p style="text-align: center;">1.1.2. Principles of safety integration</p> <p><i>Machinery must be supplied with all the special equipment and accessories, test procedures and/or test equipment, essential to enable it to be adjusted, maintained and used safely.</i></p> <p style="text-align: right;">  </p> <p>43</p>	<p style="text-align: center;">EHSR</p> <p style="text-align: center;">1.1.2. Principles of safety integration</p> <p><i><u>Machinery with artificial intelligence safety function must be supplied with all the special equipment and accessories, functional specific test procedures and/or specific test equipment, essential to enable it to be adjusted, maintained and used safely. The manufacturer must precise the success criteria for these specific procedures and test equipment.</u></i></p>	<p><i>FIEC supports this proposal but considers that it should be more precise.</i></p> <p><i>In order to use a machinery with incorporated safety components with AI safety functions, the user needs to test these safety functions according to “functional specific test procedures” on specific items.</i></p> <p><i>And the manufacturer must define these items and precise the success criteria for these specific tests (passed or failed).</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p style="text-align: center;">1.2 Control systems</p> <p><i>1.2.4.3. 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></p> <p><i>Machinery must be equipped with an emergency stop function, so that they can be deactivated/overridden at any time.</i></p> <p style="text-align: right;">  </p> <p>44</p>		<p><i>FIEC supports this proposal.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p style="text-align: center;">1.5. Risks due to other causes</p> <p><i>1.5.13. Emissions of hazardous materials and substances</i></p> <p><i>Machinery must be designed and constructed in such a way that risks of inhalation, ingestion, contact with the skin, eyes and mucous membranes and penetration through the skin of hazardous materials and substances which it produces can be avoided. These include hazardous chemicals, including nanomaterials, and biological materials and substances.</i></p> <p><i>Where a risk cannot be eliminated, the machinery must be so equipped that hazardous materials and substances can be contained, captured, evacuated, precipitated by water spraying, filtered or treated by another equally effective method.</i></p> <p><i>Where the process is not totally enclosed during normal operation of the machinery, the devices for containment and/or capture, filtration (separation) and evacuation must be situated in such a way as to have the maximum effect.</i></p> <p>45 </p>		<p><i>FIEC supports this proposal.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p style="text-align: center;">1.6. Maintenance</p> <p><i>1.6.2. Access to operating positions and servicing points</i></p> <p><i>Machinery must be designed and constructed in such a way as to allow access in safety to all areas where intervention is necessary during operation, adjustment, maintenance and cleaning of the machinery.</i></p> <p><i>The machinery accesses must be dimensioned and prepared for the use of rescue equipment in such a way that the immediate and gentle rescue of these persons is guaranteed at all times.</i></p> <p>46 </p>		<p><i>FIEC supports this proposal.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR 1.7 Information</p> <p><i>1.7.4 Instructions</i></p> <p><i>The instructions can be provided in a digital format and must be provided in paper format upon request.</i></p> <p><i>Instructions that are essential for the putting into service in a safe way must be provided in any case in paper format together with the machinery.</i></p> <p style="text-align: right;"></p> <p>47</p>	<p style="text-align: center;">EHSR 1.7 Information</p> <p><i>1.7.4 Instructions</i></p> <p><i>The instructions must be provided in a digital format and must be provided free of charge in paper format upon request.</i></p> <p><i>Instructions that are essential for the putting into service in a safe way and for the daily maintenance must be provided in any case in paper format together with the machinery. The safety manual must be provided in paper format on a mandatory basis.</i></p>	<p><i>FIEC understands the sense of digitalisation and supports the compromise (because it is not a fully digital option).</i></p> <p><i>However, not all users are connected to the Internet and not all the time/everywhere.</i></p> <p><i>Moreover, FIEC insists on the importance for the user to have the machinery declaration of conformity in paper format.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p style="text-align: center;">1.7 Information</p> <p><i>1.7.4.2. Contents of the instructions</i></p> <p>1. Each instruction manual must contain, where applicable, at least the following information:</p> <p>...</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 taking account of the restrictions and actual and foreseeable working conditions.</p> <p>48 </p>		<p><i>FIEC supports this proposal.</i></p> <p><i>Manufacturers must provide realistic instructions taking account of operational working conditions and maintenance constraints.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR 1.7 Information</p> <p><i>1.7.4.2. Contents of the instructions</i></p> <p>1. Each instruction manual must contain, where applicable, at least the following information:</p> <p><i>(w) the following information on emissions of hazardous substances from the machinery:</i></p> <ul style="list-style-type: none"> - 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 coming from the machinery or from materials/ substances used with the machinery, or - the effectiveness of the capturing or filtration device and the conditions to be observed to maintain its effectiveness over time. <p><i>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.</i></p> <p>49 </p>	<p style="text-align: center;">EHSR 1.7. Information</p> <p>(...)</p> <ul style="list-style-type: none"> - <u><i>how to capture, filter or reduce as efficiently as possible the hazardous substances which are released during the processing of materials in the course of their intended use.</i></u> 	<p><i>FIEC supports this proposal.</i></p> <p>The proposed complementary sentence could be added.</p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR 1.7 Information</p> <p><i>1.7.4.2. Contents of the instructions</i></p> <p>1. Each instruction manual must contain, where applicable, at least the following information:</p> <p>...</p> <p>(y) the intended life limit of the machinery and/or of its components which have impact for the safety aspects;</p> <p>50 </p>		<p><i>FIEC is opposed to this proposal.</i></p> <p><i>Manufacturer cannot limit the lifetime of their machinery. It fully depends on the use conditions, the environmental conditions, the maintenance...</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p>1.7.4.2. Contents of the instructions</p> <p>2. Each safety manual must contain, where applicable, at least the following information:</p> <ul style="list-style-type: none"> • The business name and full address of the manufacturer and of his authorized representative; • The designation of the machinery as marked on the machinery itself; • A description of the intended use of the machinery; • A description of all the conditions which must be met with a view to start safely the utilization of machinery; • Warnings to prevent a foreseeable misuse of the machinery; • Where appropriate, a description of the necessary personal protective equipment; • The sequence of operations to be performed to start using the machinery; • Any necessary additional safety information required, depending on the risk assessment of the machinery; • Where appropriate, instructions for transport, assembly and installation. If software is required, the safety instructions shall explain how to install and make operational the software in a safe way; • Unique link to download access of the complete instruction manual, if the manual is not supplied in digital form together with the machine <p>51</p> 	<p>1.7.4.2. Contents of the instructions</p> <p>2. Each safety manual must contain, where applicable, at least the following information:</p> <ul style="list-style-type: none"> • The business name and full address of the manufacturer and of his authorized representative; • The designation of the machinery as marked on the machinery itself; • A description of the intended use of the machinery; • A description of all the conditions which must be met with a view to start safely the utilization of machinery; • Warnings to prevent a foreseeable misuse of the machinery; • Where appropriate, a description of the necessary personal protective equipment; • a designation of applicable safety warnings ; • The sequence of operations to be performed to start using the machinery; (...). 	<p>FIEC supports this proposal and suggests adding a mention regarding the designation of applicable safety warnings.</p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p>2.2. Portable hand-held and/or hand-guided machinery</p> <p><i>2.2.1. General</i> <i>Portable hand-held and/or hand-guided machinery must:</i> ... <i>- have, where necessary, a device to capture emissions of hazardous substances at the source</i></p> <p>52 </p>	<p style="text-align: center;">EHSR</p> <p>2.2. Portable hand-held and/or hand-guided machinery</p> <p>2.2.1. General <i>Portable hand-held and/or hand-guided machinery must:</i> ... <i>-have, where necessary, a device to capture emissions of hazardous substances at the source. <u>In case this capture device is a separate one and not preinstalled on the machinery, safety manual must contain a description of the necessary conditions and operations for its installation on the machinery.</u></i></p>	<p><i>FIEC supports this proposal</i> which is in relation to dust and carcinogenic substances.</p> <p><i>FIEC suggests to precise this requirement by adding a sentence.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p>2.2. Portable hand-held and/or hand-guided machinery</p> <p><i>2.2.1.1. Instructions</i></p> <p><i>The instructions must give the following information concerning vibrations, expressed as acceleration [m/s²], and transmitted by portable handheld and hand-guided machinery:</i></p> <ul style="list-style-type: none"> <i>— the vibration total value from continuous vibrations to which the hand-arm system is subjected,</i> <i>— the mean value of the peak amplitude of the acceleration from repeated shock vibrations, to which the hand-arm system is subjected,</i> <i>— the uncertainty of both measurements.</i> <p style="text-align: right;">  </p> <p>53</p>		<p><i>FIEC supports this proposal.</i></p> <p><i>Emission and exposure are closely connected.</i></p> <p><i>This requirement will fit with the one which is already in the work safety directive.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p style="text-align: center;">3. Offset risks due to the mobility of machinery</p> <p><i>3.2.2 Seating</i></p> <p><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, the machinery must be designed or equipped with a restraint system so as to keep the persons in their seats and/ or in the protective structure, without restricting movements necessary for operations or movements relative to the structure caused by the suspension of the seats. Such restraint systems should not be fitted if they increase the risk.</i></p> <p><i>It must not be possible for the machinery to move if the restraint system is not active, except if it increases the risk. In that case, the driver has to be alerted by a visual or audible signal at the driving position combined with an automatic speed limitation of the machine.</i></p> <p>54 </p>	<p style="text-align: center;">EHSR</p> <p style="text-align: center;">3. Offset risks due to the mobility of machinery</p> <p><i>3.2.2 Seating</i></p> <p><i>Where there is a risk that operators or other persons transported by the machinery may be crushed (...).</i></p> <p><i>It must not be possible for the machinery to move if the restraint system is not active, except if it increases the risk. In that case, the driver has to be alerted by a visual or audible signal at the driving position combined with an automatic speed limitation of the machine.</i></p>	<p><i>FIEC welcomes this proposal.</i></p> <p><i>However, FIEC proposes to delete part of the last sentence.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p style="text-align: center;">3.5. Protection against other risks</p> <p><i>3.5.3. Emissions of hazardous substances</i> <i>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.</i></p> <p><i>Ride-on mobile machinery designed for spraying or likely to be used for spraying chemicals must be equipped with filtration cabs or equivalent safety measures.</i></p> <p>55 </p>		<p><i>FIEC fully supports this proposal related to correct level of protection and filtration cabs to protect operators.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p style="text-align: center;">3.5 Protection against other risks</p> <p>3.5.4 Risk of contact with live overhead power lines <i>Mobile machinery is designed and manufactured so as to prevent the risk of contact or the risk of creating an electric arc 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></p> <p><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.</i></p> <p><i>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.</i></p> <p>56 </p>	<p style="text-align: center;">EHSR</p> <p style="text-align: center;">3.5 Protection against other risks</p> <p>3.5.4 Risk of contact with live overhead power lines</p> <p><u>The following requirements should depend on the height of the machinery and be part of the instructions of the machinery:</u></p> <p><i>Mobile machinery is designed and manufactured so as to prevent the risk of contact or the risk of creating an electric arc 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></p> <p>(...)</p>	<p>FIEC supports this proposal.</p> <p>Contact with live overhead power lines is a very important risk.</p> <p>FIEC proposes to add a sentence in introduction of the paragraph.</p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p style="text-align: center;">4. Offset risks due to lifting operations</p> <p><i>4.1.3. Fitness for purpose</i></p> <p><i>Where the machinery cannot be assembled in the manufacturer's premises or in the premises of his authorised representative, the appropriate measures must be taken at the place of use by the manufacturer or on his behalf. Otherwise, the measures may be taken either in the manufacturer's premises or at the place of use.</i></p> <p style="text-align: right;">  </p> <p>57</p>		<p><i>FIEC supports this proposal regarding the assembling and the installation of the machinery.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">EHSR</p> <p>6.2 Control devices for machinery with lifting of persons</p> <p>OPTION 1 <i>The control devices for these movements must be of the hold-to-run type manned at all times except where the carrier itself is completely enclosed.</i></p> <p>OPTION 2 <i>The control devices for these movements must be of the hold-to-run type except where the carrier itself is completely enclosed. If there is no risk of the persons or the goods on the carrier colliding or falling and no other risks are added, the said devices may be replaced by control devices authorising automatic stops at preselected positions without the operator holding a hold-to-run control device.</i></p> <p>58 </p>		<p><i>No comment.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">Annex II- Declaration of conformity</p> <p style="text-align: center;"><i>EU DECLARATION OF CONFORMITY OF THE MACHINERY</i></p> <p><i>The EU declaration of conformity must contain the following particulars:</i></p> <p>...</p> <p><i>- The address where the machine is installed, only for lifting machinery installed in a building or a structure,</i></p> <p style="text-align: right;">59 </p>	<p style="text-align: center;"><i>Annex II-Declaration of conformity</i></p> <p style="text-align: center;"><i>EU DECLARATION OF CONFORMITY OF THE MACHINERY</i></p> <p><i>The EU declaration of conformity must contain the following particulars:</i></p> <p>...</p> <p><i>- The address where the machine is <u>permanently</u> installed, only for lifting machinery <u>for persons</u> installed in a building or a structure,</i></p>	<p><i>FIEC does not support this proposal.</i></p> <p><i>We must take in consideration, for example, the possible change of place of cranes (reinstallation in new situation). Moreover, this requirement may limit the choice of lifting equipment and situations of use.</i></p> <p><i>The wording must be adapted for machineries like conventional lifts only.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">Principles of human centric principles</p> <p>➤ <i>Recitals and/or</i></p> <p>➤ <i>1.1.2. Principles of safety integration</i> (b) Machinery shall remain subject to an appropriate level of human oversight and be designed and implemented in such a way that its functioning can be controlled and overseen by humans. Human oversight shall include the ability of humans to override or reverse the outputs of artificial intelligence and prevent its further use.</p> <p>➤ <i>1.1.6. Ergonomics</i> <i>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 principles such as:</i> - Adapting machinery in a human-centric way that respects human dignity and personal autonomy of the humans who use it or may be affected by it.</p> <p>61 </p>		<p>1.1.2.</p> <p>FIEC supports this relevant proposal for AI but the old 1.1.2(b) must not be deleted, because human centric principles are broader than AI.</p> <p>Question : -> Is this a new paragraph 1.1.2 (b) instead of the old 1.1.2(b)?</p> <p>1.1.6.</p> <p>FIEC supports this proposal. As there are already some standards for ergonomic which are not implemented, this proposal must be clearer with concrete requirements with respected to the human centric principles.</p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p data-bbox="208 435 230 451">□</p> <p data-bbox="421 483 777 512" style="text-align: center;">Substantial modification</p> <p data-bbox="253 568 389 588">➤ Definition</p> <p data-bbox="253 624 922 775"><i>Means a modification on the machinery, by physical or digital means, after being placed on the market and/ or put into service, not foreseen by the manufacturer, as a result of which the compliance of the machinery with this Regulation may be affected and when the machinery is made available on the market.</i></p> <p data-bbox="253 799 900 871"><i>Own use is excluded from this definition when the person that modifies the machinery is the only user and the function of the machinery is not modified.</i></p> <p data-bbox="253 879 819 927"><i>E.g. a private person increases the power of his/her lawnmower</i></p> <p data-bbox="215 978 232 994">62</p> 	<p data-bbox="1111 467 1413 496" style="text-align: center;">Substantial modification</p> <p data-bbox="1055 536 1227 564">➤ Definition</p> <p data-bbox="1005 612 1503 927"><i>Means a modification on the machinery, by <u>relevant</u> physical or digital means, after being placed on the market and/or put into service, not foreseen by the manufacturer, as a result of which the compliance of the machinery with this Regulation may be affected and when the machinery is made available on the market.</i></p> <p data-bbox="1005 935 1514 1110"><i>Own <u>and non-commercial</u> use is excluded from this definition when the person that modifies the machinery is the only user <u>and the function of the machinery is not modified.</u></i></p> <p data-bbox="1005 1150 1469 1326"><i><u>When a substantially modified machinery is made available on the market or used commercially, only RA certified by a third party must be supplied.</u></i></p>	<p data-bbox="1541 432 2038 533"><i>FIEC thanks the commission to take the opportunity of this revision to clarify the rules regarding substantial modification.</i></p> <p data-bbox="1541 576 2038 639"><i>However, FIEC disagrees with this proposed definition.</i></p> <p data-bbox="1541 683 2038 783"><i>FIEC welcomes the distinction between machinery made available on the market and machinery in own use.</i></p> <p data-bbox="1541 826 2038 1145"><i>After the first putting into service, Directive 2009/104 on safety and health requirements for the use of work equipment directive applies and in case of modification on machinery, the employer has to carry out a risk analysis and keep the equipment in compliance with the technical regulations applicable at the first put into service.</i></p> <p data-bbox="1541 1153 2038 1254"><i>Many SMEs adapt their machineries according to their organisation and needs.</i></p> <p data-bbox="1541 1262 2038 1394"><i>If these machineries are made available again on the market, it will multiply the cases considered as substantial modification. Every machinery</i></p>



		<p><i>modification must be determined regarding its safety-related impact.</i></p> <p><i>Moreover, FIEC suggests working on criteria for substantial modifications and suggests identifying and limiting and focusing on cases on which a new simplified conformity assessment procedure is necessary (situations with new risks hazards resulted from the modification or with an increase of existing risks).</i></p>
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Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">Substantial modification</p> <p>➤ Simplified conformity assessment:</p> <ul style="list-style-type: none"> • Only for the modified aspects if the safety of the whole product is ensured. • Ad hoc technical file <p style="text-align: right;">  </p> <p>63</p>	<p style="text-align: center;">Substantial modification</p> <p style="text-align: center;">Simplified conformity assessment:</p> <p style="text-align: center;"><i>“When such substantially modified machinery is made available on the market, a risk assessment for the modified aspects must be supplied in the simplified conformity assessment, as an <u>ad hoc technical file.</u>”</i></p>	<p><i>FIEC supports the proposal of a simplified conformity assessment only for modified aspects.</i></p> <p><i>Moreover, FIEC asks for more precisions on the content of this simplified conformity assessment and the clear content of the technical file.</i></p> <p><i>A possible wording for slide 63 could read as indicated.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p style="text-align: center;">Categories of machinery Annex IV List of machinery</p> <ul style="list-style-type: none"> • The list does not represent the current state of the art in terms of high risks • A categorisation by risks is not the best option because the machinery use is based on the function e.g. cutting wood and not on the risk as other EU legislation e.g. PPE products • Lack of information now to update the list: Delegated act • Item to be added in the list: A machinery contains an AI system/ component to ensure a safety function while this component is integrated directly by the manufacturer without having recourse to a component of Annex V. <p>64 </p>		<p><i>FIEC agrees with this proposal.</i></p>

Text proposed by the European Commission	Proposed amendment by FIEC	Comments
<p data-bbox="210 496 232 517">□</p> <p data-bbox="353 544 842 619">Categories of machinery Annex IV Conformity assessment</p> <p data-bbox="271 678 797 703">To keep or not the internal check option:</p> <ul data-bbox="271 735 931 943" style="list-style-type: none"> - If the updated list contains only high risk machines, a third party conformity assessment is more justified. - If the internal check option is kept when applying harmonised standards, the existence of harmonised standards is even more relevant. <p data-bbox="215 1034 232 1046">65</p> 		<p data-bbox="1532 528 1991 592"><i>FIEC wants to keep the internal check option.</i></p> <p data-bbox="1532 635 2029 735"><i>Presumption of conformity of harmonized standards must remain to facilitate and help manufacturers.</i></p> <p data-bbox="1532 746 2018 810"><i>Machinery embedded with AI system is a high-risk product.</i></p> <p data-bbox="1532 815 2007 954"><i>If there is high risk in the conformity assessment procedure (risks which may affect safety of the machines), there should be an intervention of third party.</i></p>