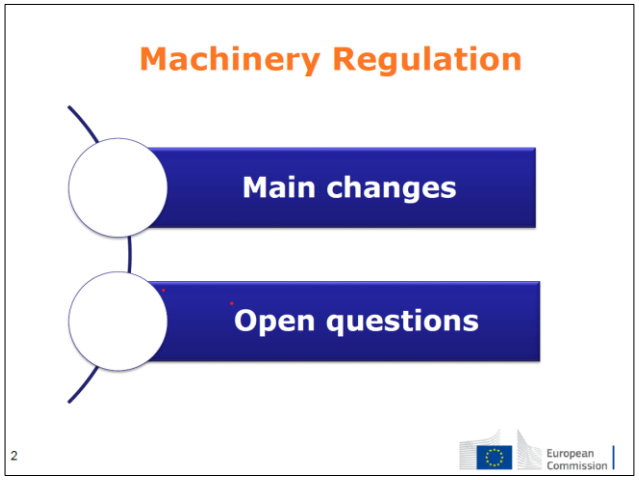
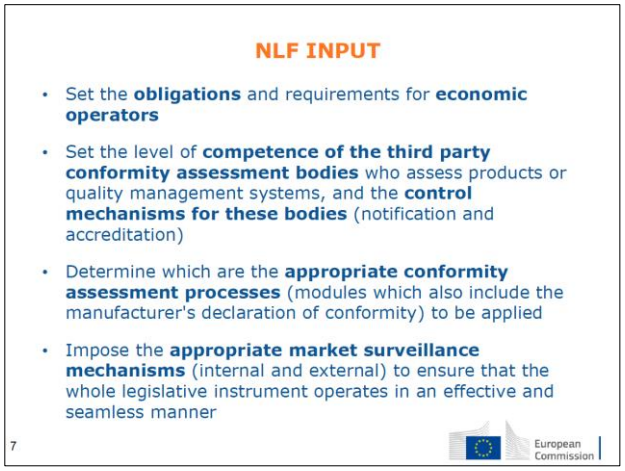
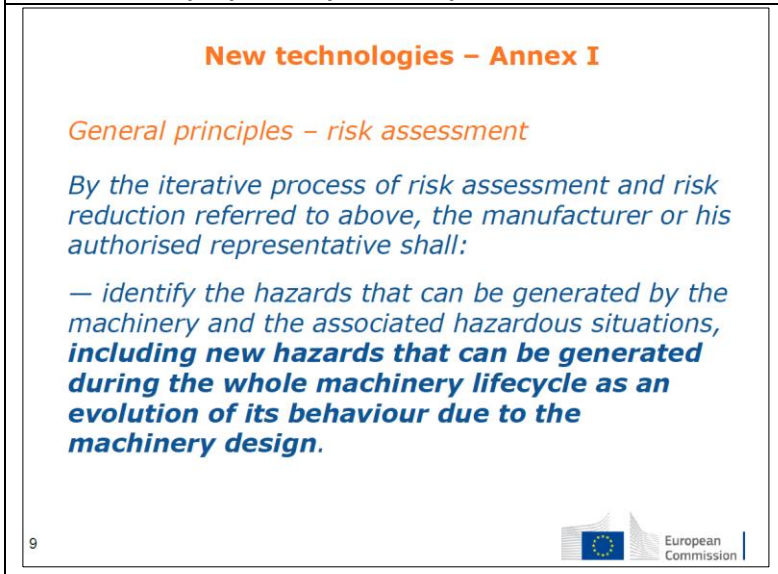
Revision of the Machinery Directive 2006/42/EC



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

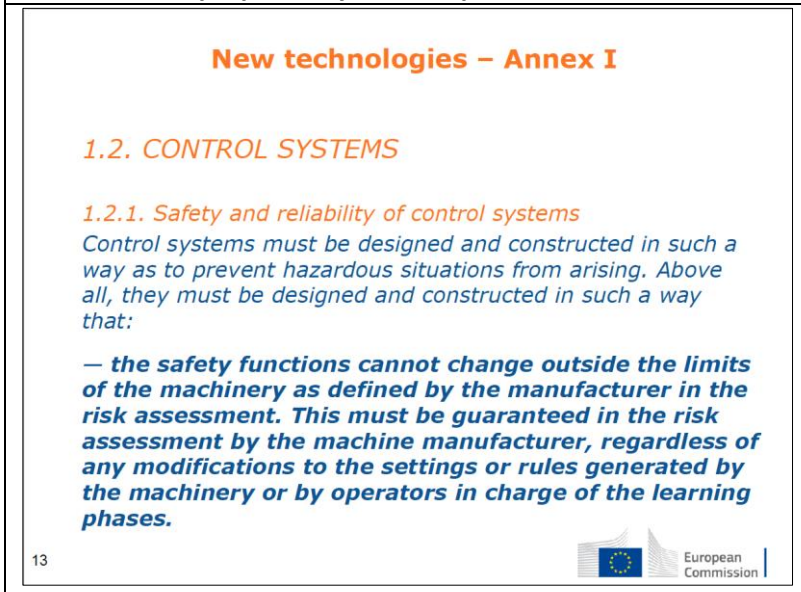


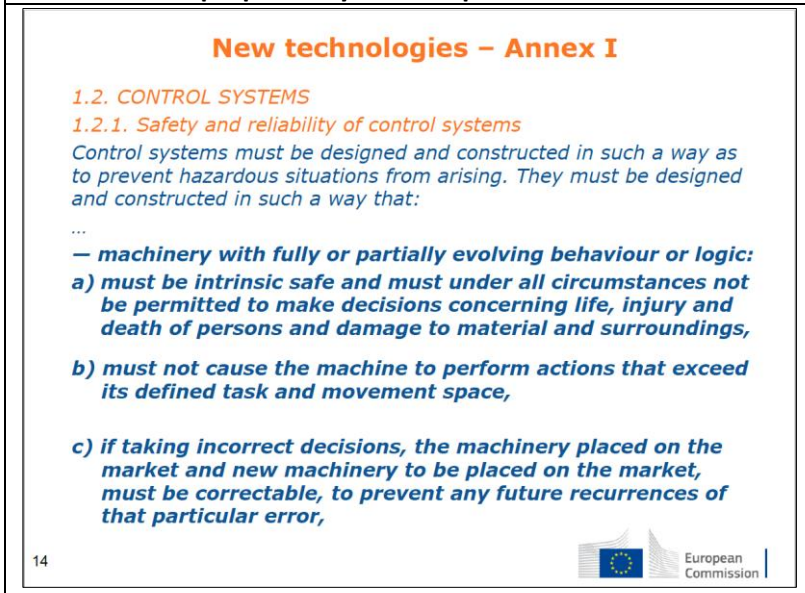
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		*FIEC appreciates the technology neutrality of the Machinery Directive (MD) with the RA and RR principles.* *All the risks must be assessed, and all the changes and machine learning capabilities must be anticipated and predicted by the manufacturer before placing into the market.* ***FIEC agrees with this proposal** with respect to the enhancement of machinery capabilities due to machine learning.* *Machine learning phase is up to the manufacturer control and must be covered in the RA of the manufacturer.*

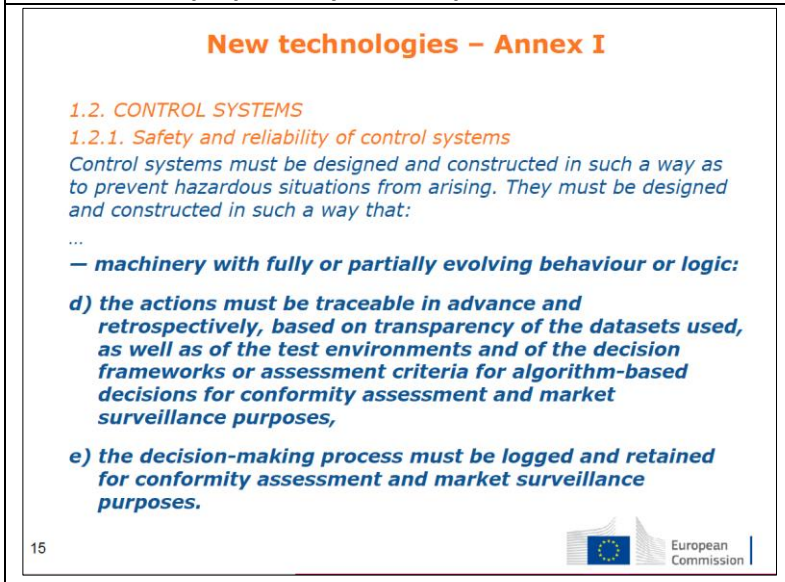
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.*** *Ergonomic principles must include machine learning capabilities, not adding new risks not addressed by the manufacturer.*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	New technologies –Annex I 1.1.9 Protection against corruption **- (…)** ***- Software that is critical for the machinery compliance with the relevant health and safety requirements shall be identified as such and shall be secured <u>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>*** ***- (…)*** ***- 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 <u>and shall fulfil the cybersecurity legislation</u>.***	***FIEC supports this proposal, including the proposed rewording.*** *Moreover, this software security must include all updates in its lifecycle, in all operating modes.*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal***. *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.*

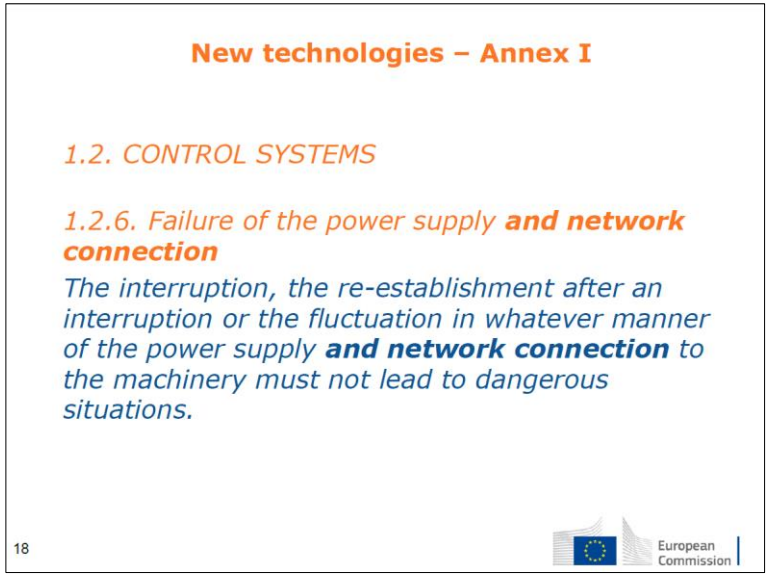
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal*** *and the wording: "safety functions must be* ***guaranteed*** *in the RA by the machine manufacturer."* *Limits, settings, and scope must be defined by the manufacturer.*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.***

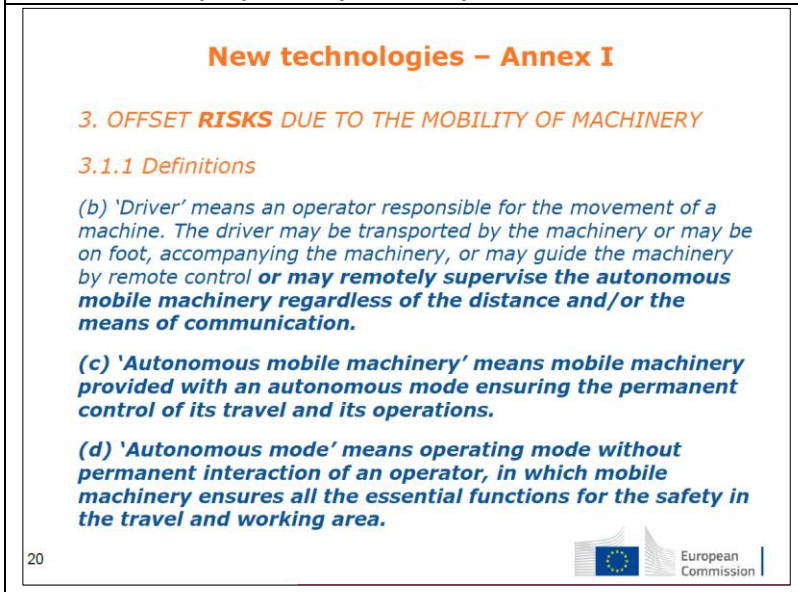
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.***

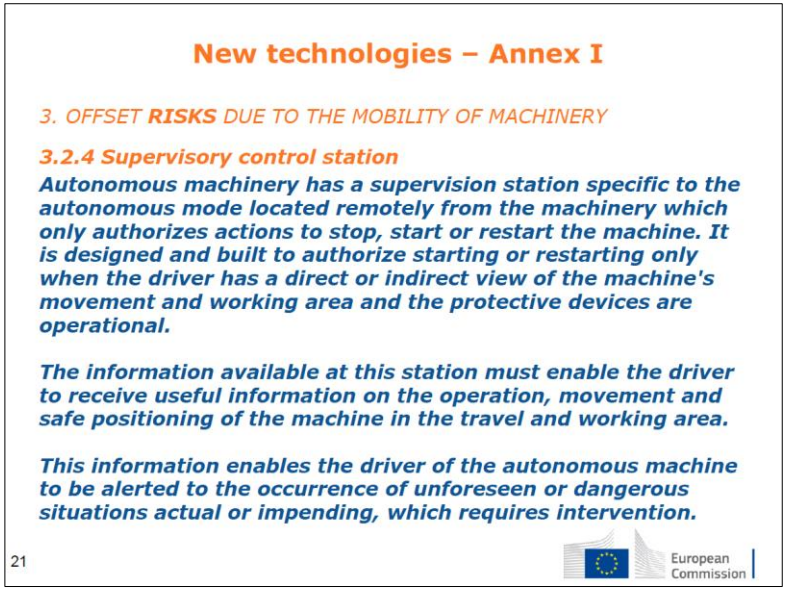
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.***

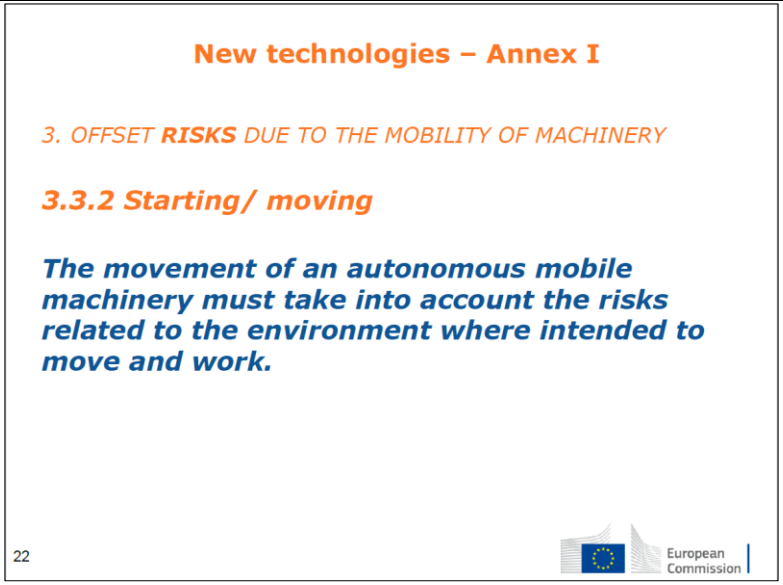
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.***

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.***

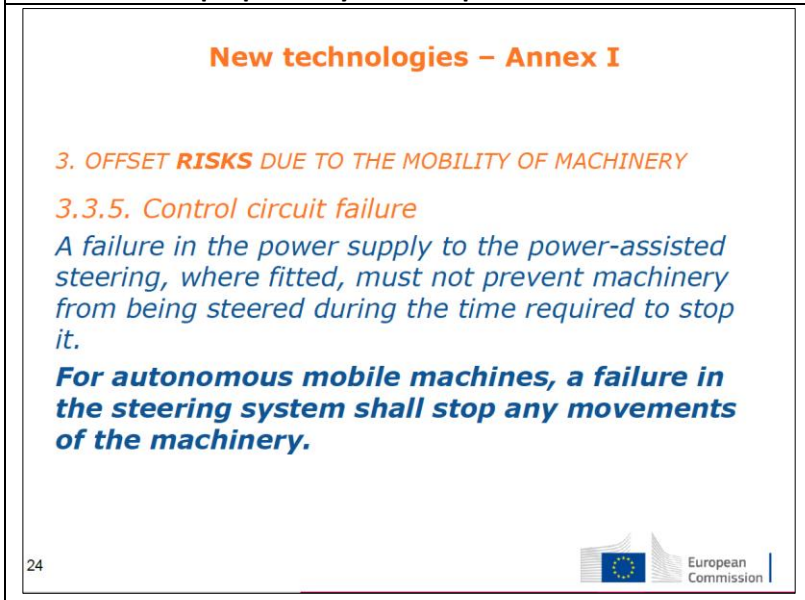
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**New technologies –Annex I** **1.3. PROTECTION AGAINST MECHANICAL RISKS** **1.3.7. Risks related to moving parts** ***The prevention of risks (…)*** ***Machinerywith fully or partially evolving behaviour or logic must indicate which action they are about to perform. This indication must be ensured for machinery with no network connection or with an issue of power supply.***	***FIEC welcomes this new wording,*** *incorporating coexistence and interaction, and including the proposed wording.* *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.*

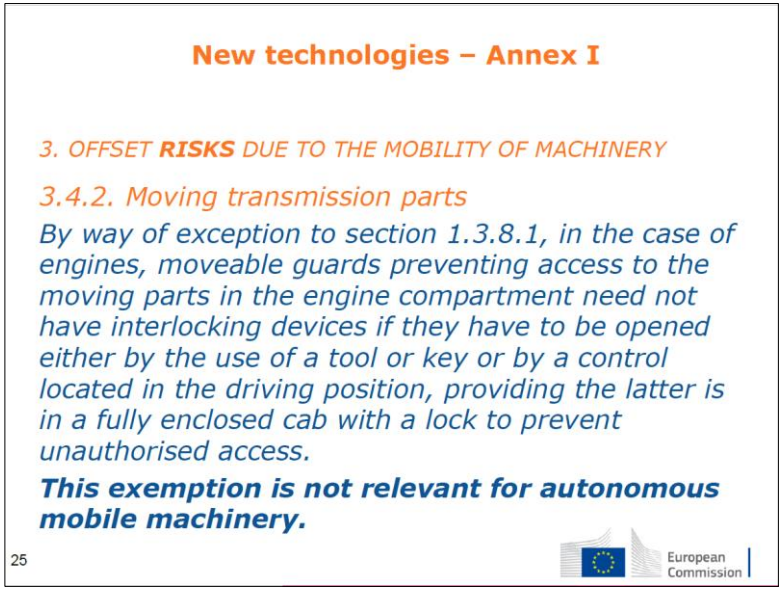
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports these new definitions.***

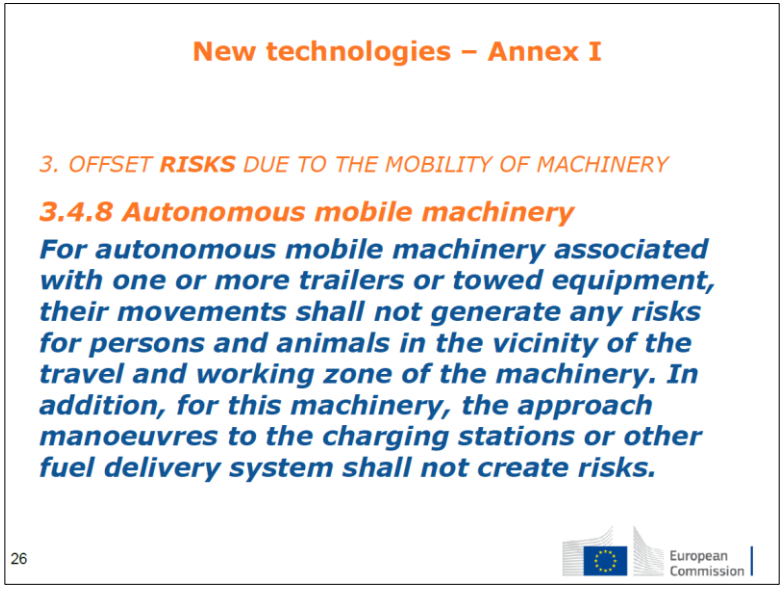
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**New technologies –Annex I** **3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY** **3.2.4 Supervisory control station** ***(…)*** ***This information enables the driver of the autonomous machine to be alerted to the occurrence of unforeseen or dangerous situations actual or impending, which requires intervention.*** ***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.***	***FIEC supports this proposal*** *and proposes to add an element regarding the supervisor of the autonomous machinery.*

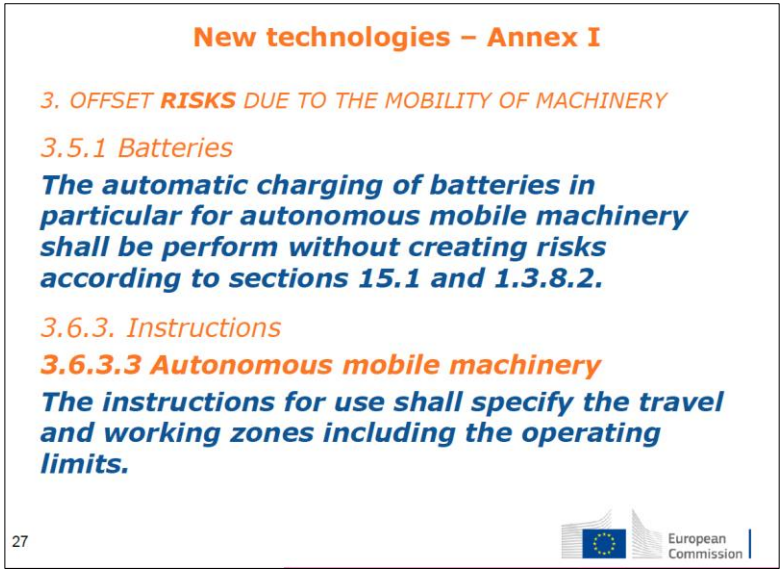
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**New technologies –Annex I** **3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY** **3.3.2 Starting/ moving** ***The movement of an autonomous mobile machinery must take into account the risks related to the configuration (area, conditions, surroundings) of the environment where intended to move and work.***	***FIEC welcomes this proposal but the wording "environment" must be clarified.*** *FIEC suggests replacing "environment" by "the configuration (area, conditions, surroundings) of the environment".*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**New technologies –Annex I** **3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY** **3.3.3 Travelling function** ***(…) 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:*** ***• where a person or an animal is detected in the travel and ~~working area~~ danger zone;*** ***• 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.*** ***The danger zone of the machinery must be defined by the manufacturer.***	***FIEC supports this proposal and proposes to add an element regarding the danger zone*** *(instead of working area).*

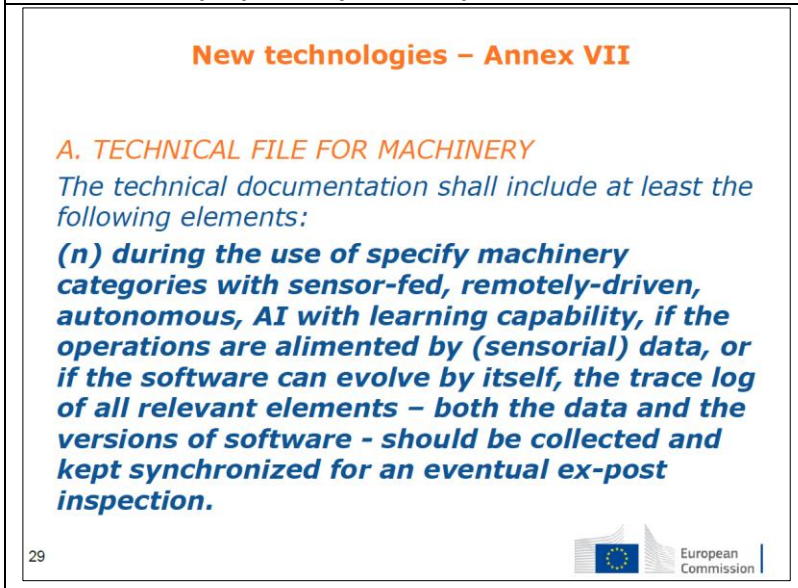
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.***

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**New technologies –Annex I** **3. OFFSET RISKS DUE TO THE MOBILITY OF MACHINERY** **3.4.2. Moving transmission parts** ***(…) This exemption is not relevant for autonomous mobile machinery in an autonomous mode.***	***FIEC supports this proposal and proposes to add an element regarding the autonomous mode.***

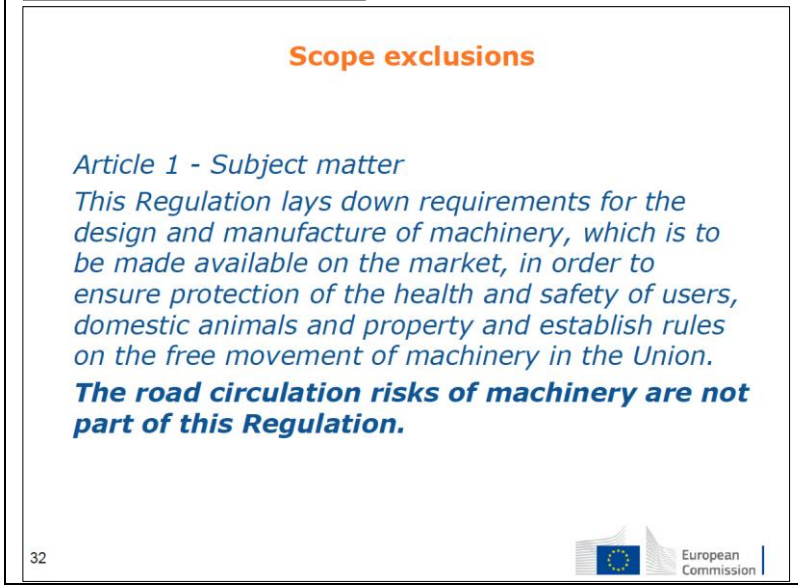
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.***

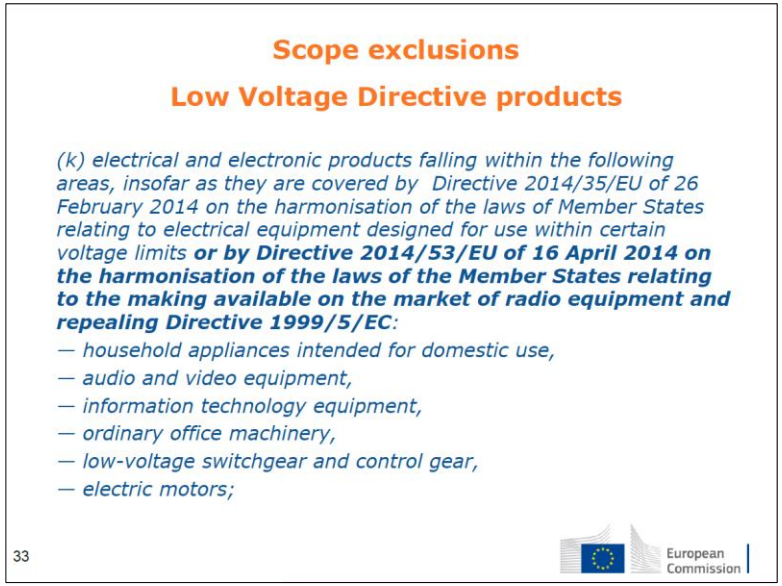
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal***. *With respect to RA and RR made by the manufacturer, these risks are already covered.*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**New technologies –Annex V** **INDICATIVE LIST OF THE SAFETY COMPONENTS** ***…*** ***(h) software with safety functions*** ***(i) artificial intelligence with safety functions*** ***(j) safety component with artificial intelligence safety function***	***FIEC supports this proposal****.* *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.*

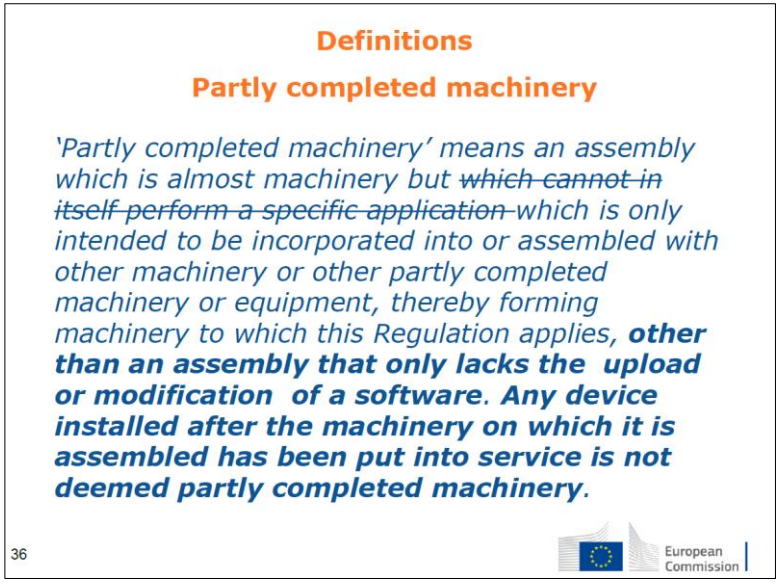
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		*No comment.*

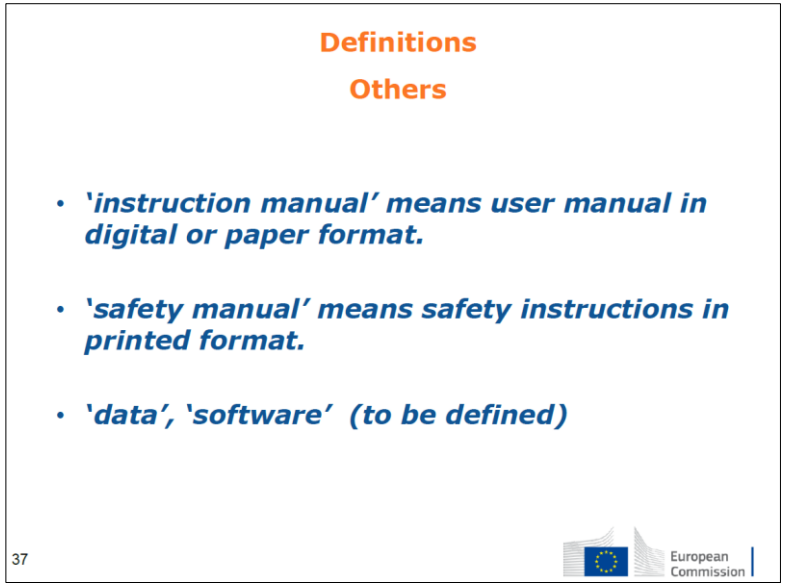
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		*No comment.*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
 		***FIEC supports this proposal**. Only safety aspects are included in the machinery regulation.*

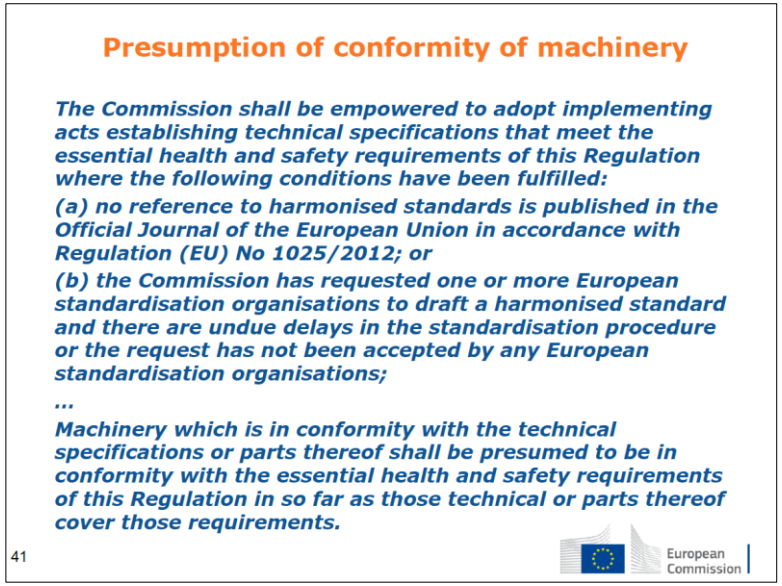
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		*No comment.*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
Definitions **Safety component** *'safety component' means a component:* *— **having any support, physical or digital, including a software*** *— which serves to fulfil a safety function,* *— which is independently placed on the market,* *— the failure and/or malfunction of which endangers the safety of persons, and* *— 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.* 35 European Commission		***FIEC supports this additional precision for the definition of a safety component.***

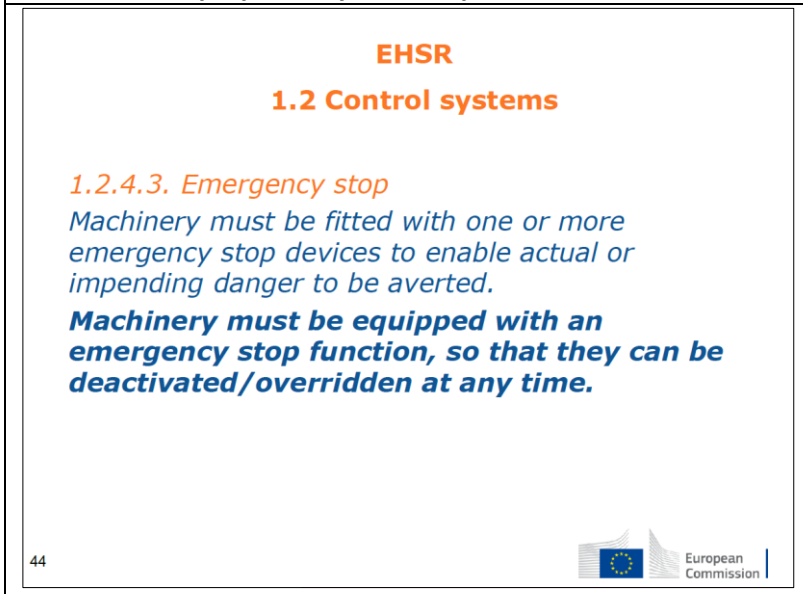
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	Definitions Partly completed machinery ***'Partly completed machinery' means an assembly which is almost machinery but which cannot in itself perform a specific application which is only intended to be incorporated into or 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 isassembled has been put into service is not deemed partly completed machinery.~~***	***FIEC does not support this proposal.*** *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.* *FIEC suggests keeping the text as it is.* *FIEC suggests deleting the last sentence.*

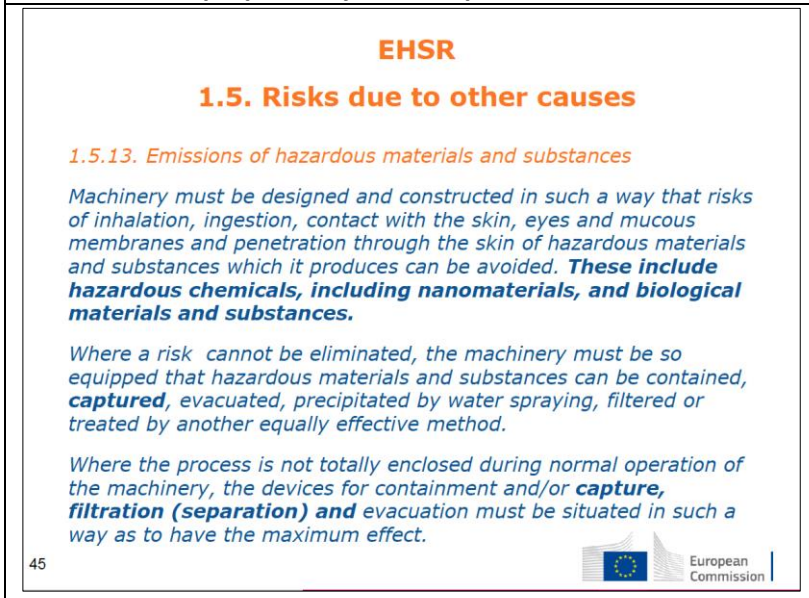
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**Definitions** **Others** • ***'instruction manual' means user manual in digital or paper format.*** • ***'safety manual' means safety instructions <u>as an extracted version from the instruction manual, provided</u> in printed format.*** • ***'data', 'software' (to be defined)***	*There is a confusion with these 2 first definitions because safety manual (=safety instructions) is part of the instruction manual.* *FIEC suggests 2 main recommendations:* *- we must use the same wording for the same document: only one document called "instructions for use" is provided by the manufacturer* *- 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* *(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).*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***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.*

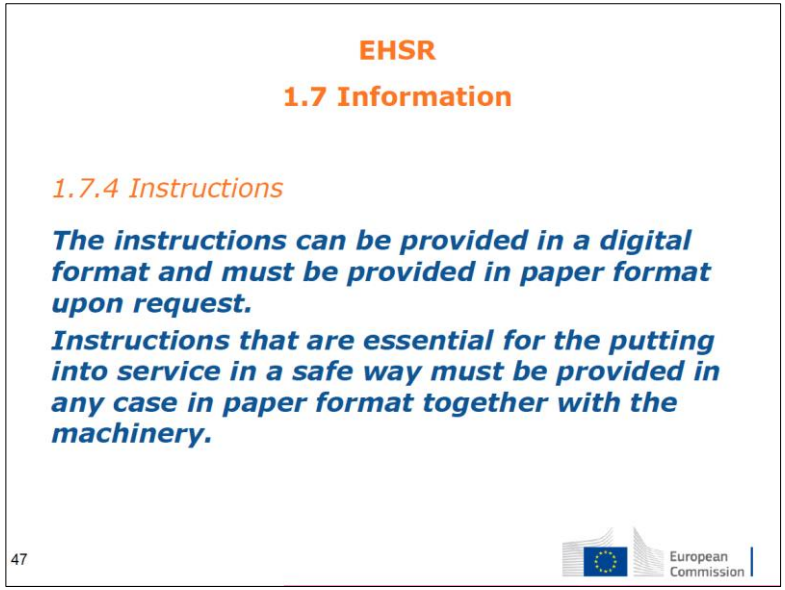
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**Presumption of conformity of machinery** ***The Commission shall be empowered to adopt implementing acts establishing technical specifications that meet the essential health and safety requirements of this Regulation where the following conditions have been fulfilled:*** ***(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*** ***(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;*** ***…*** ***(…)***	***FIEC supports this proposal.*** *Today, the system is based on a new approach directive and harmonised standards.* *If (a) and (b) are cumulative conditions, FIEC will suggest replacing "or" by "and".*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**EHSR** **1.1.2. Principles of safety integration** ***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.***	***FIEC supports this proposal but considers that it should be more precise.*** *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.* *And the manufacturer must define these items and precise the **success criteria** for these specific tests (passed or failed).*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.***

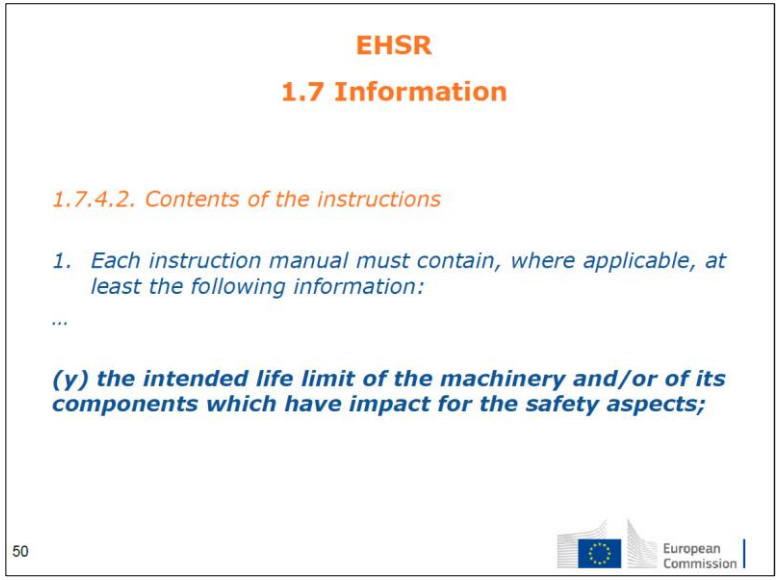
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.***

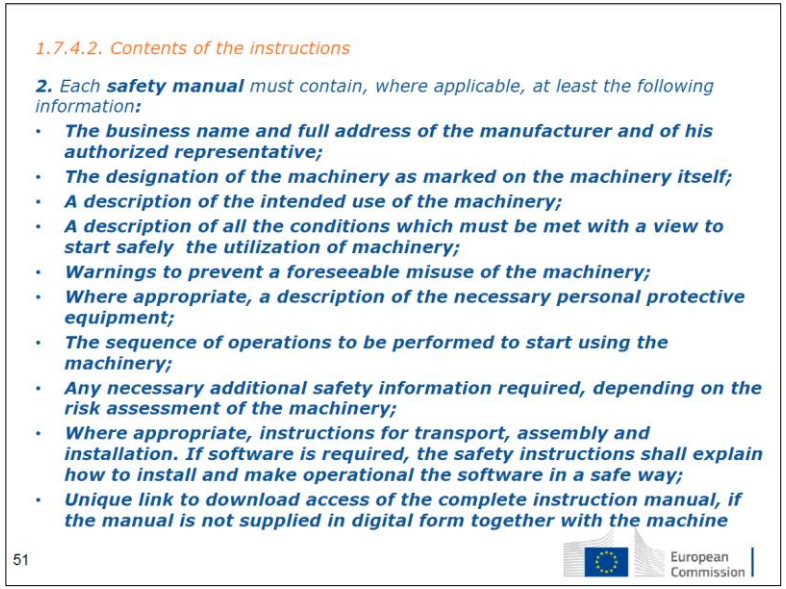
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.***

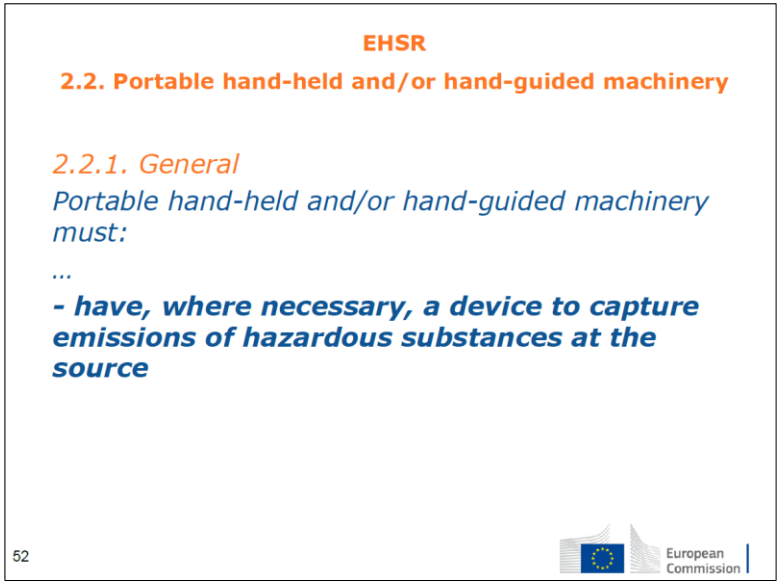
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**EHSR** **1.7 Information** ***1.7.4 Instructions*** ***The instructions must be provided in a digital format and must be provided free of charge in paper format upon request.*** ***Instructions that are essential for the 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.***	*FIEC understands the sense of digitalisation and supports the compromise (because it is not a fully digital option).* *However, not all users are connected to the Internet and not all the time/everywhere.* *Moreover, FIEC insists on the importance for the user to have the machinery declaration of conformity in paper format.*

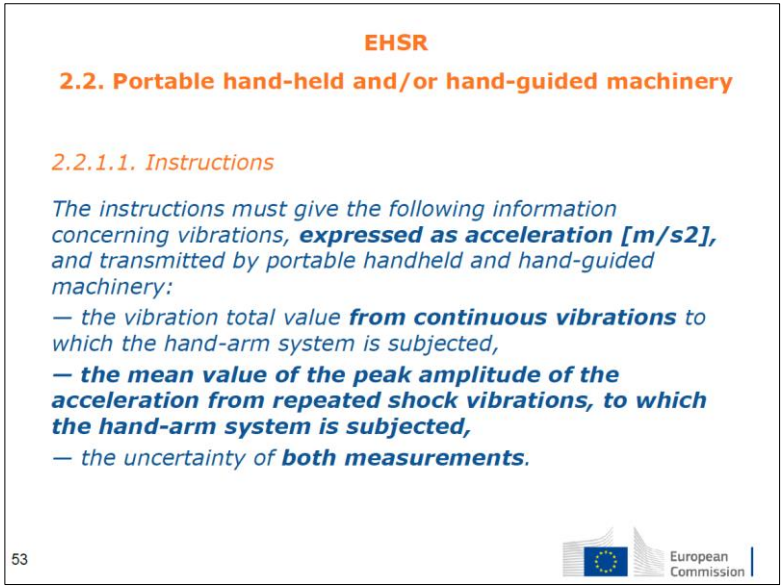
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal.*** *Manufacturers must provide realistic instructions taking account of operational working conditions and maintenance constraints.*

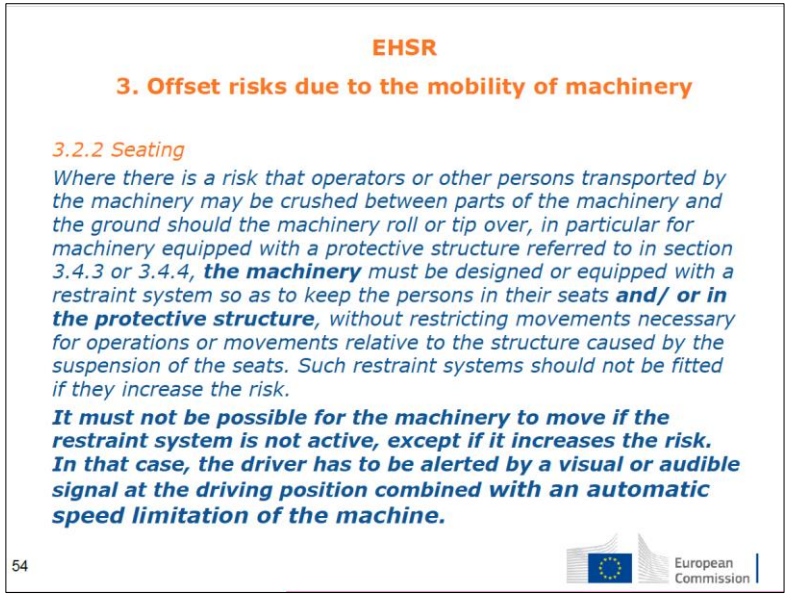
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
EHSR **1.7 Information** *1.7.4.2. Contents of the instructions* *1. Each instruction manual must contain, where applicable, at least the following information:* ***(w) the following information on emissions of hazardous substances from the machinery:*** ***- 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.*** ***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.*** 49 European Commission	**EHSR** **1.7. Information** ***(…)*** - ***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.***	***FIEC supports this proposal.*** The proposed complementary sentence could be added.

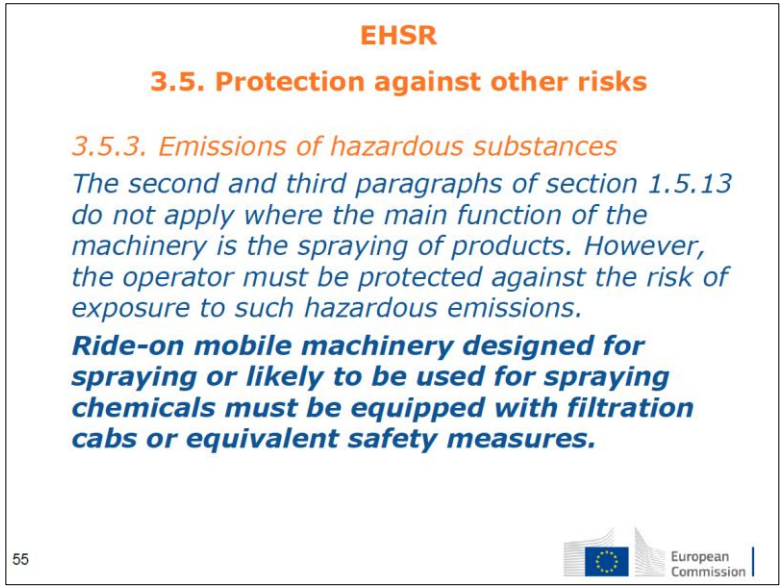
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC is opposed to this proposal***. *Manufacturer cannot limit the lifetime of their machinery.* *It fully depends on the use conditions, the environmental conditions, the maintenance…*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**1.7.4.2. Contents of the instructions** ***2. Each safety manual must contain, where applicable, at least the following information:*** ***• 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;*** ***(…).***	***FIEC supports this proposal*** *and suggests adding a mention regarding the designation of applicable safety warnings.*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	**EHSR** **2.2. Portable hand-held and/or hand-guided machinery** **2.2.1. General** ***Portable hand-held and/or hand-guided machinery must:*** ***…*** ***-have, where necessary, a device to capture emissions of hazardous substances at the source. 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.***	***FIEC supports this proposal*** *which is in relation to dust and carcinogenic substances.* *FIEC suggests to precise this requirement by adding a sentence.*

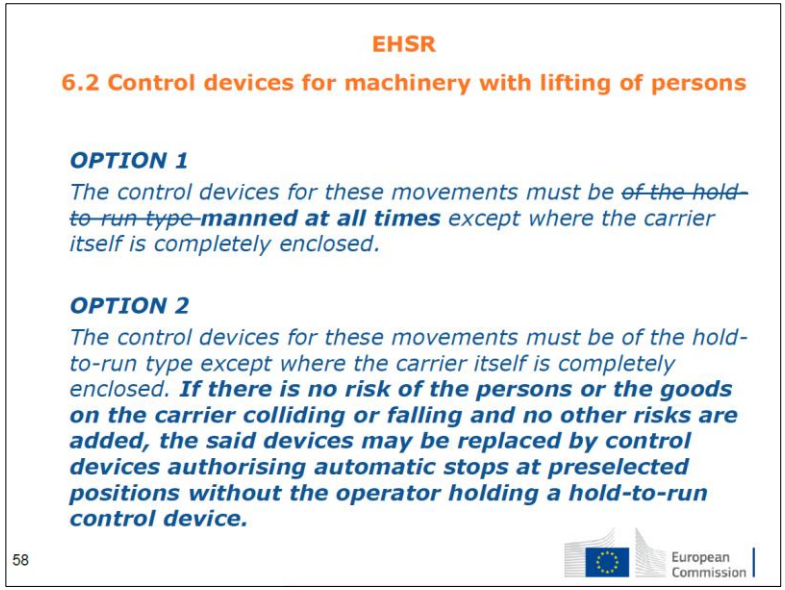
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal***. *Emission and exposure are closely connected.* *This requirement will fit with the one which is already in the work safety directive.*

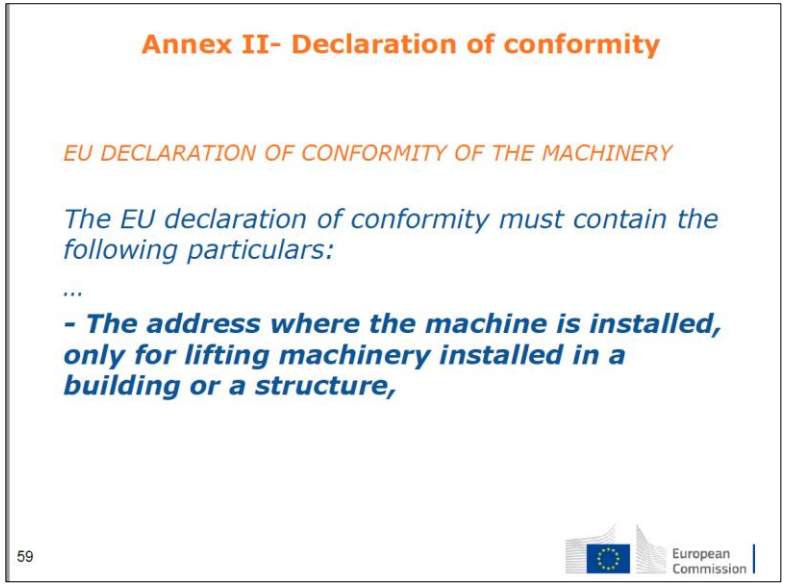
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	***EHSR*** ***3. Offset risks due to the mobility of machinery*** ***3.2.2 Seating*** ***Where there is a risk that operators or other persons transported by the machinery may be crushed (…).*** ***It must not be possible 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~~.***	***FIEC welcomes this proposal.*** *However, FIEC proposes to delete part of the last sentence.*

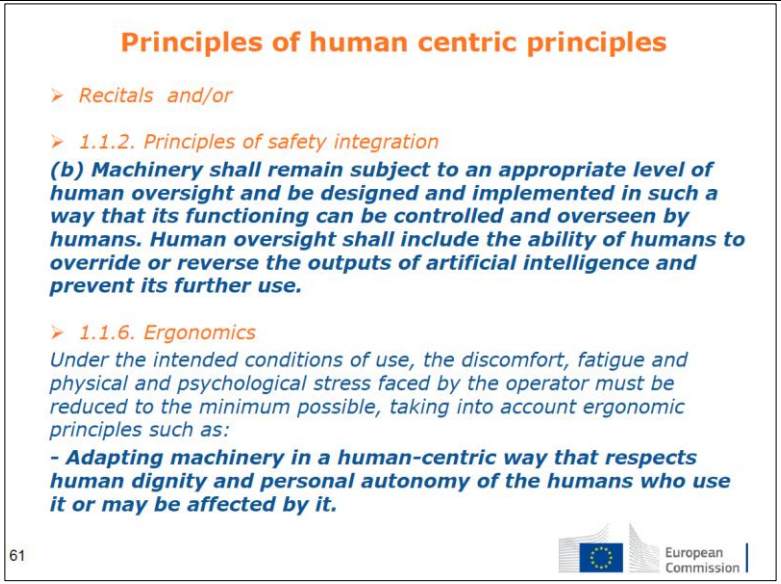
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC fully supports this proposal related to correct level of protection and filtration cabs to protect operators.***

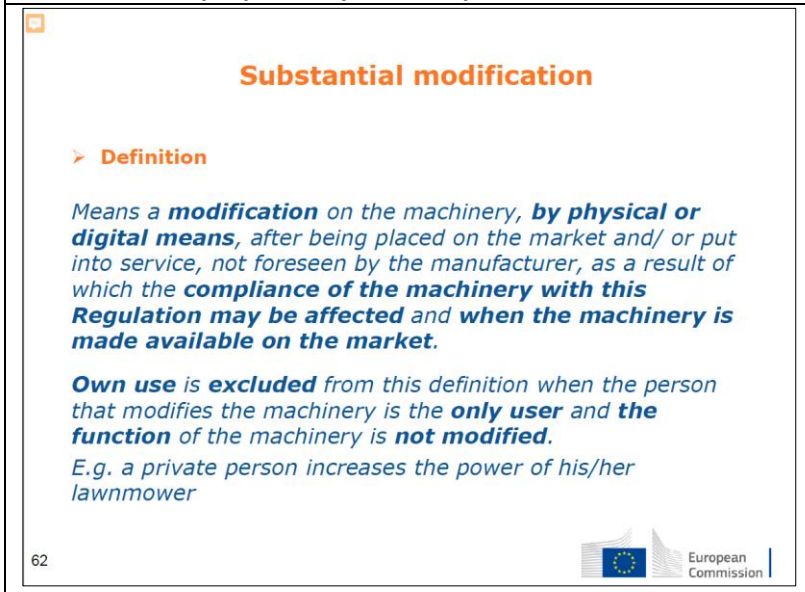
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	*EHSR* *3.5 Protection against other risks* *3.5.4 Risk of contact with live overhead power lines* ***The following requirements should depend on the height of the machinery and be part of the instructions of the machinery:*** ***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.*** ***(…)***	***FIEC supports this proposal.*** *Contact with live overhead power lines is a very important risk.* *FIEC proposes to add a sentence in introduction of the paragraph.*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC supports this proposal*** *regarding the assembling and the installation of the machinery.*

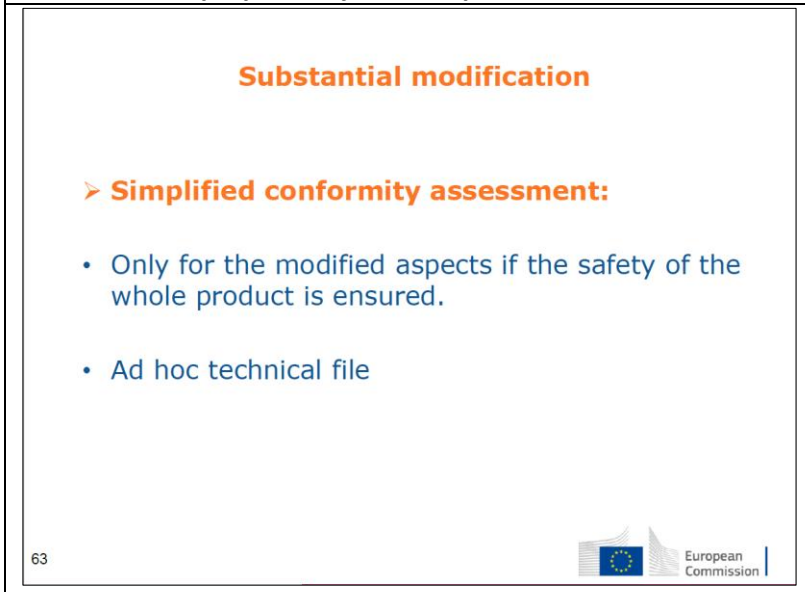
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		*No comment.*

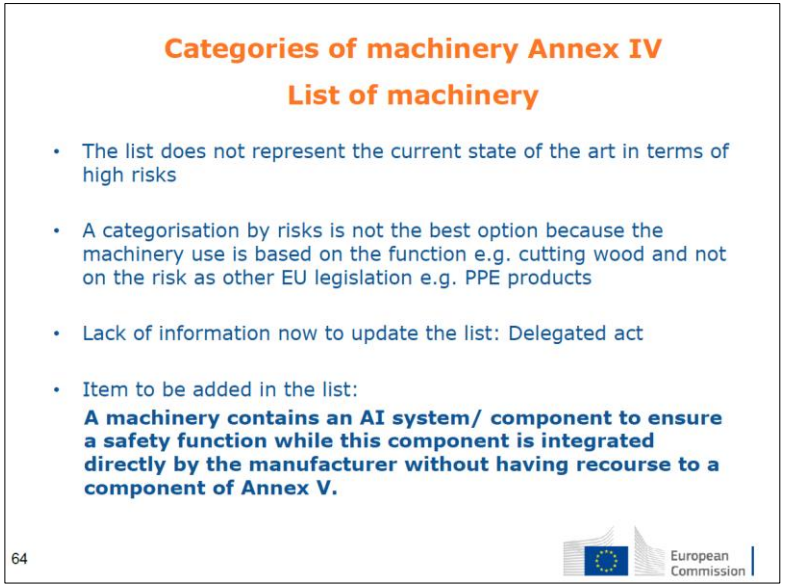
Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	*Annex II-Declaration of conformity* ***EU DECLARATION OF CONFORMITY OF THE MACHINERY*** ***The EU declaration of conformity must contain the following particulars:*** ***…*** ***- The address where the machine is permanently installed,*** ***only for lifting machinery for persons installed in a building or a structure,***	***FIEC does not support this proposal.*** *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.* *The wording must be adapted for machineries like conventional lifts only.*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		**1.1.2.** **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. Question : -> Is this a new paragraph 1.1.2 (b) instead of the old 1.1.2(b)? **1.1.6.** **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.

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	*Substantial modification* ➢ *Definition* ***Means a modification on the machinery, by relevant 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.*** ***Own and non-commercial 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.~~*** ***When a substantially modified machinery is made available on the market or used commercially, only RA certified by a third party must be supplied.***	*FIEC thanks the commission to take the opportunity of this revision to clarify the rules regarding substantial modification.* ***However, FIEC disagrees with this proposed definition**.* *FIEC welcomes the distinction between machinery made available on the market and machinery in own use.* *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.* *Many SMEs adapt their machineries according to their organisation and needs.* *If these machineries are made available again on the market, it will multiply the cases considered as substantial modification. Every machinery*

		modification must be determined regarding its safety-related impact. *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).*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
	Substantial modification Simplified conformity assessment: ***"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 ad hoc technical file."***	***FIEC supports the proposal of a simplified conformity assessment only for modified aspects.*** *Moreover, FIEC asks for more precisions on the content of this simplified conformity assessment and the clear content of the technical file.* *A possible wording for slide 63 could read as indicated.*

Text proposed by the European Commission	Proposed amendment by FIEC	*Comments*
		***FIEC agrees with this proposal.***

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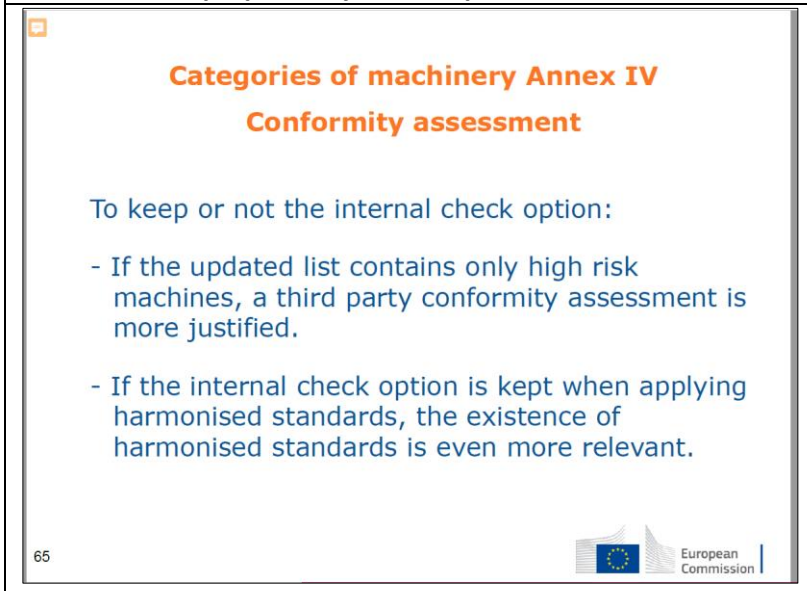		***FIEC wants to keep the internal check option***. *Presumption of conformity of harmonized standards must remain to facilitate and help manufacturers.* *Machinery embedded with AI system is a high-risk product.* *If there is high risk in the conformity assessment procedure (risks which may affect safety of the machines), there should be an intervention of third party.*