FIEC is the European Construction Industry Federation, representing via its 33 National Member Federations in 29 countries (25 EU, Norway, Switzerland, Ukraine & Turkey) construction enterprises of all sizes, i.e. small and medium-sized enterprises as well as "global players", carrying out all forms of building and civil engineering activities.

POSITION PAPER 05/11/2021

FIEC amendments' proposals to the Machinery Products Regulation COM(2021)202 FINAL

Article 3 paragraph (16) – Definition of substantial modification

Commission's proposal:	*FIEC proposed amendment:*
'substantial modification' means a **modification** of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen by the manufacturer and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements **may be** affected;	'substantial modification' means **a change of a specific application** of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen **or planned** for by the manufacturer and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements **are** affected;

Justification:

In principle, a definition of "substantial modification" is useful.

However, it must be prevented in any case that every "modification/change/alteration" to a machine or to a machinery product is equivalent to a substantial modification. The proposed definition of substantial modification might lead to a massive increase of the amount of such modifications. New conformity assessments will become mandatory for digital modifications which are aimed to lead to an increased level of safety and will have an important impact on the employer's organisation.

In practise, for example, the digital modification/update of safety devices and the installation of safety devices which do not enable any additional functions, that inevitably lead to an increase of the level of safety of the machine, shall not be considered as substantial modifications, and shall not require the intervention of a third party.

Contact @ FIEC: C. Le Forestier
Email: info@fiec.eu

www.fiec.eu
info@fiec.eu
@FIEC_Brussels
FIEC EU

FIEC - European Construction Industry Federation
Belgium - Brussels / **Tel.** +32-2-514 55 35
Transparency Reg. 92221016212-42
aisbl Nr Entreprise : BE 0688 919.140

Example[1]:

The machine is safe even after modification without additional protective measures.	There is **no** significant change.
The machine is no longer safe after the modification without additional protective measures. The new hazard or the increased risk can be eliminated or at least sufficiently minimised by simple protective devices.	There is **no** significant change.
The machine is no longer safe after the modification without additional protective measures and a sufficient risk reduction cannot be achieved by simple protective devices.	There **is** a significant change.

Article 7 – Requirements for machinery products

Commission's proposal:	*FIEC proposed amendment:*
Machinery products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended purpose or under conditions which can reasonably be foreseen, they meet the essential health and safety requirements set out in Annex III.	Machinery products shall only be made available on the market or put into service if, where properly installed and maintained and used for their intended purpose or under conditions which can reasonably be foreseen **taking into account foreseeable misuse,** they meet the essential health and safety requirements set out in Annex III.

Justification:

It has been proven that serious accidents occur time and again in the EU due to misuse of machinery. The foreseeable misuse is to be applied in depth in planning, design and construction and the accompanying risk assessment. Market monitoring must be expanded to include the aspect of foreseeable misuse.

[1] BMAS, 01.03.2015 - IIIb5-39607-3 - in GMBl 2015, Nr. 10, S. 183-186 (https://www.bmas.de/DE/Arbeit/Arbeitsschutz/Produktsicherheit/interpretationspapierwesentliche-veraenderung-von-maschinen.html)

FIEC is the European Construction Industry Federation, representing via its 33 National Member Federations in 29 countries (25 EU, Norway, Switzerland, Ukraine & Turkey) construction enterprises of all sizes, i.e. small and medium-sized enterprises as well as "global players", carrying out all forms of building and civil engineering activities.

ANNEX I – High-risk machinery products

Commission's proposal:	*FIEC proposed amendment:*
§ 24 "Software ensuring safety functions, including AI systems"	**deleted**
Commission's proposal:	*FIEC proposed amendment:*
§ 25 "Machinery embedding AI systems ensuring safety functions"	**deleted**

Justification:

We believe that it is disproportionate to introduce a concept of high risk by default for all AI technologies with additional requirements for new technology machinery and introduction of 3rd party conformity assessment.

The risks posed by some of these techniques and concepts can be reliably assessed using currently available and proven methods. These include, for example, deductive, more knowledge-based (symbolic) techniques and concepts such as the statistical approaches and Bayesian estimation, search and optimisation methods mentioned in Annex I c) of the proposed AI regulation.

Such artificial intelligence (AI) techniques and concepts are already used today for safety-relevant functions of machines, evaluated and safely placed on the market without the involvement of notified bodies. It is therefore also not necessary in future to involve a notified body in the conformity assessment for the techniques and concepts listed in Annex I c) of the Commission proposal for a regulation on artificial intelligence.

ANNEX I – High-risk machinery products => full alternative proposal

As a full alternative to the new Annex I, FIEC proposes the following:

The new Annex I should cover all products listed in the Regulation's scope of application.

A classification would be made according to 3 risk categories (i.e. similar to the EU Regulation 2016/425 on Personal Protective Equipment). If the machine is designed and a risk assessment is carried out, a residual risk remains at the end. The classification into the 3 risk categories results from the remaining residual risk. All operating states / life cycles / life phases must be taken into account (maintenance, servicing, assembly, disassembly, operation, etc.). The basis for determining risks and the remaining residual risks are the EHSR. Reasonably foreseeable misuse must also be included. Furthermore, the residual risks are to be defined based on the contents of other directives such as the Low Voltage Directive (2014/35/EU), for instance. Risks cumulating from this are to be defined. Again, the remaining residual risks are used for classification.

Contact @ FIEC: C. Le Forestier
Email: info@fiec.eu

www.fiec.eu
info@fiec.eu
@FIEC_Brussels
FIEC EU

FIEC - European Construction Industry Federation
Belgium - Brussels / **Tel.** +32-2-514 55 35
Transparency Reg. 92221016212-42
aisbl Nr Entreprise : BE 0688 919.140

Classification:	Corresponding conformity assessment procedure:
Category I It shall include all residual risks with minor injury potential such as: a) superficial mechanical injuries b) contact with slightly aggressive working substances c) brief contact with hot surfaces whose temperature does not exceed 60 °C	Internal production control in accordance with Annex VI or Annex VIII
Category II It shall include all residual risks that are not listed under Category I or Category III	Full quality assurance in accordance with Annex IX
Category III It shall include all residual risks which may lead to very serious consequences such as death or irreversible damage to the health of operators and third parties. Safety components would fall into Category III.	EU type-examination according to Annex VII or application / taking into account the harmonised standards e.g. In the case of a circular saw, work must be carried out on the open circular saw blade, which automatically places it in category III.

ANNEX III – EHSR

Paragraph 1.2.1. Safety and reliability of control systems

Commission's proposal:	*FIEC proposed amendment:*
(d) the safety functions cannot be changed beyond the limits defined by the manufacturer in the machinery product risk assessment. The establishment of the limits of the safety functions shall be part of the risk assessment performed by the manufacturer, including any modifications to the settings or rules generated by the machinery product or by operators, covering also the learning phase, which cannot go beyond the limits addressed in the risk assessment;	(d) the safety functions cannot be changed beyond the limits defined by the manufacturer in the machinery product risk assessment. The establishment of the limits of the safety functions shall be part of the risk assessment performed by the manufacturer, including any modifications to the settings or rules generated by the machinery product or by operators, covering also the learning phase, which cannot go beyond the limits addressed in the risk assessment; **the safety functions upgrades are part of the limits defined by the manufacturer;**
Justification: *The limits of the safety functions are part of RA of the manufacturer. Therefore, important machinery changes will be part of the substantial modification criteria. With this wording, important changes or safety updates will be impossible without the original manufacturer. Safety updates lead to an increased level of safety of the machine and are aimed to improve the machinery working conditions. These situations should not be considered as substantial modifications. See our comments on this in Art. 3 (16).*	

Contact @ FIEC: C. Le Forestier
Email: info@fiec.eu

www.fiec.eu
info@fiec.eu
@FIEC_Brussels
FIEC EU

FIEC - European Construction Industry Federation
Belgium - Brussels / **Tel.** +32-2-514 55 35
Transparency Reg. 92221016212-42
aisbl Nr Entreprise : BE 0688 919.140

Commission's proposal:	*FIEC proposed amendment:*
(f) the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery product has been placed on the market or put into service, is enabled for five years after such upload, exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority;	(f) the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery product has been placed on the market or put into service, is enabled for five years after such upload **by the manufacturer or software provider**, exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority;
Justification: *This provision is addressed directly to the manufacturer or software provider. In this respect, this must be specified in the text of the regulation.*	
Commission's proposal:	*FIEC proposed amendment:*
(g) recording of data on the safety related decision-making process after the machinery product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection, exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority.	(g) recording of data on the safety related decision-making process after the machinery product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection **by the manufacturer or software provider**, exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority.
Justification: *Same as above.*	

ANNEX III – EHSR

Paragraph 1.7.4. Instructions

Commission's proposal:	*FIEC proposed amendment:*
(…) The instructions may be provided in a digital format. However, upon purchaser's request at the time of the purchase of the machinery product, the instructions shall be provided in paper format free of charge. When the instructions are provided in digital format, the manufacturer shall:	(…) The instructions may be provided in a digital format. However, upon purchaser's request at the time of the purchase of the machinery product, the instructions shall be provided in paper format free of charge. When the instructions are provided in digital format, the manufacturer shall:

Contact @ FIEC: C. Le Forestier
Email: info@fiec.eu

www.fiec.eu
info@fiec.eu
@FIEC_Brussels
FIEC EU

FIEC - European Construction Industry Federation
Belgium - Brussels / **Tel.** +32-2-514 55 35
Transparency Reg. 92221016212-42
aisbl Nr Entreprise : BE 0688 919.140

(a) mark on the machinery product and in an accompanying paper how to access the digital instructions; (b) clearly describe which version of the instructions corresponds to the machinery product model; (c) **be presented** in a format that makes it is possible for the end user to download the instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machine. This requirement also applies to a machinery product where the instruction manual is embedded in the software of the machinery product.	(a) mark on the machinery product and in an accompanying paper how to access the digital instructions; (b) clearly describe which version of the instructions corresponds to the machinery product model; (c) **provide the instructions** in a format **over the whole lifecycle of the machinery product and in all the different versions** that makes it is possible for the end user to download the instructions and save them on an electronic device so that he or she can access them at all times, in particular during a breakdown of the machine. This requirement also applies to a machinery product where the instruction manual is embedded in the software of the machinery product.

Justification:

Machinery will be delivered with digital instructions only. The digitalisation aspects are welcome. This new requirement has an important impact on the relevance and availability of instruction manuals in the whole lifecycle of the machinery.

However, the wording "how to access the digital instructions" is not clear enough and need precisions in relation to longevity and availability. Manufacturer's companies often update their websites. It may be very difficult to find the instruction guide in the successive versions of each manufacturer's website. There should be more requirements to ensure the accessibility of digital instructions over the lifecycle of the machinery products.

ANNEX III – EHSR

Paragraph 1.7.4.2. Contents of the instructions

Commission's proposal:	*FIEC proposed amendment:*
(c) the EU declaration of conformity, or a document setting out the contents of the EU declaration of conformity, showing the particulars of the machinery product, not necessarily including the serial number and the signature, or the internet address where the EU declaration of conformity can be accessed;	(c) the EU declaration of conformity, or a document setting out the contents of the EU declaration of conformity, showing the particulars of the machinery product, not necessarily including the serial number and the signature, or the internet address where the EU declaration of conformity can be accessed **over the whole lifecycle of the machinery product;**

Contact @ FIEC: C. Le Forestier
Email: info@fiec.eu

www.fiec.eu
info@fiec.eu
@FIEC_Brussels
FIEC EU

FIEC - European Construction Industry Federation
Belgium - Brussels / **Tel.** +32-2-514 55 35
Transparency Reg. 92221016212-42
aisbl Nr Entreprise : BE 0688 919.140

Justification:

According to this proposal, EU declaration has not to be attached to the machinery. This will have a huge impact on the availability of this key document of the machinery during all its lifetime and all successive uses in different construction jobsites. The validity of the internet address should be specified. The URL shall be active all the lifetime of the machinery. There should be more requirements to ensure the accessibility of digital documents over the lifecycle of the machinery products.

ANNEX III – EHSR

Paragraph 3.2.2. Seating

Commission's proposal:	*FIEC proposed amendment:*
(…) A visual **or** audible signal shall be provided at the driving position alerting the driver when the restraint system is not active.	(…) A visual **and** audible signal shall be provided at the driving position alerting the driver when the restraint system is not active.

Justification:

This specific requirement is a real great progress to improve safety and enhance the state of the art. This proposal is welcome but not sufficient. Indeed, a visual signal alone is not sufficient for the driver to be alerted.

Contact @ FIEC: C. Le Forestier
Email: info@fiec.eu

www.fiec.eu
info@fiec.eu
@FIEC_Brussels
FIEC EU

FIEC - European Construction Industry Federation
Belgium - Brussels / **Tel.** +32-2-514 55 35
Transparency Reg. 92221016212-42
aisbl Nr Entreprise : BE 0688 919.140