

VOTING RECOMMENDATIONS 28/01/2022

Machinery Products Regulation - COM(2021)202 FINAL FIEC voting recommendations to the IMCO Committee

PROPOSAL FOR A COMPROMISE AMENDMENT

Article 3 paragraph (16) – Definition of substantial modification

Commission's proposal: '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;

FIEC proposed compromise amendment: '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 is affected; a substantial modification is given if the remaining risk is increased by the modification of the machine under the application of all necessary protective measures; maintenance and repair operations by third parties are not substantial modifications;

Justification:

It must be prevented that every "modification/change/alteration" to a machinery product is equivalent to a substantial modification. 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.

The proposed compromise amendment aims at providing the right balance.





GREEN LIST => PLEASE SUPPORT

AM 131 (Konecna (Left))

Article 1 Paragraph 1

Text proposed by the Commission
This Regulation lays down requirements for the design and construction of machinery products to allow the making available on the market or putting into service of machinery products, and establishes rules on the free movement of machinery products in the Union.

Amendment

This Regulation lays down requirements for the design and construction of machinery products to allow the making available on the market or putting into service of machinery products, and establishes rules on the free movement of machinery products in the Union *ensuring a high level of protection for EU workers and citizens*.

AM 167 (Stefanec (EPP))

Article 3 Paragraph 1 Point 3

Text proposed by the Commission 'safety component' means a physical common of the commission of the co

(3) 'safety component' means a physical or digital component, including software, of machinery which *serves* to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endangers the safety of persons but which is not necessary in order for the machinery to function or may be substituted by normal components in order for the machinery to function;

Amendment

(3) 'safety component' means a physical or digital component, including software, of a machinery product which is designed or intended to fulfil a safety function and which is independently placed on the market, the failure or malfunction of which endangers the safety of persons but which is not necessary in order for the machinery to function or may be substituted by normal components in order for the machinery to function. In the case of software of machinery serves to fulfil a safety function, the required hardware is covered by the conformity assessment procedure and specified in the instructions;

AM 191 (Hahn/Renew)

Article 5 - title

Text proposed by the Commission

High-risk machinery products

Amendment

Machinery products referred to in Annex I



AM 193 (Gozi + Yon-Courtin (Renew FR)

Article 5 Paragraph 1

| ı | rext proposed by the Commission | |
|---|---|--|
| | 1. High-risk machinery products listed in | |
| | Annex I shall be subject to a specific conformity | |
| | assessment procedure, as referred to in Article | |
| ı | 21(2) | |

Taxt proposed by the Commission

Amendment

 High-risk machinery products listed in Annex I shall be subject to a specific conformity assessment procedure, requiring participation of a notified body as referred to in Article 21(2).

AM 196 (Gozi + Yon-Courtin (Renew FR))

Article 5 Paragraph 1 a (new)

| Text proposed by the Commission | Amendment |
|---------------------------------|--|
| | 1 a. The Commission shall update Annex I |
| | before the date referred to Article 52 to ensure |
| | relevant machineries are subject to the specific |
| | conformity assessment procedure. |

AM 207 (Konecna (Left))

Article 5 Paragraph 5

Text proposed by the Commission

5. A Member State which has concerns about a machinery product being listed or not listed in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof.

Amendment

5. A Member State which has concerns about a machinery product being listed or not listed in Annex I shall immediately inform the Commission of its concerns and provide reasons in support thereof. If at least three Member States request to list a new machinery product in Annex I, the Commission shall without delay analyse this request.

AM 221 (Hahn/Renew)

Article 10 Paragraph 10 a (new)

| Text proposed by the Commission | Amendment |
|---------------------------------|---|
| | 10 a. Manufacturers shall provide users with |
| | information on security-related updates and |
| | identified cyber risks in a timely and reliable |
| | manner. |



AM 222 (Hahn/Renew)

Article 10 Paragraph 10 b (new)

| Text proposed by the Commission | Amendment |
|---------------------------------|--|
| | 10 b. Manufacturers shall ensure access to |
| | stable and ongoing technical support over the |
| | normal lifetime of a machinery product, if its |
| | safety depends on software. |

AM 315 (Schaldemose (S&D))

Annex I Point 24

| Text proposed by the Commission | Amendment |
|---|----------------------|
| Software ensuring safety functions, including | <mark>deleted</mark> |
| AI systems. | |

AM 320 (Campomenosi + Basso (ID))

Annex I Point 25

| Text proposed by the Commission | Amendment |
|---|----------------------|
| Machinery embedding AI systems ensuring | <mark>deleted</mark> |
| safety functions. | |

AM 343 (S&D)

Annex III Part 1 Point 1.1 Point 1.1.2 Point e a (new)

| Text proposed by the Commission | Amendment |
|---------------------------------|--|
| | The manufacturer shall inform the user about |
| | vulnerabilities that might arise and provide |
| | remedial measures. |

AM 346 (Konecna (Left))

Annex III Part 1 Point 1.1 Point 1.1.6 Point e

Text proposed by the Commission adapting the human-machinery product interface to the foreseeable characteristics of the operators, including with respect to a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy;

Amendment

adapting the human-machinery product interface, as well as the security systems and the emergency stop systems, to the foreseeable characteristics of the operators, including with respect to a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy;





AM 352 (Konecna (Left))

Annex III Part 1 Point 1.1 Point 1.1.9 Paragraph 1

Text proposed by the Commission

The machinery product shall be designed and constructed so that the connection to it of another device, via any feature of the connected device itself or via any remote device that communicates with the machinery product does not lead to a hazardous situation.

Amendment

The machinery product shall be designed and constructed so that the connection to it of another device, via any feature of the connected device itself or via any remote device that communicates with the machinery product does not lead to other unintended (and potentially hazardous) functions.

AM 362 (Konecna Left))

Annex III Part 1 Point 1.2 Point 1.2.1 Paragraph 2 Point a

Text proposed by the Commission they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including malicious attempts from third parties to create a hazardous situation;

Amendment

they can withstand, where appropriate to the circumstances and the risks, the intended operating stresses and intended and unintended external influences, including malicious attempts from third parties to create other unintended (and potentially hazardous) functions;

AM 365 (Fidanza/ECR)

Annex III Part 1 Point 1.2 Point Point 1.2.1 Paragraph 2 Point d

Text proposed by the Commission 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;

Amendment

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;



AM 387 (Konecna (Left))

Annex III Part 1 Point 1.7 point 1.7.4 Paragraph 3

Text proposed by the Commission
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.

Amendment

For up to five years after the time of the purchase of the machinery product, the instructions shall be provided in paper format free of charge upon request from the purchaser. If a purchaser gives her or his explicit consent to only receive a digital format of the instructions, at least a quick start must be delivered in a printed version free of charge.

AM 391 (Fidanza/ECR)

Annex III Part 1 Point 1.7 Point 1.7.4 Paragraph 4 Point c

Text proposed by the Commission 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. General principles for the drafting of instructions

Amendment

provide 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.

AM 81 (Stefanec (EPP))

Annex III Part 1 Point 1.7 Point 1.7.4 Point 1.7.4.2 Point 1 Point c

Text proposed by the Commission 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.

Amendment

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 entire lifecycle of the machinery product;



AM 409 (Fidanza/ECR)

Annex III Part 3 Point 3.2 Point 3.2.2 Paragraph 2

| Text proposed by the Commission | | |
|--|--|--|
| A visual <i>or</i> audible signal shall be provided at | | |
| the driving position alerting the driver when the | | |
| restraint system is not active. | | |

Amendment

A visual **and** audible signal shall be provided at the driving position alerting the driver when the restraint system is not active.



RED LIST => DON'T SUPPORT

AM 146 (Cormand (Greens))

Article 2 Paragraph 2 Point e

Text proposed by the Commission

(e) vehicles which have as their only objective the transport of goods or persons by **road**, air, water or rail except for machinery mounted on those vehicles;

Amendment

(e) vehicles which have as their only objective the transport of goods or persons by air, water or rail except for machinery mounted on those vehicles:

AMs 168, 169, 172, 173, 181, 182, 185, 186 to Article 3 (Definitions) => FIEC is AGAINST the exclusion of partly completed machinery (PCM), from the definitions / scope of the legislation!

AM 230 (Schaldemose (S&D))

Article 15 Paragraph 1

Text proposed by the Commission

A natural or legal person, other than the manufacturer, the importer or the distributor, that carries out a substantial modification of the machinery product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for the part of the machinery product that is affected by the modification or, if the substantial modification has an impact on the safety of the machinery product as a whole, for the entire machinery product.

Amendment

A natural or legal person, other than the manufacturer, the importer or the distributor, that carries out a substantial modification of the machinery product shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer set out in Article 10 for the part of the machinery product that is affected by the modification or, if the substantial modification has an impact on the safety of the machinery product as a whole, for the entire machinery product. If a substantial modification that only affects a part the machinery product is carried out by a natural or legal person other than the manufacturer, the importer or the distributor, the manufacturer shall be subject to Article 10 point 1, 3, 7, 8, 10 and fill in the declaration in Annex V for the part that has been changed.



AM 265 (S&D)

Article 21 Paragraph 4

Text proposed by the Commission

4. Notified bodies shall take into account the specific interests and needs of small and medium sized enterprises when setting the fees for conformity assessment and reduce those fees proportionately to their specific interests and needs.

Amendment deleted

AMs to articles 49 (Repeals) and 50 (Transitional provisions) => FIEC is against any extension of the deadlines in this respect!

AM 339 (Campomenosi + Basso (ID))

Annex III Part 1 Point 1.1 Point 1.1.2 Point e

Text proposed by the Commission

A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions, and the machinery product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.

Amendment

A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions where applicable. A machinery product must be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.

AM 340 (Hahn/Renew)

Annex III Part 1 Point 1.1 Point 1.1.2 Point e

Text proposed by the Commission

A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions, and the machinery product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.

Amendment

A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions where applicable. The machinery product shall be supplied with all the special equipment and accessories essential to enable it to be adjusted, maintained and used safely.





AM 341 (de Meo + Caroppo (EPP))

Annex III Part 1 Point 1.1 Point 1.1.2 Point e

Text proposed by the Commission

A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions, and the machinery product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.

Amendment

A machinery product shall be designed and constructed in such a way that it is possible to test the safety functions, and the machinery product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.

AM 342 (Fidanza/ECR)

Annex III Part 1 Point 1.1 Point 1.1.2 Point e

Text proposed by the Commission

A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions, and the machinery product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.

Amendment

A machinery product shall be designed and constructed in such a way that it is possible to test the safety functions, and the machinery product shall be supplied with all the special equipment and accessories, and where appropriate, with the description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely.

AM 348 (Hahn/Renew)

Annex III Part 1 Point 1.1 Point 1.1.6 Point f

Text proposed by the Commission adapting a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy to respond to people adequately and appropriately (verbally through words and nonverbally through gestures, facial expressions or body movement) and to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner.

Amendment

adapting a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy to respond to people adequately and appropriately (verbally through words and nonverbally through gestures, facial expressions or body movement).



AM 349 (Fidanza/ECR)

Annex III Part 1 Point 1.1 Point 1.1.6 Point f

Text proposed by the Commission adapting a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy to respond to people adequately and appropriately (verbally through words and non-verbally through gestures, facial expressions or body movement) and to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner.

Amendment adapting a machinery product with intended fully or partially evolving behaviour or logic that is designed to operate with varying levels of autonomy and to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner if the outcome of the planned action has a safety

AM 351 (Schaldemose (S&D))

Annex III Part 1 Point 1.1 Point 1.1.9 Paragraph 1

Text proposed by the Commission **Amendment** The machinery product shall be designed and deleted constructed so that the connection to it of another device, via any feature of the connected device itself or via any remote device that communicates with the machinery product does not lead to a hazardous situation.

impact.

AM 353 (Schaldemose (S&D))

Contact @ FIEC: C. Le Forestier

Email: info@fiec.eu

Annex III Part 1 Point 1.1 Point 1.1.9 Paragraph 2

Text proposed by the Commission Amendment deleted A hardware component for connection that is critical for the compliance of the machinery product with the relevant health and safety requirements shall be designed so that it is adequately protected against accidental or intentional corruption. The machinery product shall collect evidence of a legitimate or illegitimate intervention in the hardware component.

AMs 357 to 361 to Annex III Part 1 Point 1.1.9 related to software security/safety => FIEC is against the deletion of these provisions!





AM 369 (Fidanza/ECR)

Annex III Part 1 Point 1.2 Point 1.2.1 Paragraph 2 Point g

| Text proposed by the Commission | Amendment |
|--|-----------|
| recording of data on the safety related | deleted |
| 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. | |

AM 372 (Hahn/Renew)

Annex III Part 1 Point 1.2 Point 1.2.1 Paragraph 6

| Text proposed by the Commission | Amendment |
|---|--------------------|
| For autonomous mobile machinery products, | deleted |
| the control system shall be designed to | |
| perform the safety functions by itself as set out | |
| in this section, even when actions are ordered | |
| by using a remote supervisory function. | |

AM 375 (Kokalari (EPP))

Annex III Part 1 Point 1.3 Point 1.3.7 Paragraph 4 Point b

| Text proposed by the Commission | Amendment |
|---------------------------------|----------------------|
| human-machine interaction. | <mark>deleted</mark> |

AMs 378 to 380

Annex III Part 1 Point 1.3 Point 1.3.7 Paragraph 5

| Text proposed by the Commission | Amendment |
|---|-----------|
| The machinery product with fully or partially | deleted |
| evolving behaviour or logic that is designed to | |
| operate with varying levels of autonomy shall | |
| be adapted to respond to people adequately | |
| and appropriately (verbally through words or | |
| nonverbally through gestures, facial | |
| expressions or body movement) and to | |
| communicate its planned actions (what it is | |
| going to do and why) to operators in a | |
| comprehensible manner. | |





AM 413 (Hahn/Renew)

Annex III Part 3 Point 3.2 Point 3.2.4 Paragraph 2

| Text proposed by the Commission | Amendment |
|---|-----------|
| The information the driver receives from the | deleted |
| machine when the supervisory control function | |
| is active shall enable the driver to have a | |
| complete and accurate view of the operation, | |
| movement and safe positioning of the machine | |
| in its travel and working area. | |

AM 420 (Campomenosi + Basso (ID))

Annex III Part 3 Point 3.5 Point 3.5.4 Paragraph 2

| Text proposed by the Commission | Amendment |
|--|----------------------|
| When the risk of contact or electric arc with an | <mark>deleted</mark> |
| energised overhead power line cannot be fully | |
| avoided, mobile machinery products shall be | |
| designed, constructed and equipped in such a | |
| way that all hazards of an electrical nature are | |
| prevented or can be prevented in the event of | |
| contact or electrical arc with an energized | |
| power line. | |

AM 431 (Campomenosi + Basso (ID))

Annex IV Part A Pagraph 2 Point n

| Text proposed by the Commission | Amendment |
|---|-----------|
| the source code or programmed logic of the | deleted |
| safety related software to demonstrate the | |
| conformity of the machinery product with this | |
| Regulation further to a reasoned request from | |
| a competent national authority provided that | |
| is necessary in order for those authorities to be | |
| able to check compliance with the essential | |
| health and safety requirements set out in | |
| Annex III; | |