

Brussels, 01 August 2019



CECE answer to the European Commission's Open Public Consultation on the revision of the Directive 2006/42/EC on machinery

General questions

18 What kind of machinery is relevant for you or your organisation/institution? [select as many as relevant]

- (X) Construction
- () Agriculture
- (X) Mining and quarrying
- () Food processing
- () Car and vehicle manufacture
- () Wind energy
- () Other power production
- () General manufacturing
- () Horticulture and gardening
- () Power tools for personal use
- () Leisure industry
- () Machine tool manufacture
- (X) Other

19 Please explain:

Earth-moving machinery (e.g. loaders, excavators, dumpers, rollers), road construction machinery (pavers, finishers, asphalt mixing plant), concrete plant and machinery, aggregate processing plant and machinery, foundation equipment.

20 Have you experienced (or heard about) difficulties in buying machinery from or selling machinery to other countries in the EU/EFTA/Switzerland/Turkey?

- (X) Yes
- () No
- () No opinion

21 Has any of the following aspects caused difficulties?

- Identifying the risks
 (X) No difficulties I () Some difficulties I () Major difficulties I () No opinion
- Identifying the essential health and safety requirements
 (X) No difficulties I () Some difficulties I () Major difficulties I () No opinion
- Finding the right standard





(X) No difficulties I () Some difficulties I () Major difficulties I () No opinion

- Doing the conformity assessment
 (X) No difficulties I () Some difficulties I () Major difficulties I () No opinion
- Preparing documentation

 (X) No difficulties I () Some difficulties I () Major difficulties I () No opinion

 Translating documentation into other EU languages
- (X) No difficulties I () Some difficulties I () Major difficulties I () No opinion Provide the correct Declaration of Conformity
- Receiving the correct Declaration of Conformity
 () No difficulties I () Some difficulties I () Major difficulties I (X) No opinion
- Receiving correct instructions
 () No difficulties I () Some difficulties I () Major difficulties I (X) No opinion
- Understanding where responsibility lies for CE marking of machinery or assemblies of machinery

()No difficulties I (X) Some difficulties I () Major difficulties I () No opinion

22 Please explain your choices:

On question 20, our manufacturers have experienced difficulties into exporting quick couplers to Switzerland. Specifically, the Swiss National Accident Insurance Fund (SUVA) does not recognize the presumption of conformity conferred by the harmonized standard EN 474-1.

Additionally, we should mention that there are some challenges to import into Turkey where, in certain situations, the CE marking and Declaration of Conformity (DoC) do not seem enough and authorities ask for additional documents.

23 Have you ever encountered (or heard about) situations in which the safety of users (or domestic animals or property) was at risk when using machinery?

() Yes

(X) No

() No opinion

26 Have you ever encountered (or heard about) situations in which the safety of users (or domestic animals or property) was at risk as a result of the internet connection of the machinery?

() Yes

(X) No

() No opinion

29. Have you ever experienced difficulties in understanding or finding the information you needed in the user manual provided with machinery you purchased or used (or have you seen evidence of such difficulties)?

() Yes

(X) No

- () I do not usually read the user manual
- () No opinion





32 How should machinery manuals be delivered to users? [select the two methods you most prefer]

- () Always a printed user manual
- () Printed manual should be available on demand only
- () Access to a digital user manual (online or displayed by the product)
- () Access to manual on external device such as DVD/USB stick
- () A short printed Quick-Start Guide and an access to a more in-depth online user manual (X) Other

33 Please specify:

Our manufacturers would like to have a flexible approach, to be able to choose between the possibility to provide the operator's manual in a printed and/or provide it in a digital format via different means.

36 What would be the impact of switching solely to online manuals?

(X) Users would use online manuals only

- (X) Users would print the online manual, but only in their own language
- (X) Users would print just relevant parts of the manual
- (X) For those without internet access it would be much more difficult to access the manual

(X) Other

37 Please explain:

Users may download the manual only when needed and in case an issue arises when the machine is off they may not be able to access the manual. Another foreseeable risk is that users will only focus on specific parts of the manual without reading it in its entirety with a high chance that users will miss some of the information they need to be aware before using the machine.

38 When preparing manuals, what is the current cost of the following elements?

- (X) Translating a manual into EU languages where the product is placed on the market
- (X) Printing the manual
- (X) Shipping cost (the manual adds weight to the package)
- (X) Other

39 Please explain:

Administrative costs for managing the logistics. In providing a copy of the printed manual with each product there is also an administration charge that should be considered. This charge covers the management of the books at the production facility and covers elements such as storage, picking (selection of the book), transfer to the appropriate machine and confirmation by the responsible shipping agent. This cost is increasing in relation to the size of the organization and complexity of the products where multiple Instruction Manuals will require such management. We estimate an average cost of this activity to be approximately €25,000.





40 Please try to provide an estimate of the cost in man-hours, or percentage of turnover, or percentage of production cost (purchasing costs), or just describe how significant it is. Please describe also the product you refer to:

For a hydraulic excavator, the costs on average are:

- Translating a manual into an EU language costs approximately €10.000per language;
- Printing the manual is around €10 per copy;
- Administrative costs range between €5.000 and €20.000 per part number.

41 Could you estimate the total annual volume of paper used for printing the manuals that accompanies the machinery? You can provide a number of individual manuals, number of pages, cubic meters or other ways of measuring it: Each machine sold require between 100 and 800 A4 pages per language.

42 Have you had the need to update manuals?

(X) Yes

() No

43 Do you need to send new copies to existing customers? Give any example:

Yes. For example, when manufacturers need to revise maintenance information, they send an updated printed copy to the user.

44 Would having electronic manuals make updates easier?

(X) Yes

() No

45 Please assess the potential cost saving of the following options and explain their magnitude (how does it compare to the current situation and what cost savings you would expect as a % of total costs now)?

(X) On-line manuals only

(X) On-line manuals + printouts on demand

(X) On-line manuals + printed Quick Start Guide

46 Please detail how it compares to the current situation and what cost savings you would expect as a % of total costs now:

The saved cost would be the printing cost, which is around €10 per copy. We estimate that with a printed Quick Start Guide there would be no difference in costs and with the printouts on demand it would depend on the demand.

47 Do you currently own or have you previously owned any of the following types of autonomous domestic robots?

- () A robot vacuum cleaner
- () A robot lawn mower

() A drone

() A robotic walker

() A robot pet/companion





() A robot assistant (a physical robot intended to assist in tasks such as cleaning, security, smart home control, and/or messaging and schedule management)

- () A robotic toy (a physical robot intended for entertainment purposes only)
- () Other domestic robot
- (X) None of them

54 Do you have security/safety/privacy concerns which impact your willingness to buy household appliances with internet connection?

- () I have no related security concerns
- () I am concerned, but I use the internet connection anyway
- () I am concerned, and use the internet connection only when necessary, and/or I have

taken other measures (such as covering the camera, disabling the microphone or limiting the areas of the house I use the robot in)

() I am concerned, and as a consequence I do not use the internet connection

() I am obliged to use the internet connection since otherwise my domestic robot can not function properly

() Other concerns

(X) I do not buy such appliances

Questions for potential improvement/simplification of existing provisions

This section intends to collect feedback from stakeholders on:

- the scope of the Directive and whether it is sufficient in some particular cases;
- the need for additional definitions;
- some essential health and safety requirements and whether they are sufficient;
- the categories of machinery subject to conformity assessment involving a Notified Body.

Questions related to the scope (Article 1)

56 When producing/importing/distributing machinery, where do you search for information on what is required for compliance?

(X) In the Official Journal of the EU

- (X) On the Commission website
- (X) In the Machinery Guide
- (X) On national authorities' webpages
- (X) On industry association webpages/or in their guidance
- () On a consultant/Notified Body website
- () Other

58 Are you a manufacturer, importer or distributor of:

- (X) Electrical and electronic equipment
- (X) Pressure equipment





() Lifts() Nuclear machinery(X) Other machinery

59 After your search, was it difficult to identify what piece of legislation (safety requirements and procedures) you need to follow to obtain a CE marking?

- () Yes
- (X) No

() Not applicable

64 Have you encountered problems due to exclusions of certain low voltage machinery from the scope of the Machinery Directive (Article 1.2(k))?

- ()Yes
- (X) No
- () I do not know

66 Would the following changes make it clearer as to which rules (Machinery Directive 2006/42/EC or Low Voltage Directive 2014/35/EU) to follow?

- Differentiate explicitly between consumer and commercial/professional products, so that low voltage machinery for consumer use is excluded, whereas the products for commercial/professional use are not

 () Agree I () Disagree I (X) No opinion
- Remove the exclusion of low voltage machinery in Art. 1.2 (k) of Machinery Directive so that the machinery whose risks are mainly of electrical origin are covered exclusively by the Low Voltage Directive
 - () Agree I () Disagree I (X) No opinion
- More standards available for these products
 () Agree I () Disagree I (X) No opinion
- Other
 () Agree I () Disagree I (X) No opinion

67 Please explain your choices:

The current texts of the Machinery Directive and the Low Voltage Directive are sufficiently clear for our sector.

68 Would the above changes require some one-off investments, such as staff training, new equipment, new internal procedures, etc.?

()Yes

(X) No

() No opinion

72 Would the above changes lead to change in recurrent annual costs of compliance with the Directive requirements?

- () Costs would increase
- (X) Costs would not change





() Costs would decrease

86 The Pressure Equipment Directive 2014/68/EU contains specific essential safety requirements to address hazards due to pressure. However, pressure equipment classified no higher than category I is excluded from the Pressure Equipment Directive and can be covered by the Machinery Directive (e.g. motorised valves, pressure cookers). As a consequence, that product can be selfassessed by the manufacturer instead of involving a third party conformity assessment body to certify it.

Do you consider that this exclusion from the Pressure Equipment Directive (which has specific essential safety requirements to address hazards due to pressure) leads to increased safety concerns (such as explosion due to pressure)?

() Yes

(X) No

() No opinion

87 Would it be beneficial for the safety of the machinery if, in addition to the Machinery Directive, the Pressure Equipment Directive also applied even if the items of pressure equipment are classified no higher than category I under the Pressure Equipment Directive?

- () Yes
- (X) No
- () No opinion

88 Would this change lead to increased or reduced costs for your organisation:

- () Increased
- () Reduced
- (X) No change

89 Please provide an estimate of the costs of such change [at your choice]:

- (X) In man-hours
- ()% of your turnover
- ()% of your total production or purchasing costs

90 Please provide your estimate here:

The online questionnaire did not allow us to include an answer on question 90 so we included the following comment under question 163: Not applicable as there is no change. Therefore, please do not consider our answer on question 89.

91 The Machinery Directive applies to lifting appliance whose speed is not greater than 0.15 m/s. Lifts whose speed is above 0.15 m/s are covered by the Lifts Directive 2014/33/EU. Given the technical progress in lifts sector, there are suggestions to increase the maximum speed for lifting appliance/platforms under the Machinery Directive from 0.15 m/s to 0.50 m/s. As a consequence, that product can be self-assessed by the manufacturer itself instead





of involving a third-party conformity assessment body to certify it as required by the Lifts Directive. Do you consider that such increase of the speed limit for lifts creates safety problems?

() Yes () No (X) No opinion

93 Would such a speed limit increase for lifts lead to increased or reduced costs for your organisation:

() Increased

() Reduced

(X) No change

96 The Machinery Directive excludes machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity. Do you agree that the exclusion should refer only to machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in a direct emission of radioactivity by the machinery itself?

() Yes () No

(X) No opinion

101 The Machinery Directive applies to products placed on the market for their intended use as defined and described in the manufacturer's instructions. There has been identified the need to establish criteria for machinery substantially modified during their use, that requires new declaration of conformity under the Machinery Directive.

Have you every modified your machinery during its use?

()Yes

(X) No

107 Please explain what would be the appropriate criterion to define a substantial modification of machinery, considering also the Commission Blue Guide[1] guidance in this respect.

[1] The Blue Guide on the implementation of EU products rules 2016, section 2.1. Not applicable, CECE does not have an opinion. There are conflicting interpretations on what represents a substantial modification of a machinery and we believe the European Commission should solve this in the relevant legal act. On question 110, we cannot anticipate the impact, our preferable answer would be "not applicable" but that option is not available.

108 Should the Directive define criteria for machinery modified substantially?

() Yes () No (X) No opinion





110 Would this change lead to increased or reduced costs for your organization?

- () Increased
- () Reduced
- (X) No change

Questions related to definitions (Article 2)

113 According to the definitions in Article 2, a 'machinery performs a 'specific application' while 'partly completed machinery' (PCM) cannot itself perform a specific application. The notion of 'specific application' is, however, not defined. Did you experience any problems, such as:

() It led to wrong classification of the product, for instance as machinery instead of partly completed machinery

() The manufacturer of partly completed machinery did not fulfil all the applicable safety requirements which caused problems for the CE marking of the final machinery () Other

(X) I did not experience any such problems

115 How would you define the notion of 'specific application'?

We are satisfied with the definition in the "Guide to the Application of the Machinery Directive 2006/42/EC" (Edition 2.1 – July 2017 - page 34). "Machinery must be useable for a specific application as applying to the complete machine and its intended use. Typical machinery specific applications include, for example, the processing, treatment, or packaging of materials, or the moving of materials, objects or persons."

116 Do you think that other definitions or concepts need to be revised?

- Manufacturer
 - () Yes I (X) No I () No opinion
- Partly completed machinery
 (X) Yes I () No I () No opinion
- Assembly

 () Yes I (X) No I () No opinion
- State of the art
 () Yes I (X) No I () No opinion
- Nuclear purposes

 Yes I () No I (X) No opinion
- Other
 () Yes I (X) No I () No opinion

117 Please specify/elaborate:

On our answer to the previous Machinery Directive consultation, the members advised that there should be a clarification on Partly Completed Machinery.





Questions related to essential health and safety requirements (Annex I)

118 In the case of a lifting platform with carrier which is not completely enclosed, the current rules prescribe the technical solution, where the user needs to press a button throughout the movement of the platform. Such a requirement may restrict innovation given that there are other technological solutions on the market, such as for example light barrier curtains.

Do you think that the safety requirements should be revised to allow innovative technologies to be used, such as for example light barrier curtains, for carriers which are not completely enclosed?

- ()Yes ()No
- (X) No opinion

119 Please explain whether these new technologies give rise to safety concerns or if they provide the same level of safety as hold-to-run buttons. No opinion as we do not manufacture such products.

120 Would the revision of the safety requirements to allow such innovative technologies lead to increased/reduced costs for your organization?

- () Increased
- () Reduced
- (X) No change

123 Do you think that essential health and safety requirement (EHSR 1.5.8) on noise is coherent with the requirements of Outdoor Noise Directive 2000/14/EC?

- (X) Yes, to a great extent
- () Yes, to some extent
- () Yes, to a minor extent
- () No, to no extent

124 Please elaborate:

There is no contradiction between both the Machinery Directive and Outdoor Noise Directive.

Questions related to categories of machinery which may be subject to conformity assessment involving a Notified Body (Annex IV)

125 Annex IV of the Directive sets out a strict list of categories of machinery which may be subject to one of the two conformity assessment procedures involving a Notified Body (EC type-examination or Full quality assurance) and to self-assessment by the manufacturer when it is manufactured in accordance with harmonised standards that cover all of the applicable essential health and safety requirements.





When an Annex IV machinery is manufactured in accordance with harmonized standards that cover all of the applicable essential health and safety requirements, do you think that the option of self-assessment by the manufacturer leads to safety concerns?

() Yes (X) No

() No opinion

126 Please elaborate:

The principle of the "New Approach" allows the presumption of conformity to the Machinery Directive using harmonized standards. This is reinforced by the new legal status of the harmonized standards.

127 Do you think that removing the self-assessment option when the product is manufactured in accordance with harmonised standards that cover all of the applicable essential health and safety requirements?

(X) Yes, it will increase costs

- () Yes, it will reduce costs
- () No change expected
- () I do not know

128 Please provide an estimate of the additional / reduced costs of such change at your choice:

(X) In man-hours

- ()% of your turnover
- ()% of your total production or purchasing costs

129 Please provide your estimate here:

The online questionnaire did not allow us to include an answer on question 129 so we included the following comment under question 163: We cannot estimate an average. Therefore, our manufacturers will provide more specific estimates in one or more format of their choice: in man-hours, % of turnover and/or % of total production or purchasing costs. Please consider that likely all of the question 128 options will contribute to the estimate.

130 Do you think that other high-risk categories of machinery should be added to Annex IV, therefore subject to conformity assessment procedures involving a notified body when harmonized standards that cover all of the applicable essential health and safety requirements are not used?

- ()Yes
- (X) No

() No opinion





Questions for potential adaptation to robotics and artificial intelligence (machine learning)

Today's emerging digital technologies, for example, artificial intelligence (AI) and the Internet of things (where machinery used at work and/or at home is connected to the internet), have characteristics such as complexity, opacity of algorithms (black boxes), autonomy, data-dependence and vulnerability to cyberattacks, which may bring new challenges in terms of ensuring the safety of machinery. Consequently, manufacturers must consider and address potential new risks.

The machines integrating these technologies have higher degrees of movement (they have more flexible and extended movements outside previous limits) and thanks to improved sensors, they can interact better with their environment. Furthermore, the increased digitisation means that machines are more connected to each other and to internet via the Internet of things networks.

133 Do you think that the Machinery Directive sufficiently covers the safety of human-robot collaboration (i.e. robots working in the same operating space as humans)?

(X) Yes

() No

() No opinion

134 Please elaborate:

Under the Machinery Directive, before placing a machine on the market, the manufacturer will make sure that it will remain safe throughout its life cycle. Fulfilling this objective begins at the design phase, following which the product undergoes a compulsory risk assessment, and finally a series of conformity assessment procedures. When implementing the safety concept, the manufacturer will give priority to safety functions over all other functions of the machine. Even if a machine integrates AI functions, the actions it performs will always be within the scope of the intended use as defined by the manufacturer.

135 Do you think any essential health and safety requirements should be adapted to take into account humans and robots sharing a given space, and if yes, which ones?

() Yes(X) No() No opinion

136 Please explain:

The current MD and the essential requirements can be easily applied to machinery integrating AI functions. AI-embedded machinery functions exclusively within a working perimeter defined by the manufacturer. This working perimeter is either a structured environment or an unstructured environment under strict human supervision, such as the premises of a factory. It is therefore misleading to make any comparison between this kind





of machinery operating in a specific working environment and, for example, driverless vehicles in an unstructured environment.

137 Do you think any new essential health and safety requirements should be added to take into account humans and robots sharing a given space, and if yes, which ones?

() Yes
(X) No
() No opinion

138 Please explain:

Despite the rapid evolution of these AI-embedded machines – operating on the basis of narrow artificial intelligence – manufacturers can continue to rely on a robust regulatory framework and the development of a large number of standards (a process which our companies are actively involved in). This will continue to guarantee the placing on the market of safe machines while ensuring a high level of trust among both machine users and consumers for many years to come.

141 Machine learning enables machines to operate by recognising patterns in complex data and to learn to operate in a new or modified way using experience or data. Do you think that the Machinery Directive should explicitly address transparency of algorithms and datasets?

() Yes(X) No() No opinion

142 Please explain:

Since machine learning takes place within the range that the manufacturer has defined as the intended use, new or modified machine functions are completely covered by the machine's protection or safety concept.

143 Machine learning software is programmed by humans (manufacturers) who must be able to reasonably foresee the risks posed by machinery integrating machine learning and consequently frame its learning capabilities to avoid harm to users or consumers. Do you think that Machinery Directive should explicitly address software updates?

- () Yes
- (X) No
- () No opinion

145 Do you think that software which ensures a safety function and is placed independently on the market should be explicitly covered by the Machinery Directive and therefore considered a safety component (Article 2c)?

- () Yes
- () No
- (X) No opinion





146 Do you think that the concept of placing on the market is still relevant, in particular when software updates are added later on to the machinery?

(X) Yes() No() No opinion

147 Please explain:

We consider that software updates are covered by the Machinery Directive. Either such change is considered as a modification in the sense of the principle of "modification of machinery" described for example in §140 National regulations on the health and safety of workers of MD guidelines or such change is considered as a maintenance operation within the range defined by the original manufacturer and described in the instruction's handbook.

148 Do you think that the concept of foreseeable misuse as defined in the Machinery Directive is still relevant?

(X) Yes

() No

() No opinion

149 Please explain:

We consider the definition clear enough and should not make any distinction when it comes to software updates.

Questions for potential adaptation to cybersecurity

Cybersecurity can be considered as protection against the criminal or unauthorized use of electronic data or the machine control system, or the measures taken to achieve this.

150 Do you think that the Machinery Directive covers cyber threats affecting health and safety, for instance hacking and taking control of a machine/robot? (X) Yes

() No

() No opinion

151 Please explain how:

The Machinery Directive does not and should not directly address cyber security requirements. Nevertheless, the health and safety requirements according to Annex I cover the possible effects of a cyber-attack on machinery safety. The Machinery Directive requires manufacturers to ensure that a risk assessment is carried out in order to determine the health and safety requirements which apply to the machinery. As a consequence, the manufacturer carries out a risk assessment determining the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof.

152 What requirements if any should be added?

() Only requirements concerning safety should be added





() Safety and security requirements should be added

() Only security requirements should be added

(X) No obligatory requirements should be added

153 How should cybersecurity requirements for manufacturers of machinery be implemented in the EU?

(X) Via voluntary certification and labelling, for example the Cybersecurity Act

() Via sectorial legislation, for example the Machinery Directive

() Through a cross-cutting legislation applying to all products

() Via cross-cutting legislation complemented with more specific requirements in sectoral legislation.

() Other

154 Please specify or explain why:

Because the Cybersecurity Act provides a sufficient framework for the future needs on cybersecurity.

Questions on conversion into a Regulation

155 The evaluation of the Machinery Directive found that in some EU Member States the transposition into national law was delayed. Have you experienced problems due to these delays?

() Yes () No (X) I do not know

157 Have you experienced other problems due to differences in the transpositions of EU Member States?

() Yes () No (X) I do not know

159 Would you be in favour of having exactly the same rules on machinery safety applicable at the same time across the EU (converting the Directive into a Regulation)?

(X) Yes

() No

() I do not know

160 Please elaborate:

It facilitates uniform application across all European Union Member States and therefore the free movement of goods.





Questions for alignment to the NLF

The New Legislative Framework (NLF), adopted in 2008, is a package of measures to improve market surveillance in the EU and the quality of conformity assessments. In addition, it clarifies the use of the CE marking and creates a measures toolbox for use in product legislation. The NLF consists of Regulation (EC) 765/2008 setting out the requirements for accreditation and the market surveillance of products, Decision 768/2008 on a common framework for the marketing of products, and Regulation (EC) 764/2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another EU country.

161 Would you be in favour of aligning the Machinery Directive to the New Legislative Framework?

- (X) Yes
- () No

() I do not know

162 Please elaborate:

For coherence with the other legislative acts and horizontal transparency.

Closing Questions

163 Please share any additional comments or remarks you may have regarding the topic of this public consultation.

Once I selected my profile as an industry association, I received some questions that should not be addressed to associations. Our manufacturers will answer them.

164 Please feel free to upload a concise document, such as a position paper to support your responses. The maximum file size is 1 MB Only files of the type pdf,txt,doc,docx,odt,rtf are allowed