Contribution ID: b803b8ca-3213-43f2-8e43-b795742b6dbd
Date: 28/08/2019 17:30:15

Open Public Consultation on the revision of the Directive 2006/42/EC on machinery

Fields marked with * are mandatory.

Introduction

The Machinery Directive is the core European legislation regulating products of the mechanical engineering industries. It aims at (i) ensuring a high level of safety and protection for machinery users and other exposed persons and (ii) securing the free movement of machinery in the internal market.

An evaluation of the Directive was finalized in 2018. The overall conclusion of this evaluation was that the Directive is generally relevant, effective, efficient, coherent and has EU added value. However, a need for greater legal clarity of some of its provisions and better coherence with other legislation was identified. It further detected some administrative requirements that affect the efficiency of the Directive and could be simplified. In addition, the evaluation indicated that shortcomings in monitoring and enforcement of the Directive have affected its effectiveness. The evaluation showed that the Directive, supported by the New Approach principles, is relatively flexible to allow technological developments in a digital era. Yet, new innovations in digitisation may test the Directive's effectiveness and fitness for purpose going forward.

The Commission is following up on the findings of the evaluation and will analyse the impacts of possible areas for improvement and implications through an impact assessment. This questionnaire is one of the contributions to this impact assessment.

About you

* 1 Language of my contribution
  - ○ Bulgarian
  - ○ Croatian
  - ○ Czech
  - ○ Danish
  - ○ Dutch
  - ◉ English
  - ○ Estonian
  - ○ Finnish
  - ○ French
  - ○ Gaelic
  - ○ German
  - ○ Greek
  - ○ Hungarian

- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

* 2 I am giving my contribution as
- Academic/research institution
- (•) Business association
- Company/business organisation
- Consumer organisation
- EU citizen
- Environmental organisation
- Non-EU citizen
- Non-governmental organisation (NGO)
- Public authority
- Trade union
- Other

* 3 First name

Maitane

* 4 Surname

OLABARRIA

* 5 Email (this won't be published)

maitane.olabarria@cecimo.eu

* 7 Organisation name

255 character(s) maximum

CECIMO-European Association of the Machine Tool Industries and related Manufacturing Technologies

* 8 Organisation size
- (•) Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)

- ( ) Large (250 or more)

9 Transparency register number

255 character(s) maximum

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

79464041975-17

* 10 Country of origin

Please add your country of origin, or that of your organisation.

- ( ) Afghanistan
- ( ) Åland Islands
- ( ) Albania
- ( ) Algeria
- ( ) American Samoa
- ( ) Andorra
- ( ) Angola
- ( ) Anguilla
- ( ) Antarctica
- ( ) Antigua and Barbuda
- ( ) Argentina
- ( ) Armenia
- ( ) Aruba
- ( ) Australia
- ( ) Austria
- ( ) Azerbaijan
- ( ) Bahamas
- ( ) Bahrain
- ( ) Bangladesh
- ( ) Barbados
- ( ) Belarus
- (•) Belgium
- ( ) Belize
- ( ) Benin
- ( ) Djibouti
- ( ) Dominica
- ( ) Dominican Republic
- ( ) Ecuador
- ( ) Egypt
- ( ) El Salvador
- ( ) Equatorial Guinea
- ( ) Eritrea
- ( ) Estonia
- ( ) Ethiopia
- ( ) Falkland Islands
- ( ) Faroe Islands
- ( ) Fiji
- ( ) Finland
- ( ) North Macedonia
- ( ) France
- ( ) French Guiana
- ( ) French Polynesia
- ( ) French Southern and Antarctic Lands
- ( ) Gabon
- ( ) Georgia
- ( ) Germany
- ( ) Ghana
- ( ) Gibraltar
- ( ) Libya
- ( ) Liechtenstein
- ( ) Lithuania
- ( ) Luxembourg
- ( ) Macau
- ( ) Madagascar
- ( ) Malawi
- ( ) Malaysia
- ( ) Maldives
- ( ) Mali
- ( ) Malta
- ( ) Marshall Islands
- ( ) Martinique
- ( ) Mauritania
- ( ) Mauritius
- ( ) Mayotte
- ( ) Mexico
- ( ) Micronesia
- ( ) Moldova
- ( ) Monaco
- ( ) Mongolia
- ( ) Montenegro
- ( ) Montserrat
- ( ) Morocco
- ( ) Saint Pierre and Miquelon
- ( ) Saint Vincent and the Grenadines
- ( ) Samoa
- ( ) San Marino
- ( ) São Tomé and Príncipe
- ( ) Saudi Arabia
- ( ) Senegal
- ( ) Serbia
- ( ) Seychelles
- ( ) Sierra Leone
- ( ) Singapore
- ( ) Sint Maarten
- ( ) Slovakia
- ( ) Slovenia
- ( ) Solomon Islands
- ( ) Somalia
- ( ) South Africa
- ( ) South Georgia and the South Sandwich Islands
- ( ) South Korea
- ( ) South Sudan
- ( ) Spain
- ( ) Sri Lanka
- ( ) Sudan
- ( ) Suriname

- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Mozambique
- Myanmar /Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- North Korea
- Northern Mariana Islands
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Svalbard and Jan Mayen
- Swaziland
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu

- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Saint Martin
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

* 11 Publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- **Anonymous**
  Only your type, country of origin and contribution will be published. All other personal details (name, organisation name and size, transparency register number) will not be published.
- **Public**
  Your personal details (name, organisation name and size, transparency register number, country of origin) will be published with your contribution.

☑ 12 I agree with the personal data protection provisions

* 13 How familiar are you with Directive 2006/42/EC on machinery?

- I have detailed knowledge of the Directive, its objectives, the limits and the requirements/obligations that it imposes across all industry sectors
- I have detailed knowledge of the Directive, its objectives, the limits and the requirements/obligations that it imposes on a specific sector
- I am aware of the existence of the Directive but not of all its specific contents
- I do not really know the Directive

* 14 Are you or do you represent a:

- Manufacturer of machinery (or parts)
- Importer of machinery (or parts)
- Distributor of machinery (or parts)
- Industry association of producers, importers or distributors of machinery (or parts)

- ○ Professional/worker using machinery
- ○ Private user of machinery
- ○ Consumer organisation
- ○ Researcher/academia
- ○ Machinery safety consultant
- ○ Authority that enforces machinery rules
- ○ Standardisation organisation
- ○ Notified Body
- ○ Other

General questions

* 18 What kind of machinery is relevant for you or your organisation/institution? [select as many as relevant]
  - ☐ Construction
  - ☐ Agriculture
  - ☐ 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
  - ☐ Other

* 20 Have you experienced (or heard about) difficulties in buying machinery from or selling machinery to other countries in the EU/EFTA/Switzerland/Turkey?
  - ◉ Yes
  - ○ No
  - ○ No opinion

21 Has any of the following aspects caused difficulties?

	No difficulties	Some difficulties	Major difficulties	No opinion
* Identifying the risks	◉	○	○	○

* Identifying the essential health and safety requirements	◉	○	○	○
* Finding the right standard	○	○	◉	○
* Doing the conformity assessment	◉	○	○	○
* Preparing documentation	○	◉	○	○
* Translating documentation into other EU languages	◉	○	○	○
* Receiving the correct Declaration of Conformity	◉	○	○	○
* Receiving correct instructions	◉	○	○	○
* Understanding where responsibility lies for CE marking of machinery or assemblies of machinery	◉	○	○	○

* 22 Please explain your choices:

In general, the machine tool manufacturers represented by CECIMO are well acquainted with the provisions and obligations of the Machinery Directive and have not encountered any difficulties in relation to the above-mentioned aspects. Some difficulties have been reported though in relation to Turkish customs authorities. In some cases, machine manufacturers have been requested by customers, based on a demand from the customs authority, to provide the full report of the risk assessment and machine drawings. They were arguing that the CE marking and the Declaration of Conformity were not enough.

Finding the right standards is also in general not a difficulty. Nevertheless, in the case of Additive Manufacturing (AM) machinery, there is a lack of type C standards. The need to develop standards in this area has been identified by the AM companies represented by CECIMO. This should facilitate compliance and conformity assessment of this equipment with the essential health and safety requirements of the Directive.

CECIMO's opinion is that the Directive is fit for purpose and we have only identified isolated issues that are more related with its implementation rather than the actual content and text of the Directive.

* 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
- ○ No
- ○ No opinion

* 24 Please specify the problem and the type of machinery:

In the context of some verification activities conducted in Italy between 2008 and 2011 by the Italian Notified Body under the Machinery Directive on behalf of the Customs Agency, non-conformities were found in relation to machine tools coming from outside the EU. This activity was carried out following a collaboration agreement between UCIMU (Italian association member of CECIMO) and the Customs Agency aimed at verifying the conformity of some types of machines (mainly lathes and machining centers) from countries in the Far East. The activity aimed at protecting the Italian users and without any intention to create obstacles to the circulation of goods from outside the EU. The activity started following reports from manufacturers /users and visits to stands at fairs, which showed obvious non-conformities of products from countries in the Far East.

The final data of the verification activities pointed out that for those machines where no-conformities were identified, some of the most critical points were related to electrical hazards, safety electrical equipment and instructions for use. The final report of the exercise in 2011 pointed out that in the period from 1/07/2009 to 06/30/2010 53% of the machines showed non-conformities (26 machines out of 49 verified) while in 2011 it was around 38% (16 machines out of 42 verified). Although there was a slight improvement, the quantity of negatives suggested that the percentage could increase by analyzing a larger sample.

The drastic drop in imports, probably due to changes in customs entrances and to the economic crisis, led to the suspension (and later cancellation) of the verification activity. At the same time the context has changed and certainly the import part from China and Korea has been increasing. It is therefore presumable that today the picture of non-conformities may be different, but we do not believe that the phenomenon has disappeared or drastically changed.

Often these machines are distributed by machine tool dealers in the EU. In this context market surveillance in essential to protect users but also to ensure a level playing field.

* 25 Was the machinery that caused the problem purchased from a company in the EU/EFTA/Switzerland/Turkey?
  - (●) Yes
  - ( ) No
  - ( ) I do not know

* 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
  - (●) 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
  - (●) 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
- [x] Printed manual should be available on demand only
- [x] 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
- [ ] Other

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

- [x] Users would use online manuals only
- [ ] Users would print the online manual, but only in their own language
- [ ] Users would print just relevant parts of the manual
- [ ] For those without internet access it would be much more difficult to access the manual
- [ ] Other

* 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
- [ ] Shipping cost (the manual adds weight to the package)
- [ ] Other

* 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:

It is difficult to provide an estimation of the costs since this may vary depending on the complexity of the machine. Machine tools are complex capital goods. For complex machines and machine systems the manual can be very large and as a result the costs of translation and printing can be rather high in comparison with other products.

Some estimations provided to us by some of our companies go from EUR 1,000 to 5,000 for editing costs per machine (type) and EUR 1,000 to 2,000 for translation costs per language and EUR 60,000 overall printing costs on a calendar year basis. Nevertheless, as stated these costs vary considerably depending on the different type and complexity of the machine.

In the B2B context, the possibility of contractual agreements between the machine manufacturer and the user of the machine considering the training of operators should be foreseen.

* 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:

In the case of machine tools different manuals are normally provided. Some estimations received regarding the number of pages per machine manual are around 1,000 pages for each machine sold. These pages include user manual, electrical schemes, manual of specific spare parts and tools... Some customers ask for

2 or 3 copies (ex. double copy in a language or a copy in different language), which means about 2,000 – 3,000 pages for each machine. Some annual estimations of the printed number of pages are of 1,7 million pages (both sides) per year.
As explained before the volume of pages can change considerably depending on the complexity of the machine.

* 42 Have you had the need to update manuals?
  - (●) Yes
  - ( ) No

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

Corrections to the manuals may be necessary for example after software updates. In some cases, corrections may also be needed due to experience gained in the field. In those cases, the manufacturer may issue specific warnings or working instructions to the customer but does not normally send the full manual. The advantage of online manuals in this case would be that changes can be made and delivered to the user much quicker.

* 44 Would having electronic manuals make updates easier?
  - (●) 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)?
  - [ ] On-line manuals only
  - [x] On-line manuals + printouts on demand
  - [ ] 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 highest percentage of the costs related to the production of manuals are in producing the content, editing and translation. Some cost would be saved in relation to printing but the main driver for moving to online manuals is the advantages it provides in relation to updating, quicker search for relevant information and reduction of environmental impact.

* 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
  - (•) 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?
  - [ ] 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:
  - [ ] Electrical and electronic equipment
  - [ ] Pressure equipment
  - [ ] Lifts
  - [ ] Nuclear machinery
  - [x] Other machinery

* 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
  - ◉ No
  - ○ I do not know

* 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 self-assessed 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
  - ◉ 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
  - ◉ No
  - ○ No opinion

* 88 Would this change lead to increased or reduced costs for your organisation:
  - ◉ Increased
  - ○ Reduced
  - ○ No change

* 89 Please provide an estimate of the costs of such change [at your choice]:
  - ○ In man-hours
  - ○ % of your turnover
  - ◉ % of your total production or purchasing costs

* 90 Please provide your estimate here:

  0.5

* 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
- ◉ No opinion

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

- ○ Increased
- ○ Reduced
- ◉ 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
- ◉ No opinion

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

- ○ Increased
- ○ Reduced
- ◉ No change

* 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
- ○ No

* 102 Was your CE marking questioned by authorities?

- ○ Yes
- ◉ No

* 103 Did you go through a certification process again?

- ◉ Yes
- ○ No

* 104 Did you encounter any problem?
  - ○ Yes
  - ◉ 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.

A modification is substantial when it involves a modification of the original performance and/or purpose and /or technologies used and/or functions of the machine in such a way that generates new risks or increases the existing risk levels. The generation of new or increased risks is therefore the key criterion. Changes aimed only at improving safety do not constitute a substantial change.
To this respect the following document from the German Federal Ministry of Labour and Social Affairs is relevant and provides a clear explanation and criteria in relation to the concept of substantial modification: https://www.bmas.de/SharedDocs/Downloads/DE/Thema-Arbeitsschutz/en-interpretation-paper-substantial-modification-to-machinery.pdf;jsessionid=9D77750E29E6C9DE46DD39E96D7AE886?__blob=publicationFile&v=1

* 108 Should the Directive define criteria for machinery modified substantially?
  - ◉ Yes
  - ○ No
  - ○ No opinion

* 109 Please explain:

Currently there are some diverging interpretations on what a substantial modification is and the obligations derived from introducing such modifications. It would be beneficial to have a common definition and common agreed criteria across Europe. This could also be achieved by including further explanation and guidance in the Guide to the Machinery Directive.

* 110 Would this change lead to increased or reduced costs for your organization?
  - ○ Increased
  - ○ Reduced
  - ◉ 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
- ☐ I did not experience any such problems

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

‘Specific application’ is the purpose for which the machine was designed and built for, this is, the intended use as defined by the manufacturer. The machine must be able to complete the application autonomously, without needing to be assembled with other machines or quasi-machines, even if this is still possible.

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

	Yes	No	No opinion
* Manufacturer	○	◉	○
* Partly completed machinery	○	◉	○
* Assembly	○	◉	○
* State of the art	○	◉	○
* Nuclear purposes	○	○	◉
* Other	○	◉	○

* 117 Please specify/elaborate:

In general, In general, the concepts are well understood. There have been though some particular cases in which it has been difficult to establish the right classification for machines that can work stand alone, but also be inserted in lines with different functionalities and safety needs (see our reply to Q 113). Adding some further examples in the Guide to the Machinery Directive could be helpful.

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
- ◉ 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.

The Machinery Directive defines mandatory essential health and safety requirements, leaving the definition of technical details to meet those requirements to harmonised standards developed by stakeholders in line with technological developments and the state-of-the-art. The Directive should describe requirements in a technology neutral way and not focus on specific technological solutions.

* 120 Would the revision of the safety requirements to allow such innovative technologies lead to increased/reduced costs for your organization?
  - ○ Increased
  - ◉ Reduced
  - ○ No change

* 121 Please provide an estimate of the costs of such change [at your choice]:
  - ○ In man-hours
  - ○ % of your turnover
  - ◉ % of your total production or purchasing costs

* 122 Please provide your estimate here:

0

* 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?
  - ◉ Yes, to a great extent
  - ○ Yes, to some extent
  - ○ Yes, to a minor extent
  - ○ No, to no extent

* 124 Please elaborate:

The requirements are not formulated in contradictory terms

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 harmonised 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
- (•) No
- No opinion

* 126 Please elaborate:

From our perspective the application of the harmonized type C standards covering all the relevant health and safety requirements is sufficient to guarantee an adequate level of safety. In these cases, the manufacturer has enough expertise and knowledge to assess the conformity of its products in line with the procedure described in Annex VIII of the Directive (conformity through manufacturer's internal checks or self-assessment).

As indicated by the Commission in the staff working document of the evaluation of the Machinery Directive, the effectiveness of self-assessment in ensuring the safety of products covered by Annex IV is also backed up by the results of the joint market surveillance action carried out by market surveillance authorities between 2016 and 2018. The action covered two categories of products covered by Annex IV and the results indicated the number of technical non-conformities detected was significantly higher for products subject to EC type-examination than for products subject to self-assessment. The products for which no technical non-conformities were detected were all subject to self-assessment.

* 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?
- (•) 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:
- In man-hours
- % of your turnover
- (•) % of your total production or purchasing costs

* 129 Please provide your estimate here:

3

* 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
- (•) 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 cyber-attacks, 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)?
  - (●) Yes
  - ( ) No
  - ( ) No opinion

* 134 Please elaborate:

The requirements in the Machinery Directive together with existing standards (e.g. ISO 10218 and ISO/TS 15066) already cover adequately robotic applications. The Machinery Directive establishes that during the design and manufacture of machinery, the manufacturer shall identify and evaluate all possible hazards by undertaking a risk assessment and implement all resulting safety measures. The existing standards already establish a series of safety controls and measures (maximum allowed speeds, minimum separation distances, minimizing sharp edges and protrusions) in line with the state-of-the-art and the requirements of the Machinery Directive. It is also important to highlight that robots and machinery in general is always designed for a specific function and to operate within a pre-defined range and limits set by the manufacturer, this means, it cannot perform other tasks than those it has been designed for.

* 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
  - (●) No
  - ( ) No opinion

* 136 Please explain:

See answer to Q134

* 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
  - (●) No
  - ( ) No opinion

* 138 Please explain:

As mentioned in the reply to Q134, from CECIMO's perspective the current requirements and risk assessment foreseen in the Machinery Directive already cover adequately the industrial applications of robots.

* 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
- ◉ No
- ○ No opinion

* 142 Please explain:

Machine manufacturers already today consider during the risk assessment any safety aspects related to the software component of the machine, implement safety measures if necessary, carry out checks and/or tests on the effectiveness of such measures and include this information in the technical file of the machine. If machine learning is used, the risk assessment will also identify any foreseeable hazards and estimate any possible risks linked to machine learning. On this basis, we consider there is no need to disclose the datasets or algorithms to the user. All relevant information is already provided in the maintenance and operating instructions. It is also important to consider that the algorithms are the intellectual property of the manufacturer.

* 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
- ◉ 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
- ○ 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?

- ◉ Yes
- ○ No
- ○ No opinion

* 147 Please explain:

Nowadays, machines contain both hardware and software, both of which need to be considered and are necessary for the operation of the machine. As explained before (see answer to question 142) when placing machinery, including software on the market, the software component needs to be and is already considered in the risk assessment and implementation of safety measures. Currently, there are a series of standards (e. g. IEC 61508, ISO 13849) which are used by manufacturers to ensure safety of control systems and software.

Any software updates that do not constitute a substantial modification of the machine (see question 107) are part of the normal after-sales technical assistance and maintenance activities.

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

- (●) Yes
- ( ) No
- ( ) No opinion

* 149 Please explain:

The concept of reasonably foreseeable misuse is clearly defined and there do not seem to be problems with this concept.

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?

- ( ) Yes
- (●) No
- ( ) No opinion

* 151 Please explain how:

The Machinery Directive does not directly address cybersecurity requirements. Nevertheless, the health and safety requirements according to Annex I cover the possible effects of a cyber-attack on machinery safety.

* 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
- (●) No obligatory requirements should be added

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

- ( ) 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:

Cybersecurity is not a machinery specific issue and it affects all sectors. It does not only depend on the machine builder but on a wide range of actors including suppliers, software providers and users.

The scope of the Machinery Directive is limited to establishing essential requirements for manufacturers placing machinery for the first time in the EU market. The inclusion of cybersecurity requirements in a revised Directive would therefore not lead to an effective approach to cybersecurity and may instead open the way to a situation where different sector specific pieces of legislation include different and inconsistent requirements on cybersecurity. CECIMO's view is that a horizontal approach would be better suited to provide a clear general framework for cybersecurity and to define the obligations and liability of each actor.

The specific form of this approach would still need to be discussed but it is important to consider the interplay with other existing pieces of legislation such as the EU cybersecurity act and the future European cybersecurity certification schemes. The main purpose of cybersecurity actions concerns exogenous attacks. In this context, the machine must be seen and managed as a node of a computer system including computers, servers, routers, etc.

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
  - I do not know

* 156 Please elaborate:

This created a temporary misalignment with the legislation of other Member States. For example, in Italy the major problem occurred at the beginning when the implementation of the initial Machinery Directive of 1995 took place with a year of delay.

* 157 Have you experienced other problems due to differences in the transpositions of EU Member States?
  - Yes
  - No
  - I do not know

* 158 Please elaborate:

There are certainly some differences in interpretation in relation for example with the concept of substantial modification but the most substantial differences concern differences in enforcement due to differences in market surveillance systems and lack of cooperation of the different authorities at European level. Market surveillance authorities often lack resources and sanctions are also different. The aim of the recently adopted Regulation on compliance with and enforcement of Union harmonisation legislation is precisely to tackle these issues.

* 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)?
  - (●) Yes
  - ( ) No
  - ( ) I do not know

* 160 Please elaborate:

The conversion into a Regulation should normally lead to more uniform application of the legal requirements in the different Member States and leave less room for differences in interpretation by national authorities.

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?
  - (●) Yes
  - ( ) No
  - ( ) I do not know

* 162 Please elaborate:

This should lead to more consistency between definitions and the provisions of different product specific legislation.

Closing Questions

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

Comment in relation to Q32
It is important to highlight that machine tools are complex capital goods and that in our case we are

operating in a B2B context. Manufacturers should be free to choose the best means to provide the required instruction manuals as long as the required information is provided, and they keep track of the delivery of the manual. This means that manufacturers should have the possibility to provide manuals in a digital form. By digital form we mean online, displayed by the product or also in other supports such as DVD or USB sticks. From CECIMO's perspective the use of a Quick-Start Guide may be more appropriate in the B2C context or in the case of less complex goods. For complex goods such as machine tools it would be difficult to define and delimit the information that should be included in such a Quick-Start Guide. It is also important to note that in a B2B context a possible lack of access to the Internet is not an issue and therefore there should not be a problem in accessing online manuals.
Several companies in our sector are already providing manuals in digital form. From CECIMO's point of view this is already possible under the provisions of the Directive, which does not specify the form (digital or paper) in which the documentation needs to be provided. There is though the need to update the Guide to the application of the Machinery Directive which refers to the need to supply the instructions in paper form. There are many advantages in the use of digital manuals including the possibility of easier updates, reduction of printing costs and environmental impact. Moreover, the (increasingly frequent) availability of the manual on machine computer systems with the possibility of online updates - if the system is connected to the internet - should also be considered. In the case of complex machinery, manuals are often needed for operations and processes. Since complex machinery is usually accompanied by complex manuals, these solutions would allow to find the right information quickly, especially if integrated with augmented reality solutions.

Comment in relation to Q90
It is difficult to provide an estimate but if the involvement of Notified Bodies or third parties would be required costs will for sure increase. Some companies have provided us with a rough estimate of 0.5% of total production or purchasing costs.

Comments in relation to Q120
Our reply to Q120 refers to innovative technologies in general. New technological solutions can indeed lead to reduced costs while keeping the same or even higher safety levels. As mentioned above (Q119) our opinion is that the Directive should describe requirements in a technology neutral way. The view of our sector is that the Directive already provides the necessary framework to ensure safety of products including new technologies and therefore from the side of our sector we do not see the need to introduce changes at this stage

Comments in relation to Q129
The need to involve a third party for conformity assessment will indeed lead to increased costs. It is difficult to give a general estimation since machine tools are highly customized products and the cost is expected to increase in line with the customization of products. Some estimates received from some companies point at a 3% increase in total production costs.

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

Contact

grow-c3@ec.europa.eu