

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

Luca

* 4 Surname

Conti

* 5 Email (this won't be published)

secretariat@ceir.eu

* 7 Organisation name

255 character(s) maximum

CEIR - The European association for the Taps and Valves Industry

* 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.

54018122087-60

* 10 Country of origin

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

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

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

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

* 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

* 19 Please explain:

Valves

* 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	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Identifying the essential health and safety requirements	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Finding the right standard	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Doing the conformity assessment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Preparing documentation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Translating documentation into other EU languages	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Receiving the correct Declaration of Conformity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Receiving correct instructions	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Understanding where responsibility lies for CE marking of machinery or assemblies of machinery	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

* 22 Please explain your choices:

Machinery Directive does not apply to valves manufacturers

* 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

* 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
☐ 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
- ☐ Other

* 34 What should be included in the Quick Start Guide in addition to setting up the machine and turning it on?

- ☒ Basic handling information, weights etc.
- ☒ Details of controls
- ☒ Details of safety related control systems
- ☐ Other

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

- ☐ 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?

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

* 39 Please explain:

With each modification/update of the documentation, the documentation stock becomes obsolete and will be wasted

* 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:

CEIR is not able to assess the estimated cost

* 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:

CEIR is not able to assess the estimated cost

* 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:

Yes. Documentation lost by users, updates, etc

* 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
- ☐ 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:

CEIR is not able to assess the estimated cost

* 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
- ☒ 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
- ☒ On the Commission website
- ☒ In the Machinery Guide
- ☒ On national authorities' webpages
- ☒ 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
- ☐ 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
- ☒ 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
- ☒ 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?

	Agree	Disagree	No opinion
* 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	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* 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	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* More standards available for these products	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
* Other	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

* 67 Please explain your choices:

It is necessary to limit the grey areas of the legislation and to allow an easier understanding

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

- ☐ Yes
☒ No
☐ No opinion

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

- ☐ Costs would increase
☒ 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 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:

100

* 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

* 97 Please explain:

There are no significant accidents that would require such a change

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

- ☒ Increased
- ☐ Reduced
- ☐ No change

* 99 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

* 100 Please provide your estimate here:

100

* 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

* 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.

We have already faced cases where the reconstruction of equipment has not been done by the original manufacturer, which modifies the results of the initial risk analysis (Surface treatment that generates an ATEX risk).

* 108 Should the Directive define criteria for machinery modified substantially?

- ☐ Yes
- ☒ No
- ☐ No opinion

* 109 Please explain:

This should be clarified in the MD Guidelines

* 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'?

See reply to question 117

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

	Yes	No	No opinion
* Manufacturer	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Partly completed machinery	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Assembly	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* State of the art	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Nuclear purposes	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
* Other	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>

- * 117 Please specify/elaborate:

The definitions are fine. CEIR calls for consistency with the clarifications provided by the 1999 Machinery Directive Implementation Guide - more comments in the paper at the end of the Questionnaire

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.

No opinion

* 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

* 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 two directives do not have the same objectives: one directive aims at reducing environmental outdoor noise (Outdoor Noise Directive), while the other one aims at minimising the noise emitted by a machine (Machinery 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 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

* 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:

* 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:

It is a new technological way of meeting a user need, but the requirements and obligations for risk assessment remain the same.

* 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:

Please see answer 134

* 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:

Please see answer 134

* 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:

The manufacturer must place safe machines on the market. This principle also applies to algorithms and logic/intelligence embedded in the machine.

* 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:

The software update is a maintenance operation recommended by the manufacturer. There is no link with machinery. The question is redundant.

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

- ☐ Yes
- ☐ No
- ☒ No opinion

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:

Please see answer 134

* 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:

There is a need for cross-cutting legislation that defines the general framework of cybersecurity requirements and more specific requirements related to the type of product in sectoral legislation.

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

* 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 is a problem with Directive 2012/19/EU on waste electrical and electronic equipment, where different product scopes have different application dates in different countries.

* 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:

It seems to be too premature for CEIR to convert the Directive into a Regulation. There are still too many uncertainties about future texts and too many possible interpretations of the current text at national level.

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 alignment is useful and would clarify the obligations of the different operators.

Closing Questions

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

Some notes, comments, and further elaboration are reported in the document attached at question 164.

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

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_ContributionRevisionMachineryDirectivePublicConsultation_August2019.pdf

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