

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

Helena

* 4 Surname

LE GOFF

* 5 Email (this won't be published)

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* 7 Organisation name

255 character(s) maximum

ORGALIM-Europe's technology industries

* 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.

ID number: 20210641335-88

* 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

- | | | | |
|--|----------------------------------|---|---|
| <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:

All machinery covered by the scope of the Machinery Directive are relevant for Orgalim (ex: fork lift trucks, garden machinery).

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

* 22 Please explain your choices:

Machine manufacturers from our constituency have longstanding experience with the current Machinery Directive and are used to performing the various steps required before placing a machine on the market. Thanks to the Machinery Directive, for which Module A -self-assessment- is widely used, manufacturers from our industry have acquired expertise and do not have any problem in identifying all these steps.

There exist some problems of interpretation which are not linked to the way the directive is written but rather to specific issues of interpretation, for instance with the customs authorities in Turkey and in Switzerland there are different interpretations of standards. These problems can be solved through clarification directly with the market surveillance authorities involved. These problems are not related to the legal framework but rather to market issues.

Orgalim as an umbrella organisation considers that the MD is fit for purpose.

* 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

* 33 Please specify:

Digitalisation is knocking on the door of all companies globally and European manufacturers should not be left behind. To this end, next to the printed user manual which should remain available at all times, it is paramount that the machine users can access the manual through a digital user manual.

* 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

* 37 Please explain:

As Orgalim represents a wide variety of manufacturers and sectors, it is hard to give information on the impact. The rule would be that not only online manuals should be available but other alternatives should be used, such as the printed version if needed.

* 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:

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 increases in relation to the size of the organisation and complexity of the products in the case when multiple instruction manuals are required to accompany a machine.

- * 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:

Due to the variety of sectors Orgalim represents, as an industry association, we cannot provide an estimation.

- * 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:

Same as above

- * 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:

In case of corrections of the operating manual new copies have to be sent to the customer and the distributor. Corrections to the instruction handbook may become necessary as a result of the manufacturer's market observations.

The advantage of the electronic operating manual is the possibility to make the modified operating manual directly available to the user.

- * 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:

As an industry organisation, we cannot give an estimate of the cost savings for the various options.

* 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 type="radio"/>	<input checked="" 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 checked="" type="radio"/>	<input type="radio"/>
* Other	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

* 67 Please explain your choices:

Our manufacturers placing equipment on the market know exactly when they have to apply the MD or the LVD.

In practice, there are no significant difficulties and the current arrangements should therefore remain unchanged. A new regime would in practice raise new and different questions. A new legal practice would have to be introduced, which would entail loss of time and problems which should be avoided. A distinction between consumer products and professional/commercial products would not bring any further clarification.

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

- Yes
- No
- No opinion

* 69 Please provide an estimate of these cost changes at your choice:

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

* 70 Please provide your estimate here:

* 71 Would you consider that initial cost as significant?

- Yes
- No

* 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

* 73 Would you consider that recurrent annual cost change as significant?

- Yes
- No

* 74 Please provide an estimate of these recurrent annual cost changes at your choice:

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

* 75 Please provide your estimate here:

* 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

* 92 Please explain:

The lift industry fears safety problems if the maximum speed of 0.15m/s for lifts under the Machinery Directive were to be increased. Therefore an increase of the maximum speed of 0.15m/s is rejected.

*

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

- Increased
- Reduced
- No change

* 94 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

* 95 Please enter the estimate here:

100

* 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:

As before, only machinery designed or used for nuclear purposes should be excluded from the scope of the Machinery Directive as their failure may lead to an emission of radioactivity.

* 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.

see question 109

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

- Yes
- No
- No opinion

- * 109 Please explain:

In an economy where recycling is not only good for the environment but also used for economic reasons, machines are very often modified (whether substantially or not). Today, in the Member States, there are sometimes diverging interpretations on what stands behind the concept of modification(whether substantial or not), this can lead to problems on the market. In order to remove this barrier, Orgalim would suggest clarifying this issue in a Commission guide.

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

- Increased
- Reduced
- No change

- * 111 Please provide an estimate of the costs of such modification [at your choice]:

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

- * 112 Please provide your estimate here:

100

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

* 114 Please specify:

A vast majority of Orgalim members believe that the term 'intended use' in the official guide of interpretation is explained in a very detailed way with no significant difficulties in its application or interpretation. In order to provide the necessary flexibility for economic operators, a definition is not requested/necessary. However, a couple of Orgalim members experienced difficulties in interpretation on this matter.

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

As explained above, the issue of specific application is clearly explained in the guide of interpretation and does not pose any particular problem to the majority of Orgalim members.

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 type="radio"/>	<input checked="" type="radio"/>
* Other	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>

* 117 Please specify/elaborate:

The alignment of the Machinery Directive to the New Legislative Framework, that we warmly welcome as industry representation, will offer all the definitions necessary for our manufacturers to place safe equipment on the market. We believe there is no further need to provide a definition of partly completed machinery or machines for nuclear purposes.

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.

It is important first of all to highlight that this category only relates to a very small group of engineering products for which the existing requirements of the Annex I of the Machinery Directive are exhaustive enough for manufacturers to place equipment on the market in a safe way. The same kind of consideration applies to a potential revision of the safety requirements due to technological developments.

* 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:

100

* 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:

Requirements from the Noise Directive and the MD should ideally be aligned as most of the equipment under the scope of the MD are also under Outdoor Noise. This would enable manufacturers to reduce costs on noise requirements.

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:

Harmonised standards represent the State of the Art and when these cover all the applicable essential health and safety requirements, manufacturers of our industries have the expertise/knowledge to assess their equipment against Module A. What is more important, they remain responsible for placing their equipment on the market. There is no need to call for notified bodies.

* 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:

100

* 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:

First of all, human-robot collaboration is not new in the manufacturing industries and has already existed for decades. The fact that these robots are working in close co-operation with humans in the factory has not spiked an increase of accidents. Whereas the development of standards in this sector is booming in order that robots are manufactured to take into account all the necessary measures to avoid any safety problem, the Machinery Directive imposes on manufacturers the performance of a risk assessment of the machine, taking into account all the risks that could occur. It must be clear that robots will only perform the tasks they have been programmed for and nothing else. A series of safety controls are put in place in order to avoid accidents in case something goes wrong (for ex: in the design phase, defining the distance at which when a robot meets an obstacle (human/animal) it will automatically stop).

* 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 justification above

* 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:

The Machinery Directive has proved to be the right legal framework and the current health and safety requirements do not present any gaps in terms of safety.

* 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:

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. Orgalim does not consider it necessary to include further health and safety protection requirements in the Machinery Directive.

It is also not necessary for data records or algorithms to be disclosed to the user. On this basis, the user does not have to take any further protective measures, e.g. in his capacity as an employer. The employer who owns a machine used as work equipment takes all the measures on the basis of the operating instructions and the risk assessment to which he is obliged as an employer.

* 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:

Since the Machinery Directive covers the placing on the market and putting into service of machinery, software updates for a machine must also correspond to what the manufacturer has defined as the safety concept in the conformity assessment procedure.

According to Orgalim, the principle of placing on the market and putting into service for the health and safety protection of machinery must not be abandoned or changed. This principle has been successfully applied for many decades and is also necessary for the delimitation of the legal areas that regulate the properties of products on the one hand and the use of work equipment on the other. These two areas of law clearly and unambiguously regulate the responsibilities of economic operators. The limitation of the manufacturer's responsibility to the condition at the time of commissioning or at the time of placing on the market means a high degree of planning security, which is particularly required in the capital goods sector and which clearly defines the legal framework and practical implementation for software updates.

* 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 this definition has proved its worth in practice.

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 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 use and any reasonably foreseeable misuse thereof. This is clearly mentioned in the current wording of the Machinery Directive under:

Safety and reliability of control systems

Control systems must be designed and constructed in such a way as to prevent hazardous situations from

arising. Above all, they must be designed and constructed in such a way that:

- they can withstand the intended operating stresses and external influences,
- a fault in the hardware or the software of the control system does not lead to hazardous situations,
- errors in the control system logic do not lead to hazardous situations,
- reasonably foreseeable human error during operation does not lead to hazardous situations.

Cybersecurity is increasingly taken into consideration, by adhering to a risk-based approach depending on the intended use of the product or solution. It applies different security requirements at different levels: functional, capability, and process.

The Machinery Directive does not and should 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 sectorial legislation.
- Other

* 154 Please specify or explain why:

Orgalim urges the policymaker to take a cautious approach when introducing cybersecurity requirements into existing product legislation. Since NLF legislation is intertwined, several CE marking rules often apply to the manufacturer of machinery. Consequently, a vertical approach to cybersecurity in product legislation risks creating inconsistencies in the individual CE marking rules as they are likely to contain incoherent cybersecurity requirements.

To ensure consistency, Orgalim suggests a horizontal approach to cybersecurity for products, solutions and processes. Consistency at a horizontal level can be achieved through a set of common cybersecurity goals including life-cycle management system. These goals could for instance be based on secure development processes that incorporate principles such as the risk-based approach, taking into account the intended use and operational environment of a product, process or solution. In turn this must be supported by European and international standards that are developed jointly by operators, consumer organisations, and the manufacturing industry.

This gives a direction for manufacturers to select the most adequate cybersecurity requirements for their product, solution or process. Additionally, the manufacturer can add technical cybersecurity requirements based on existing standards.

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:

Orgalim was not made aware of specific problems on this matter.

* 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:

No specific problems

* 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:

Converting the MD into a Regulation will ensure a uniform application of the legislation in all the Member States with less room for manoeuvre in interpretation by the 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:

It is recognised that the current version of the MD is not fully aligned with the NLF. Therefore, a full alignment, as it has been the case for other legislation of the internal market, will surely guarantee a more transparent and better application of the legislation, bringing clarification to those definitions which are not yet aligned.

Closing Questions

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

Question 17:

Orgalim members represent machinery manufacturers at European level. The companies we represent have to fulfil the obligations of the manufacturer, especially to carry out the conformity assessment procedure. In some cases, a notified body has to be involved.

Question 26:

When placing a machine on the market, the manufacturer has to perform the conformity assessment and take all measures according to the State of the Art to reduce all risks linked to external influences, including connectivity risks. The concept of safety does not change as a result of a machine being connected to the internet.

Question 32

In addition to the answer provided, Orgalim is currently preparing a position on this important issue together with all its members. This position will be finalised in September 2019 for consideration by the Machinery Working Group and integration into the Guide of Interpretation of the MD.

Question 35

The Quick Start Guide should, as a minimum, include: identification and sources of information, contents of the package, initial assembly, safety warnings, instructions for use. All other information should be contained in the "original instructions" which should be available in digital format (online).

This may be not applicable for all types of machines and might need further assessment.

Question 57 (question related to the scope)

Orgalim supports its members in the application of the Machinery Directive with regard to the conformity assessment procedure, the scope of application, the preparation of the instruction handbook and the technical documentation (e.g. distinction between machinery and partly completed machinery, cooperation in the preparation of the official guide to the Machinery Directive). Orgalim member associations also support their members by providing targeted guidance on the steps of the conformity assessment procedure.

Question 70,75,90,95,100,112,122,129

Estimate is difficult for Orgalim which represent a wide variety of sectors at EU level. We therefore insert 100% to be able to continue but more precise information might be given by single manufacturers themselves.

Question 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.

Comment:

The statement above can be misleading. As per Article 10 of the Pressure Equipment Directive, the conformity assessment procedure for the various categories are as follows:

- category I Module A. Clearly category I of PED does not require the intervention of a notified body.

Question 103 (substantial modification)

According to the way it is interpreted in the Member States, a new conformity assessment procedure is performed or not.

Question 130

Elaboration of our answer in the questionnaire:

As a step further in helping companies and European industries to be more competitive compared to their global counterparts, at the moment of aligning the Machinery Directive to the New Legislative framework, Orgalim suggests to completely remove Annex IV from the Directive as manufacturers not only take the responsibility for their machines, but they have the necessary expertise and technology to place safe machines on the market. This is all the more feasible as the Commission tabled the enforcement and compliance package ensuring that better market surveillance co-ordination will take place.

Question 144

Since the Machinery Directive covers the placing on the market and putting into service of machinery, software updates for a machine must also correspond to what the manufacturer has specified in the conformity assessment procedure. No reference needs to be made to software updates or further obligations need to be included in the Machinery Directive as a result of software updates.

Question 159

Please note that our Swiss member organisation SWISSMEM is – in line with the general Orgalim position – against any revision of the Machinery Directive. However, due to political reasons related to the framework agreement between Switzerland and the EU, SWISSMEM is further not prepared to see the directive turned into a Regulation and align it with the New legislative Framework. Indeed, this change might delay the mutual recognition of legislation for political reasons only. This would be detrimental for both European manufacturers as well as Swiss manufacturers who are dependent on such a recognition.

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

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