

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

Jethro

* 4 Surname

Schiansky

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* 7 Organisation name

255 character(s) maximum

EUnited - European Engineering Industries Association

* 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.

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* 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:

Municipal Equipment such as refuse collection vehicles, road sweepers and winter maintenance equipment, robots

* 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 type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
* Preparing documentation	<input type="radio"/>	<input checked="" 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. However, when exporting to countries such as Turkey, the CE marking and DoC is not always accepted with authorities requesting additional documentation. In addition, some of our members have found that Turkey uses the Low Voltage and Machinery Directives in parallel.

* 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:

A flexible approach should be taken and manufacturers should be able to choose between the possibility to provide the manual in printed and /or electronic form to the end user.

* 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:

All of the above. However there may also be more easily accessible and intuitive information as electronic manuals could also include videos and animations etc.

* 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:

There are additional administrative costs by providing a copy of the printed manual with each product. These costs relate to the management of the manuals by the manufacturer and include storage, picking (book-selection), transfer to the appropriate machine and possible confirmation by the responsible carrier. The total cost of the manuals is constantly increasing due to the growing complexity of the products.

* 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 range of sectors represented by EUnited, we cannot provide an estimate.

- * 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:

Due to the range of sectors represented by EUnited, we cannot provide an estimate.

- * 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 observation.

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 association we cannot give a cost estimate of the savings for 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:

EUnited's members placing equipment on the market know when they have to apply the MD or the LVD as the Directives are sufficiently clear on this point

- * 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:

100

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:

100

*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

* 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.

The risk approach should be maintained, as it has proven itself in practice.

This approach focuses on the effectiveness of the protection concept of the machine, which was implemented on the basis of a risk assessment by the manufacturer, and only the risks identified by the manufacturer are covered.

However, if further risks are created or risks increased during the change of the machine, the protective concept of the machine must be validated by the person who has "changed the machine significantly" by conducting a risk assessment and by applying further protective measures based on the result of the risk assessment in order to ensure that these new or increased risks can be addressed. Such a risk assessment is only useful in the context of a conformity assessment procedure, as this makes it possible to apply the state of the art in the protective measures and an EU Declaration of Conformity, which provides the necessary clarity for the user about the safe condition of the "substantially modified" machine.

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

- Yes
- No
- No opinion

* 109 Please explain:

Please also refer to the answer to question 107. The Commission should define substantial modification more clearly in the Directive or at the very least in the Machinery Guide. But this Guidance should include both clarifications in the context of digitisation (software updates and upgrades) but also in context of circular economy (refurbishment/reuse etc).

* 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:

Most EUnited members believe that the term 'intended use' in the official guide of interpretation is clearly explained and leads to no difficulties. However, a small number of members found issues with market surveillance authorities relating to how a product was classified.

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

See answer to 114, interpretation of intended use is sufficient.

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

* 117 Please specify/elaborate:

EUnited supports alignment of the Machinery Directive with the New Legislative Framework. This will provide all the definitions necessary for our manufacturers to place safe equipment on the market.

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 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.

- * 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 Outdoor Noise Directive and the MD should be aligned as most of the equipment within the scope of the MD are also within the scope of the Outdoor Noise Directive

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

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

When an Annex IV machinery is manufactured in accordance with 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 (they are regularly updated) and when these cover all the applicable essential health and safety requirements, EUnited's members have what they need to assess their equipment against Module A. Also, they remain responsible for placing their equipment on the market. There is no need 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:

Human-robot collaboration is not new and machines of this kind have been successfully produced for many years. The fact is that robots of this kind, which interact in close cooperation with humans, have not led to an increase in the number of accidents. The development of standards is progressing in this area. Collaborating robots can be produced in such a way that they have all the necessary protective measures in place to comply with the provisions of the Machinery Directive. The manufacturers carry out conformity assessments and equip the machine on that basis with all necessary protective measures.

Robots can only perform the tasks for which they are built and programmed or which are considered as reasonably foreseeable by the manufacturer. A series of safety tests are planned in the manufacturing process, which are determined in the conformity assessment procedures so that robots can perform their tasks safely and thus pose no risks to persons or animals which could be minimised or even eliminated by measures according to the state of the art.

PLEASE NOTE: The International Standard Organisation has developed two standards which set guidelines for the safe use of industrial robots (EN ISO 10218-1 and EN ISO 10218-2) which have been developed under the Machinery Directive 2006/42/EC and which are currently under revision. These standards are harmonised standards under the Machinery Directive and listed in the OJ. This shows that the requirements of Annex I of the Machinery Directive are sufficient for collaborative robots and all risks associated with this kind of machinery are covered from the current Directive.

* 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 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:

See answer to 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:

Since machine learning takes place in an area defined by the manufacturer, in accordance with the intended use, new or modified machine functions are completely covered by the protection or safety concept of the machine. We are not of the opinion that further safety or health protection measures are necessary in the Machinery Directive. It is not necessary for data sets or algorithms to be handed over to the user. The user in his capacity as employer does not have to take any further protective measures. Employers, who have a machine in use as work equipment, must carry out all measures on the basis of the operation manuals and the risk assessment for which they are responsible as 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:

The principle of placing on the market and commissioning of machines should not be given up or changed. This principle has been used successfully for many decades and is also used for the legal clarifications that govern the properties of products on the one hand and the use of work equipment on the other hand. Both areas clearly and unambiguously regulate responsibilities of the respective economic actors. The limitation of producer responsibility to the point of time of putting the equipment into service or placing it on the market ensures a high degree of planning security, which is particularly important in the capital goods sector and which clearly defines the legal framework and the practical implementation of 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 term is clearly defined and has proven useful 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 intended 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 cyber security 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:

EUUnited calls for 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.

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:

EUUnited isn't aware of any problems in this regard

* 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:

EUUnited isn't aware of any problems in this regard

* 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 to a Regulation will ensure a uniform application in all the Member States with less room for 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:

NLF alignment will ensure 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.

On questions 70,75,90,95,100,112,122,129, providing an estimate is difficult for EUnited which represent a wide variety of sectors at EU level. We therefore insert 100% to be able to continue but more precise information may be given by individual manufacturers

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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