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

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
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

First name
Emir

Surname
DEMIRCAN

Email (this won't be published)
edemircan@semi.org

Organisation name
SEMI

Organisation size
- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
9 Transparency register number

255 character(s) maximum

Check if your organisation is on the [transparency register](https://transparencyregister.eu). It's a voluntary database for organisations seeking to influence EU decision-making.

<table>
<thead>
<tr>
<th>Large (250 or more)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Country of origin</th>
</tr>
</thead>
</table>

- Afghanistan
- Áland 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
- Bhutan
- Bolivia
- Bosnia and Herzegovina
- Botswana
- Brazil
- Brunei Darussalam
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Central African Republic
- Chad
- Chile
- China
- Colombia
- Comoros
- Congo
- Costa Rica
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greenland
- Grenada
- Grenada
- Guatemala
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Hawaii
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Israel
- Italy
- Jamaica
- Japan
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Korea
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- 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
- Mozambique
- Myanmar
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norway
- Oman
- Pakistan
- Palau
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Poland
- Portugal
- Qatar
- Romania
- Russian Federation
- Rwanda
- 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
- Spain
- Sri Lanka
- Sudan
- Suriname
- Swaziland
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The former Yugoslav Republic of Macedonia
- Timor-Leste
- Togo
- Tonga
- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Tuvalu
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- Uruguay
- Uzbekistan
- Vanuatu
- Vatican City State (The Holy See)
- Venezuela
- Vietnam
- Yemen
- Zambia
- Zimbabwe
<table>
<thead>
<tr>
<th>Name</th>
<th>Name</th>
<th>Name</th>
<th>Name</th>
<th>Name</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bermuda</td>
<td>Greece</td>
<td>Mozambique</td>
<td>Svalbard and Jan Mayen</td>
<td>Swaziland</td>
<td></td>
</tr>
<tr>
<td>Bhutan</td>
<td>Greenland</td>
<td>Myanmar/Burma</td>
<td>Sweden</td>
<td>Switzerland</td>
<td></td>
</tr>
<tr>
<td>Bolivia</td>
<td>Grenada</td>
<td>Namibia</td>
<td>Syria</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bonaire Saint Eustatius and Saba</td>
<td>Guadeloupe</td>
<td>Nauru</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bosnia and Herzegovina</td>
<td>Guam</td>
<td>Nepal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Botswana</td>
<td>Guatemala</td>
<td>Netherlands</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bouvet Island</td>
<td>Guinea</td>
<td>New Caledonia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brazil</td>
<td>Guinea-Bissau</td>
<td>New Zealand</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>British Indian Ocean Territory</td>
<td>Guyana</td>
<td>Nicaragua</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>British Virgin Islands</td>
<td>Haiti</td>
<td>Niger</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brunei</td>
<td>Heard Island and McDonald Islands</td>
<td>Nigeria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulgaria</td>
<td>Haiti</td>
<td>Niue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burkina Faso</td>
<td>Honduras</td>
<td>Norfolk Island</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Burundi</td>
<td>Hong Kong</td>
<td>North Korea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cambodia</td>
<td>Hungary</td>
<td>Northern Mariana Islands</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cameroon</td>
<td>Iceland</td>
<td>Norway</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Canada</td>
<td>India</td>
<td>Oman</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cape Verde</td>
<td>Indonesia</td>
<td>Pakistan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cayman Islands</td>
<td>Iran</td>
<td>Palau</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central African Republic</td>
<td>Iraq</td>
<td>Palestine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chad</td>
<td>Ireland</td>
<td>Panama</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chile</td>
<td>Isle of Man</td>
<td>Papua New Guinea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>Israel</td>
<td>Paraguay</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Christmas Island</td>
<td>Italy</td>
<td>Peru</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clipperton</td>
<td>Jamaica</td>
<td>Philippines</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cocos (Keeling) Islands</td>
<td>Japan</td>
<td>Pitcairn Islands</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colombia</td>
<td>Jersey</td>
<td>Poland</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comoros</td>
<td>Jordan</td>
<td>Portugal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congo</td>
<td>Kazakhstan</td>
<td>Puerto Rico</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cook Islands</td>
<td>Kenya</td>
<td>Qatar</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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:
Semiconductor manufacturing equipment

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

21 Has any of the following aspects caused difficulties?
22 Please explain your choices:

<table>
<thead>
<tr>
<th>Difficulties</th>
<th>No difficulties</th>
<th>Some difficulties</th>
<th>Major difficulties</th>
<th>No opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Identifying the risks</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>· Identifying the essential health and safety requirements</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>· Finding the right standard</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>· Doing the conformity assessment</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>· Preparing documentation</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>· Translating documentation into other EU languages</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>· Receiving the correct Declaration of Conformity</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>· Receiving correct instructions</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>· Understanding where responsibility lies for CE marking of machinery or assemblies of machinery</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>

SEMI members have reported no issues with the initial user manual (‘Original instructions’ in Annex 1 of the Machinery Directive) provided in the official Community language by machinery manufacturers, though translating the original version to other languages of the EU Member States where the machinery is placed on the market sometimes causes problems. There are cases where the machine users report that the translated version is not clear. Also important, translating user manuals to multiple EU languages are considered as a critical cost factor in our sector. SEMI members see huge benefits in digital user manuals in English. This could provide tremendous benefits both to machinery manufacturer and user. When a machine is updated after installation, the manufacturer posts digital updates of manuals online or sends them directly to the user for easy reference any time. By providing end users with digital manuals, semiconductor manufacturing equipment suppliers save time while reducing costs, manual errors and environmental impacts. Digital manuals allow authors and subject matter experts to revise manuals quickly and easily. For machine users, digital manuals make searches for the documents fast and easy. SEMI members favour having digital manuals in English since the software implemented in semiconductor manufacturing equipment runs in English and its operation training programs are delivered in English.

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
• 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

• Is it because:
  ○ The manual was too complex / technical
  ○ The manual was badly written / translated into my language
  ○ I had to read the manual in a language that was not my mother tongue
  ○ There was no translation into my mother tongue
  ○ The manual is not available to users within the organization
  ○ Other

• Please specify:

SEMI members have reported no issues with the initial user manual (‘Original instructions’ in Annex 1) provided in the official Community language by machinery manufacturers, though translating the original version to other languages of the EU Member States where the machinery is placed on the market sometimes causes problems. There are cases where the machine users report that the translated version is not clear. Also important, translating user manuals to multiple EU languages are considered as a critical cost factor in our sector. SEMI members see huge benefits in digital user manuals in English. This could provide tremendous benefits both to machinery manufacturer and user. When a machine is updated after installation, the manufacturer posts digital updates of manuals online or sends them directly to the user for easy reference any time. By providing end users with digital manuals, semiconductor manufacturing equipment suppliers save time while reducing costs, manual errors and environmental impacts. Digital manuals allow authors and subject matter experts to revise manuals quickly and easily. For machine users, digital manuals make searches for the documents fast and easy. SEMI members favour having digital manuals in English since the software implemented in semiconductor manufacturing equipment runs in English and its operation training programs are delivered in English.

• 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

• What would be the impact of switching solely to online manuals?
  □ Users would use online manuals only
  □ Users would print the online manual, but only in their own language
  □ Users would print just relevant parts of the manual
For those without internet access it would be much more difficult to access the manual

Other

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

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

Other

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:

Translating a manual into EU languages where the machinery is placed on the market is a critical cost element. The time to develop and translate technical documents, i.e. user manuals, usually depends on the length of the documents and the time needed to review and approve the technical content. Technical writers and translators state that in average it takes 3-4 hours per page to develop, translate and/or review a user manual. One manual can be 500 pages (400 - 500 words per page) for a complex semiconductor manufacturing equipment. The cost of translation is usually 10 cents per word. This means translating a manual to one language for one semiconductor manufacturing equipment can cost 20000 - 25000 euro. For languages that are less common, the costs are higher, and it requires more time. With managing the translation process and internal reviews the translation costs can increase drastically.

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:

Up to 500 pages for some semiconductor manufacturing equipment.

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:

Such examples include but are not limited to software modifications that change or add functions of the machinery; software modifications that are accompanied with user interface appearance; and reflection of changes in component function and instructions for use.

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

Cost saving opportunities with digital-only option would mainly include:
- encouraging the manual's authors and subject matter experts to enter consistent information quickly and easily, reducing errors and manual rework,
- automating processes that accelerate the creation and distribution across devices and platforms,
- digital search tools can reduce search time by 50-75%, as users of print manuals typically spend a lot of time each day for searching information (on average 40 minutes per day).
- no paper processing is needed anymore, implying better environmental performance, as well as decreased printing, scanning, postage and archiving costs.

Developing printed user manuals causes inefficiency due to:
- updating content, managing old and new versions and formatting require considerable time of staff members,
- printed documentation does not keep up with regular product developments and quickly becomes obsolete due to rapid innovation cycles,
- printed documents’ accessibility is limited and does not align with any new working methods of machinery users,
- high costs for translations, shipping and distributions (by post),
- in the era of Industry 4.0 and as due to the cost-related issues mentioned-above, by providing end-users with digital instructions, semiconductor manufacturing equipment suppliers can better match users’ health and safety requirements and improve productivity while reducing costs and increasing environmental performance.

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

64 Have you encountered problems due to exclusions of certain low voltage machinery from the scope of the Machinery Directive (Article 1.2(k))?
- Yes
- No
- I do not know

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

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

- Yes
- No
- No opinion

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

- Yes
- No
- No opinion

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

- Increased
- Reduced
- No change

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

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

90 Please provide your estimate here:

8000

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:
In the semiconductor manufacturing industry, increasing the speed limit mentioned above wouldn’t create any safety problems.

93 Would such a speed limit increase for lifts lead to increased or reduced costs for your organisation:
- Increased
- Reduced
- No change

96 The Machinery Directive excludes machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in an emission of radioactivity.

Do you agree that the exclusion should refer only to machinery specially designed or put into service for nuclear purposes which, in the event of failure, may result in a direct emission of radioactivity by the machinery itself?
- Yes
- No
- No opinion

98 Would this change lead to increased or reduced costs for your organisation:
- Increased
- Reduced
- No change

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

Have you every modified your machinery during its use?
- Yes
- No

102 Was your CE marking questioned by authorities?
- Yes
- No

103 Did you go through a certification process again?
- Yes
- No

104 Did you encounter any problem?
- Yes
- No
107 Please explain what would be the appropriate criterion to define a substantial modification of machinery, considering also the Commission Blue Guide[1] guidance in this respect.


Manufactures need to adapt existing machinery to meet current market needs. This can be done by adapting machinery to new process chemistries or adapting to improve throughput. In some situations, such modifications could be considered substantial based on the current Blue Guide. If the modified machinery is then considered new machinery, i.e. machinery placed on the market for the first time, the whole machine has to be to assessed to regulations in force. This could lead to significant modification requirements to unrelated parts of the machine resulting in the cost of adapting the machinery to be uneconomic. The concept of ‘substantial modification’ should be removed. Requirement for any modification should be limited to requiring reassessment to ensure the modification itself and any impact on the safety functions of other parts of the machine satisfying the current EHSR.

108 Should the Directive define criteria for machinery modified substantially?

- Yes
- No
- No opinion

109 Please explain:

There will always be a very wide range of modifications for machinery. Trying to define criteria when a certain modification has crossed a re-certification boundary is not the issue. There are two principle questions: a) is the machinery safe after implementing a modification, and b) who is responsible if it is not safe?

It is important to make clear that any upgrade or modification is assessed using the EHSR and, where appropriate, compliance to EN standards. This would be required if the machine is modified by an existing user under the Work Equipment Directive for example and the user would have to document the assessment similar to the Machinery Directive TCF. If the modification is supported by the original manufacturer using upgrade/modification kits that are CE compliant at the time of the modification, then the original CE mark and DoC should remain valid. If the upgrade/modification changes the model type, i.e., changes the original intended purpose of the machine, then full recertification would be required. This scenario is already covered by the existing Machinery Directive and guidance. If it is modified by a third party based in the EU with a view to re-sate then the original manufactures CE Mark will be invalid regardless of whether the modification is substantial or not, unless the original manufacturer has supplied the modification/upgrade kit, has updated the machinery TCF and confirms that the modification/upgrade is compliant with the regulation in force at the time of the modification. If the modification is not supported by the original manufacturer then the third party who modifies the machine is fully responsible for a full recertification to the Machinery Directive in force at the time of the modification.

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
In man-hours

% of your turnover
% of total production or purchasing costs

112 Please provide your estimate here:

64,000

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
- [x] Other
- [ ] I did not experience any such problems

114 Please specify:

Please refer to our proposals for “specific application” and “partly completed machinery” in the questions 115 and 116.

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

SEMI's proposal to define the notion of “specific application is as follows: Specific application is the intended use of the machinery.

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

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>No opinion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Partly completed machinery</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Assembly</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>State of the art</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Nuclear purposes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

117 Please specify/elaborate:
SEMI's proposal to "partly completed machinery" is as follows: Partly completed machinery means an assembly which is almost completed or fully functioning machinery which is only lacking some elements to perform its specific application or which is ready to be fitted to specific machinery that is subject to this Directive and because of this incomplete status cannot comply fully with the essential health and safety requirements set out in the Annex 1.

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 Questions 118 and 119 are not relevant to semiconductor manufacturing equipment.

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

123 Do you think that essential health and safety requirement (EHSR 1.5.8) on noise is coherent with the requirements of Outdoor Noise Directive 2000/14/EC?
- Yes, to a great extent
- Yes, to some extent
- Yes, to a minor extent
- No, to no extent

124 Please elaborate:

The Questions 123 and 124 are not relevant to semiconductor manufacturing equipment as semiconductor manufacturing equipment is always used inside the fab or laboratory under controlled environment.

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

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

○ Yes
○ No
○ No opinion

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

○ Yes, it will increase costs
○ Yes, it will reduce costs
○ No change expected
○ I do not know

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

○ Yes
○ No
○ No opinion

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

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

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

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

- Yes
- No
- No opinion

134 Please elaborate:

The Machinery Directive – Annex 1 requires machinery to be designed and constructed so that it is fitted for its function, and can be operated, adjusted and maintained without putting persons at risk when these operations are carried out under the conditions foreseen. The Directive also requires that machinery must be designed and constructed in such a way as to prevent abnormal use if such use would engender a risk. This requirement is adapted for environment where robots function in the same operating space with humans. Indeed, in some semiconductor manufacturing fabs, a class of robots that is called automated guided vehicles (AGVs) or rail guided vehicles (RGVs) transport wafer carriers and load/unload carriers to/from semiconductor manufacturing equipment. Under the current Machinery Directive, it is already foreseen that in case robots e.g. AGVs and RGVs, are placed within the operational space of humans, each robot in such application must be designed and constructed to reduce any risk risen due to sharing the operating space with humans. The Machinery Directive and existing industry standards (e.g. SEMI-S17) already provide detailed and well-functioning guidance mitigating health and safety risks where robots are placed.

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:

Current essential health and safety requirements are sufficient for the Machinery Directive. If machinery for particular application or industry sector needs additional safety criteria to ensure safety and health of persons working with robots in the same operating space, they should be specified by harmonized standards for the robots considered for such applications.

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:

Current essential health and safety requirements are sufficient for the Machinery Directive. If machinery for particular application or industry sector needs additional safety criteria to ensure safety and health of persons working with robots in the same operating space, they should be specified by harmonized standards for the robots considered for such applications.
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

Please explain:

The Machinery Directive addresses essential health and safety requirements, while the task of drawing up technical specifications, including transparency algorithms and datasets, are left to entrusted organisations competent in standardisation which take the current stage of technology into account. Transparency of algorithms and datasets is not a prerequisite for the safe operation of machinery.

Annex I of the Directive requires that machinery placed on the market is safe to operate based on its intended use. To assure safety compliance, Annex I requires the machinery manufacturer or an authorized representative to conduct a risk assessment to determine the particular health and safety requirements applying to the machinery, then design and construct the machinery to meet those mandates. Also required by Annex I, machinery control systems must be designed to prevent any hazards in the event of system hardware or software errors such as failures in the control system logic, including parameter outputs by machine learning algorithm. In this context, a semiconductor manufacturing equipment integrating machine learning is already pre-programmed to learn only the specific patterns and perform only the pre-defined tasks according to the intended use specified by its manufacturer. Therefore, machine learning only enables the semiconductor manufacturing equipment to conduct the functions within the boundary of operating conditions that are already pre-set by the manufacturer. Machine learning algorithms never change the function or the intended use of semiconductor manufacturing equipment and therefore do not create any unforeseen health and safety risks. The control system of any machine under the scope of the Machinery Directive is already designed and constructed in a way that it prevents the use of machine beyond its intentional use conditions. Only when the output from machine learning constitutes a part of functional safety (e.g., the output from machine learning is used to adjust a parameter of safety-related control system (SCS) that executes functional safety), transparency of algorithm and datasets may become critical to satisfy the safety requirement, but in such case applicable harmonized standard for functional safety will address this issue.

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

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)?
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 concept of placing on the market is still highly relevant, even considering that software updates can be later added on to the machinery. Placing on the market is defined as making machinery available for distribution or use through transfers of the equipment from the manufacturer to a distributor or end user. Often, placing on the market includes a transfer of the control and/or ownership of the machinery from the manufacturer to a user. On the other hand, the common practice of installing machinery software often fixes or improves certain features, ensures interoperability, or enhances machinery performance and does not include any transfer of the control and/or ownership of the machinery.

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 foreseeable misuse as defined in the Machinery Directive is still highly relevant and ensures safe operation or a halt in operation when the user unintentionally uses the machinery in a way not intended in the instructions for use. Annex 1 of the Machinery Directive states that by the iterative process of risk assessment the manufacturer shall determine the limits of the machinery, which include the intended use and any reasonably foreseeable misuse thereof. Complying with this, semiconductor equipment manufacturers design AI-embedded machinery to operate under the pre-set intended use conditions. When conducting risk assessment, the manufacturer is aware of any risk that might arise during the use of the machine.

This is also aligned with the European Commission's communication on AI in 2018. The Communication states that the EU health and safety framework already addresses the intended and foreseeable (mis)use of products when placed on the market. This had led to the development of a solid body of standards, in the area of AI-enabled devices that are continuously being adapted in line with technological progress. The further development and promotion of such safety standards and support in EU and international standardisation organisations will help enable European businesses to benefit from a competitive advantage and increase consumer trust.

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:

A cyberthreat includes any unauthorized manipulation of a device, manipulation of remote controller devices suppressing the state of a control device, or modification of its configuration (see ENISA - Good practices for Security of Internet of Things in the context of Smart Manufacturing). These and other intentional cyberattacks are criminal acts outside the scope of the Machinery Directive and not addressed by machinery safety standards. Risk assessment standards harmonized to the Machinery Directive (e.g. ISO 12100) do not explicitly address IT security attacks, which are categorized as an intentional abuse and criminal act. The determination of the limits of the machinery as part of the strategy for risk assessment and risk reduction in ISO 12100 only considers the intended use and any reasonably foreseeable misuse (see ISO 12100:2010, Clause 4). External IT security attacks and their safety implications (via vulnerabilities of the machine control system or other electronic parts) are not considered as reasonably foreseeable misuse. However, vulnerabilities to IT security attacks are considered by manufacturers of machinery when machinery is designed to be connected to the Internet or other IT systems that can be a conduit for cyberattacks. In this case, the manufacturer refers to the guidance available in ISO/TR 22100-4. Moreover, not all machinery covered by the Machinery Directive is network-connected or even designed to be remotely monitored, controlled and to have adjustable machine parameters from outside a factory.

In addition, the recently communicated EU Cybersecurity Act introduces, for the first time, EU-wide rules for the cybersecurity certification of products. The main objective of the Cybersecurity Act is to achieve a high level of cyber-resilience and cybersecurity in Information and Communication Technology (ICT) products. The Act defines ICT products as an element or a group of network and information systems to ensure that future cybersecurity schemes specify product categories, cybersecurity requirements, standards references, evaluation protocols (e.g. self-assessment or third-party evaluation), and security assurance levels. In this light, revising the Machinery Directive to address cyberthreats, while the EU Cybersecurity Act already does so, could introduce uncertainty for manufacturers of network-connected machinery.

152 What requirements if any should be added?
- Only requirements concerning safety should be added
- Safety and security requirements should be added
- Only security requirements should be added
- No obligatory requirements should be added

153 How should cybersecurity requirements for manufacturers of machinery be implemented in the EU?
- Via voluntary certification and labelling, for example the Cybersecurity Act
- Via sectorial legislation, for example the Machinery Directive
- Through a cross-cutting legislation applying to all products
- Via cross-cutting legislation complemented with more specific requirements in sectoral legislation.
- Other
• 154 Please specify or explain why:

Standards or TR (e.g. IEC 62443 series, ISO/TR 22100-4, IEC/TR 63074) should be used as appropriate to ensure machine’s safe operation or safe stop in the event of a security breach.

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:

SEMI members have reported no health and safety problems rising due to delays in transposing the Directive into national law. Member States are asked to publish correlation tables showing the relationship between the Directive provisions and the measures transposing them into national law. While national transposition measures have force of law, the Machinery Directive text itself provides a common, well-functioning reference.

• 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:

One issue rising due to transposition of the Machinery Directive into national law is the varying requirements for translating user manuals across the EU. This causes unclarity and inefficiency as the agreements between machinery manufacturers and users takes time. That being said, such issues do not create any additional health and safety risks.

• 159 Would you be in favour of having exactly the same rules on machinery safety applicable at the same time across the EU (converting the Directive into a Regulation)?
  ○ Yes
  ○ No
  ○ I do not know

• 160 Please elaborate:

The current Machinery Directive is fit for purpose and therefore no changes to its substance (scope, definitions, essential health and safety requirements etc.) are required. As mentioned above, minor delays or differences in transposing the Machinery Directive into national law is not related to essential health and safety requirements.
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:

While not a serious concern for businesses, the Machinery Directive should align with the New Legislative Framework and adapt relevant documents such as declaration of conformity, technical file, and instructions. For instance, SEMI members have fielded requests to include an Annex IIB for partly completed machinery. Using this Annex may require clarification as necessary. In the area of enforcement, market surveillance authorities should be better coordinated since market enforcement varies from one Member State to another and in some cases is too lax, potentially posing environmental, health and safety risks to users.

Closing Questions

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

In conclusion, SEMI members are convinced that the current Machinery Directive is still fit for purpose and does not cause any legal gaps concerning health and safety. SEMI members have been using AI applications for years, without posing any health and safety risks. The Directive provides essential health and safety requirements but remains technology-neutral and allows manufacturers to comply by using harmonized standards aligned with the state-of-the-art technologies. While no drastic revision is needed, SEMI members fully support the idea of using digital user manuals and relaxed translation requirements, which can be agreed on by the machinery user and manufacturer.

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

a91cc95e-bcf1-4839-8810-f3daacea1731/SEMI_Comments_Summary_MD_Revision_August_2019.pdf
Contact
grow-c3@ec.europa.eu