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

Fields marked	l with *	are mand	latory
---------------	----------	----------	--------

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

 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	
*4 Surname *5 Email (this won't be published)	
*6 Scope International Local National Regional	
*7 Organisation name 255 character(s) maximum	
*8 Organisation size	

Lithuanian

- 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 <u>transparency register</u>. It's a voluntary database for organisations seeking to influence EU decision-making.

10 Country of origin Please add your country of origin			
Afghanistan	Djibouti	Libya	Saint Pierre and Miquelon
Åland Islands	Dominica	Liechtenstein	Saint Vincent and the Grenadines
Albania	DominicanRepublic	Lithuania	Samoa
Algeria	Ecuador	Luxembourg	San Marino
AmericanSamoa	Egypt	Macau	São Tomé and Príncipe
Andorra	El Salvador	Madagascar	Saudi Arabia
Angola	Equatorial Guinea	Malawi	Senegal
Anguilla	Eritrea	Malaysia	Serbia
Antarctica	Estonia	Maldives	Seychelles
Antigua and Barbuda	Ethiopia	Mali	Sierra Leone
Argentina	Falkland Islands	Malta	Singapore
Armenia	Faroe Islands	Marshall Islands	Sint Maarten
Aruba	© Fiji	Martinique	Slovakia
Australia	Finland	Mauritania	Slovenia
Austria	Former Yugoslav Republic of Macedonia	Mauritius	Solomon Islands
Azerbaijan	France	Mayotte	Somalia
Bahamas	French Guiana	Mexico	South Africa
Bahrain	FrenchPolynesia	Micronesia	 South Georgia and the South Sandwich Islands
Bangladesh	FrenchSouthern andAntarctic Lands	Moldova	South Korea

BarbadosBelarusBelgiumBelizeBeninBermuda	GabonGeorgiaGermanyGhanaGibraltarGreece	MonacoMongoliaMontenegroMontserratMoroccoMozambiqueMyanmar	 South Sudan Spain Sri Lanka Sudan Suriname Svalbard and Jan Mayen Swaziland
BoliviaBonaire Saint Eustatius and Saba	GrenadaGuadeloupe	/Burma Namibia Nauru	SwedenSwitzerland
Bosnia and Herzegovina	Guam	Nepal	Syria
 Botswana Bouvet Island Brazil British Indian Ocean Territory 	GuatemalaGuernseyGuineaGuinea-Bissau	NetherlandsNew CaledoniaNew ZealandNicaragua	TaiwanTajikistanTanzaniaThailand
British VirginIslands	Guyana	Niger	The Gambia
BruneiBulgaria	HaitiHeard Island and McDonald Islands	NigeriaNiue	Timor-LesteTogo
Burkina FasoBurundiCambodia	HondurasHong KongHungary	Norfolk IslandNorth KoreaNorthernMariana Islands	TokelauTongaTrinidad and Tobago
CameroonCanadaCape VerdeCayman Islands	IcelandIndiaIndonesiaIran	NorwayOmanPakistanPalau	TunisiaTurkeyTurkmenistanTurks and Caicos Islands
Central AfricanRepublic	Iraq	Palestine	Tuvalu
ChadChile	IrelandIsle of Man	PanamaPapua NewGuinea	UgandaUkraine
China	Israel	Paraguay	United Arab Emirates
Christmas Island	Italy	Peru	UnitedKingdom
ClippertonCocos (Keeling)Islands	JamaicaJapan	PhilippinesPitcairn Islands	United StatesUnited StatesMinor OutlyingIslands

Colombia	Jersey	Poland	Uruguay
Comoros	Jordan	Portugal	US Virgin Islands
Congo	Kazakhstan	Puerto Rico	Uzbekistan
Cook Islands	Kenya	Qatar	Vanuatu
Costa Rica	Kiribati	Réunion	Vatican City
Côte d'Ivoire	Kosovo	Romania	Venezuela
Croatia	Kuwait	Russia	Vietnam
Cuba	Kyrgyzstan	Rwanda	Wallis and Futuna
Curação	Laos	SaintBarthélemy	Western Sahara
Cyprus	Latvia	Saint HelenaAscension andTristan daCunha	Yemen
Czech Republic	Lebanon	Saint Kitts and Nevis	Zambia
Democratic Republic of the Congo	Lesotho	Saint Lucia	Zimbabwe
Denmark	Liberia	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)
0	Distributor of machinery (or parts)
	Industry association of producers, importers or distributors of machinery (or parts)
0	Professional/worker using machinery
0	Private user of machinery
0	Consumer organisation
	Researcher/academia
	Machinery safety consultant
	Authority that enforces machinery rules
0	Standardisation organisation
0	Notified Body
0	Other
16	Is your organization representing standardisers at: National level European level Are you involved in: EC type-examination Quality assurance Please explain:
en	eral questions
sele	What kind of machinery is relevant for you or your organisation/institution? ect 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 useLeisure industryMachine tool manufactureOther				
Please explain:				
Have you experienced (or heard about) ling machinery to other countries in the E Yes No No opinion Has any of the following aspects caused	U/EFTA/S	witzerland/		from o
That any of the following aspects causes	No difficulties	Some difficulties	Major difficulties	No opinior
* Identifying the risks	0	0	0	0
* Identifying the essential health and safety requirements	0	©	©	0
* Finding the right standard	0	0	0	0
* Doing the conformity assessment	0	0	0	0
* Preparing documentation	0	0	0	0
* Translating documentation into other EU languages	0	0	0	0
* Receiving the correct Declaration of Conformity	0	0	0	0
* Receiving correct instructions	0	©	©	0
* Understanding where responsibility lies for CE marking of machinery or assemblies of machinery	0	0	0	0
2 Please explain your choices:	'			

*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? O Yes No No opinion		
*24 Please specify the problem and the type of machinery:		
*25 Was the machinery that caused the problem purchased from a company in the EU/EFTA/Switzerland/Turkey? Yes No I do not know		
*26 Have you ever encountered (or heard about) situations in which the safety of users (or domestic animals or property) was at risk as a result of the internet connection of the machinery? Yes No No opinion 		
*27 Please specify the problem and the type of machinery:		
*28 Was the machinery that caused the problem purchased from a company in the EU/EFTA/Switzerland/Turkey? O Yes O No O I do not know		
*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)? Output Pres No I do not usually read the user manual No opinion		
*30 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
*31 Please specify:
*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:
*34 What should be included in the Quick Start Guide in addition to setting up the machine and turning it on? Basic handling information, weights etc. Details of controls Details of safety related control systems Other *35 Please specify:
*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:
*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:
*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:
*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 individua manuals, number of pages, cubic meters or other ways of measuring it:
*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:
*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:
*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 48 Please specify:
*	49 Were your domestic robots purchased in the EU/EFTA/Switzerland/Turkey? Yes No I do not know
*	50 Are any of your domestic robots connected to the internet? Ves No I do not know
y a	51 When using domestic robots, have you ever encountered situations in which your safety, or the safety of someone else, or domestic animals, or property, was at risk? Yes No I do not know
*	52 Please specify the problem:
	53 Was the machinery that caused the problem purchased in the EU/EFTA Switzerland/Turkey? Ves no I do not know
	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
*55 Please specify:
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
*57 Please specify:
*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

NoNot applicable			
*60 Was the product in question: Household appliance intended for domestic use Audio or video equipment Information technology equipment Ordinary office machinery Low-voltage switchgear or control gear Electric motor Large high-volume printer Other			
*61 Have you encountered problems in ensuring complian O Yes No	nce for y	our produ	ct?
*62 Have national authorities (market surveillance) question which directive/national rules to comply with? O Yes No	oned yo	ur decisio	n on
*63 Please explain what needs to be clarified and how:			
*64 Have you encountered problems due to exclusions of machinery from the scope of the Machinery Directive (Articon Yes No I do not know		_	je
*65 Please explain. If possible, provide statistics on the nuthere has been confusion about how to apply the Article 1.			nere
66 Would the following changes make it clearer as to white Directive 2006/42/EC or Low Voltage Directive 2014/35/EU		•	ery
	Agree	Disagree	No opinion

	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	0	0	•

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	0	0	0
* More standards available for these products	0	0	0
* Other	0	0	0
*67 Please explain your choices:			
*68 Would the above changes require some one-off investraining, new equipment, new internal procedures, etc.? O Yes	stments,	such as s	taff
NoNo opinion			
*69 Please provide an estimate of these cost changes at In man-hours % of your turnover % of your total production or purchasing costs	your cho	vice:	
*70 Please provide your estimate here:			
*71 Would you consider that initial cost as significant? © Yes © No			
*72 Would the above changes lead to change in recurrent compliance with the Directive requirements? Costs would increase Costs would not change Costs would decrease	t annual	costs of	
*73 Would you consider that recurrent annual cost chang O Yes No	e as sigr	nificant?	
*74 Please provide an estimate of these recurrent annual choice: In man-hours % of your turnover % of your total production or purchasing costs	cost cha	anges at y	our/

76 Have you encountered enforcement/standardisation pactusions of certain low voltage machinery from the scope pirective (Article 1.2(k))? Yes No I do not know	e of the	Machiner	
77 Please explain. If possible, provide statistics on the number of the statistics of the st			
78 Would the following changes make it clearer as to wheirective 2006/42/EC or Low Voltage Directive 2014/35/E		•	ery
	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	0	0	0
* 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	0	0	0
*	0	0	0
More standards available for these products			0
More standards available for these products * Other	0		
*	0		

*81 Please explain. If possible provide your estimation of the reduction of non-compliant machinery on the market:

15

*82 Would those changes result in additional or reduced costs for your administration? O Yes increased costs O Yes reduced costs O No change O I do not know
*83 Would these changes impact the annual costs for enforcement/standard setting? O Yes No I do not know
*84 Please provide an estimate of these annual costs at your choice: In man-hours % of your turnover
*85 Please provide your estimate here:
*86 The Pressure Equipment Directive 2014/68/EU contains specific essential safety requirements to address hazards due to pressure. However, pressure equipment classified no higher than category I is excluded from the Pressure Equipment Directive and can be covered by the Machinery Directive (e.g. motorised valves, pressure cookers). As a consequence, that product can be self-assessed by the manufacturer instead of involving a third party conformity assessment body to certify it.
Do you consider that this exclusion from the Pressure Equipment Directive (which has specific essential safety requirements to address hazards due to pressure) leads to increased safety concerns (such as explosion due to pressure)? Yes No No one 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:

IncreasedReducedNo 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:
*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:
*93 Would such a speed limit increase for lifts lead to increased or reduced costs for your organisation: Increased Reduced No change
*94 Please provide an estimate of the costs of such change [at your choice]: In man-hours % of your turnover % of your total production or purchasing costs
*95 Please enter the estimate here:

*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.

or put into service for nuclear purposes which, in the event of failure, may result a direct emission of radioactivity by the machinery itself? Yes No No opinion	t in
*97 Please explain:	
*98 Would this change lead to increased or reduced costs for your organisation Increased Reduced No change	า:
*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:	
*101 The Machinery Directive applies to products placed on the market for thei 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.	е
Have you every modified your machinery during its use? Ves 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	

Do you agree that the exclusion should refer only to machinery specially designed

*105 What kind of problem?
*106 How was it solved?
*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.
*108 Should the Directive define criteria for machinery modified substantially? O Yes No No opinion
*109 Please explain:
*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:
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:

instead of partly com The manufacturer of	pleted partly uireme	macl comp ents w	ninery bleted mac which caus	for instance as machinery hinery did not fulfil all the ed problems for the CE marking
*114 Please specify:				
*115 How would you defin				•
To be you trimin triat of	Yes	No	No opinion	
* Manufacturer	0	0	0	-
* Partly completed machinery	0	0	©	
* Assembly	0	0	•	
* State of the art	0	0	0	
* Nuclear purposes	0	0	•	
* Other	0	0	©	
*117 Please specify/elabo	rate:			

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

which are not completely enclosed? Ves 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.
*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:
*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? O Yes, to a great extent O Yes, to some extent O Yes, to a minor extent O No, to no extent
*124 Please elaborate:
Questions related to categories of machinery which may be subject to
conformity assessment involving a Notified Body (Annex IV)

technologies to be used such as for example light barrier curtains, for carriers

*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:
*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 reduce pasts
Yes, it will reduce costsNo change expectedI do not know
*128 Please provide an estimate of the additional / reduced costs of such change at your choice: In man-hours of your turnover of your total production or purchasing costs
*129 Please provide your estimate here:
*130 Do you think that other high risk categories of machinery should be added to Annex IV, therefore subject to conformity assessment procedures involving a notified body when harmonized standards that cover all of the applicable essential health and safety requirements are not used? Output Pes No No opinion
*131 Please provide an estimate of the additional costs of such change [at your choice]: In man-hours of your turnover of your total production or purchasing costs
*132 Please provide your estimate here:

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 cyberattacks, 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:
*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? O Yes O No O No opinion
*136 Please explain:
*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:

choice]: In man-hours of your turnover.
% of your total production or purchasing costs
140 Please provide your estimates here:
*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?
YesNo
No opinion
*142 Please explain:
*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? O Yes O No
No opinion
*144 How should software updates be treated under the Machinery Directive?
*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? O Yes No

*147 Please explain:
*148 Do you think that the concept of foreseeable misuse as defined in the Machinery Directive is still relevant? O Yes O No No opinion
*149 Please explain:
Questions for potential adaptation to cybersecurity
Cybersecurity can be considered as protection against the criminal or unauthorized use of electronic d 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? O Yes O No O No opinion
*151 Please explain how:
*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:

No opinion

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

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

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