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

Fields marked with * are mandatory.	Fields marked with
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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	
Lithuan	ian
Maltese	
Polish	
Portugu	1999
Romani	
Slovak	
Slovan	an
SpanishSwedish	
Swedisi	
*2 Lam giving	my contribution as
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	as association
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© EU citiz	
	mental organisation
Non-EL	
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Public a	· · · · · · · · · · · · · · · · · · ·
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Other	
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*3 First name	
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*4 Surname	
CAMPOGRA	ANDE
★ 5 Email (this	won't be published)
d.campograr	ado@fice.cu
u.campograf	ide@ilec.eu
*7 Organisation	on name
255 character(s)) maximum
FIEC - Europ	pean Construction Industry Federation
	•
*8 Organisation	on size
_ •	1 to 9 employees)
•	10 to 49 employees)
•	i (50 to 249 employees)
- IVICUIUII	

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.

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	Country of origin ase add your country of origin, or	that of your organisation				
(□ Afghanistan	Djibouti	0	Libya	0	Saint Pierre and Miquelon
(Åland Islands	Dominica	0	Liechtenstein	0	Saint Vincent and the
(Albania	DominicanRepublic	0	Lithuania	0	Grenadines Samoa
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(American Samoa	Egypt	0	Macau	0	São Tomé and Príncipe
(Andorra	El Salvador		Madagascar		Saudi Arabia
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(Anguilla	Eritrea		Malaysia		Serbia
(Antarctica	Estonia		Maldives		Seychelles
(Antigua and Barbuda	Ethiopia	0	Mali	0	Sierra Leone
(Argentina	Falkland Islands		Malta		Singapore
(Armenia	Faroe Islands	0	Marshall Islands	0	Sint Maarten
(Aruba	© Fiji		Martinique		Slovakia
(Australia	Finland		Mauritania		Slovenia
(Austria	North Macedonia	0	Mauritius	0	Solomon Islands
(Azerbaijan	France		Mayotte		Somalia
(Bahamas	French Guiana		Mexico		South Africa
(Bahrain	French Polynesia	0	Micronesia	0	South Georgia and the South Sandwich Islands
(Bangladesh	FrenchSouthern andAntarctic Lands	0	Moldova	0	South Korea
(Barbados	Gabon		Monaco	0	South Sudan
(Belarus	Georgia		Mongolia	0	Spain
(Belgium	Germany		Montenegro	0	Sri Lanka
([▶] Belize	Ghana		Montserrat	0	Sudan
(Benin	Gibraltar		Morocco	0	Suriname

Bermuda	Greece	Mozambique	Svalbard and Jan Mayen
Bhutan	Greenland	Myanmar /Burma	Swaziland
Bolivia	Grenada	Namibia	Sweden
Bonaire Saint	Guadeloupe	Nauru	Switzerland
Eustatius and Saba			
Bosnia and	Guam	Nepal	Syria
Herzegovina		·	_
Botswana	Guatemala	Netherlands	Taiwan
Bouvet Island	Guernsey	New Caledonia	Tajikistan
Brazil British Indian	© Guinea	New Zealand	Tanzania
British IndianOcean Territory	Guinea-Bissau	Nicaragua	Thailand
British Virgin	Guyana	Niger	The Gambia
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Brunei	Haiti	Nigeria	Timor-Leste
Bulgaria	Heard Island	Niue	Togo
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	Islands		
Burkina Faso	Honduras	Norfolk Island	Tokelau
Burundi	Hong Kong	North Korea	Tonga
Cambodia	Hungary	Northern	Trinidad and
Comoroon	♠ loolond	Mariana Islands	
CameroonCanada	IcelandIndia	NorwayOman	TunisiaTurkey
CanadaCape Verde	IndiaIndonesia	Pakistan	TurkeyTurkmenistan
Cape verdeCayman Islands	Iran	Palau	Turks and
Odyman islands	παπ	- I alau	Caicos Islands
Central African	Iraq	Palestine	Tuvalu
Republic	•		
Chad	Ireland	Panama	Uganda
Chile	Isle of Man	Papua New	Ukraine
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China	Israel	Paraguay	United ArabEmirates
Christmas	Italy	Peru	United
Island	lary	o i Giu	Kingdom
Clipperton	Jamaica	Philippines	United States
Cocos (Keeling)	Japan	Pitcairn Islands	United States
Islands	•		Minor Outlying
			Islands
Colombia	Jersey	Poland	Uruguay
Comoros	Jordan	Portugal	US Virgin
n Conso	Mozalchata:	Duarte Dies	Islands
Congo	KazakhstanKazakhstan	Puerto RicoOstar	UzbekistanVapuatu
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	Saint Barthélemy	WesternSahara
Cyprus	Latvia	Saint HelenaAscension andTristan daCunha	Yemen
Czechia	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)
 - 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]
*20 Have you experienced (or heard about) difficulties in buying machinery from or selling machinery to other countries in the EU/EFTA/Switzerland/Turkey? O Yes O No O No opinion
*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
*24 Please specify the problem and the type of machinery:

Other examples: Example 1: Poor locking of quick couplers or interchangeable equipment such as a working platform mounted on a telescopic forklift or a bucket on earthmoving machinery Example 2: Crashing of pedestrians by a construction machine when moving a machine with a lack of visibility by design; Example 3: Fall of the operator when accessing the machine: cabin, platform or points useful for his maintenance: Example 4: Unintentional start-up of a machine following inadvertent activation of the controls; Example 5: Overturning a machine due to a lack of stability; Example 6: Mechanical failures of a machine leading to its overturning, or impossibility to stop its translation; Example 7: Exposure of users to vibration levels or noise levels detrimental to their health; Example 8: Danger to users during assembly/disassembly of a machine due to the impossibility to do so safely; Example 9: Possible disablement of a security function that exposes users to an unacceptable risk *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 *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 *30 Is it because:

Machines approved by a notified body, but yet not in compliance with some national legislation or with the

harmonised standard.

- 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: Manual badly written No translations Incomplete data on OSH Manual is too complex/technical (some manuals are difficult to read and to understand) Manual is difficult to access quickly for operational staff Manual is not available to users of the organisation *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 Basic handling information, weights etc. Details of controls
- *34 What should be included in the Quick Start Guide in addition to setting up the machine and turning it on?

 - Details of safety related control systems
 - Other
- *35 Please specify:

All relevant OSH data and instructions / limitations

- *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:

Different levels of development and different uses in the different Member States require different types of accedd to manuals (on-line and printed)

- *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
- *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

None of them

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)

*64 Have you encountered problems due to exclusions of certain low voltage machinery from the scope of the Machinery Directive (Article 1.2(k))? Ves 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
*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:

Will depend on the risk analysis and can be different depending on the different situations/applications, but potentially it bears new risks

*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
- * 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.

Modifications affecting specific or general safety of the product

- * 108 Should the Directive define criteria for machinery modified substantially?
 - Yes
 - No
 - No opinion
- *109 Please explain:

Needs to be more specific and easy to apply for specific adaptations and innovations

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

* Manufacturer	0	0	•	
* Partly completed machinery	•	0	0	
* Assembly	•	0	©	
* State of the art	0	0	•	
* Nuclear purposes	0	0	•	
* Other	0	0	•	
*117 Please specify/elabor	ate.			
NA	ato.			
IVA				
O 11		11	111	- (-)
Questions related to es	sentia	ai nea	ith and s	afety requirements (Annex I)
innovation given that there for example light barrier or Do you think that the safet technologies to be used, swhich are not completely which are not completely or Yes No No opinion	e are ourtains ty requeuch as enclos	other to s. uireme s for e ed?	echnologio nts shoulo xample lig	Such a requirement may restrict cal solutions on the market, such as do be revised to allow innovative ght barrier curtains, for carriers or co-run buttons.
Same level of safety but safety	requirer	ments sh	ould be revis	ed in order to take such changes into account
*123 Do you think that essence is coherent with the Yes, to a great exter				y requirement (EHSR 1.5.8) on

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

Yes

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

No

No opinion

NA

*124 Please elaborate:

In general good synergies and similarities. Outdoor noise reduction must focus on reduction of noise at its source. Working environment would benefit from this.

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:

Self-assessment is often incomplete as regards taking into account all the relevant standards

- * 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
 - O 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:

0			

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)? O Yes O No No opinion * 134 Please elaborate:
* 134 Flease elaborate.
Human/machine interference has to be further taken into account
* 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 No No No opinion
*136 Please explain:
Safety of the worker
* 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:
Human/machine interference has to be further taken into account

139 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
140 Please provide your estimates here:
0
* 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
* 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
* 144 How should software updates be treated under the Machinery Directive?
Mentioned as manufacturers responsibility
* 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:
NA
* 148 Do you think that the concept of foreseeable misuse as defined in the Machinery Directive is still relevant?

No No opinion 149 Please explain: NA 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: Responsibility of the manufacturers 152 What requirements if any should be added? Only requirements concerning safety should be added Safety and security requirements should be added No obligatory 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	(· ·
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 Through a cross-cutting legislation applying to all products Via cross-cutting legislation complemented with more specific requirements in sectoral legislation. Other 	*153 imp	 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 How should cybersecurity requirements for manufacturers of machinery be blemented in the EU? Via voluntary certification and labelling, for example the Cybersecurity Act Via sectorial legislation, for example the Machinery Directive

*154 Please specify or explain why:

Better taking into account sectorial specificities

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?

- YesNoI do not know
- * 157 Have you experienced other problems due to differences in the transpositions of EU Member States?
 - Yes
 - No
 - I do not know
- *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 period chosen for the consultation (i.e. during the summer break) did not allow us to define a clear overall position on this important issue.

Although there are several member federations in favour, on the basis that it would improve OSH more equally throughout the EU, there are also other member federations which do not support such a change.

Due to national legislations, there may be different rules from one country to another, whether it is in the context of a Directive or of a Regulation. In all cases, the common repository of Essential Health and Safety Requirements must be maintained.

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:

Improving market surveillance and enforcement of legislation

Closing Questions

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

The period chosen for the consultation (i.e. during the summer break) did not allow us to collect input from all our members nor to discuss with them in depth the important issues at stake.

We may therefore adapt our views/positions on some of the aspects during the developments of the discussions/process.

In particular as regards question 159 (i.e. converting the Directive into a Regulation), although there are several member federations in favour, there are also others which do not support such a change.

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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