



Raising standards for consumers

POSITION PAPER

Proposal for a Regulation of the European Parliament and of the Council on MACHINERY PRODUCTS:

Key issues from a consumer perspective



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EXECUTIVE SUMMARY

On 21 April 2021, the European Commission published a Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on machinery products.

The Machinery Directive has generally worked well in providing a sufficient level of safety for consumers in the EU, as well as aiding the free movement of machinery products. Consumers benefit from the greater choice of products, and from competition. However, some limitations can still be observed.

In reply to the European Commission Inception Impact Assessment from 2019 on the Revision of the Machinery Directive 2006/42/EC, ANEC agreed the Directive needs updating to improve safety levels further, taking account of the latest IT innovations¹. As the Machinery Directive covers many consumer products, like gardening equipment, it is imperative for the revised legislation to ensure the same level of protection for consumers as for workers.

In this position paper, ANEC gives recommendations on the provisions that need to be modified in the Commission's proposal for a regulation on machinery products in order to ensure the highest practicable level of safety for consumers.

We call for:

- Fairground and amusement park equipment to be included in the scope
- Means of transport, like e-bikes and e-scooters, not to be excluded from the Regulation, OR alternatively, for dedicated legislation to be in force to cover the exclusion of means of transport.
- The inclusion of the concept of foreseeable use in the determination whether the machine poses a high risk, and not only the intended use, especially for AI systems.
- A revitalisation of the European Injury Database (EU-IDB), in order to assess whether a machine is posing a high risk for consumers.
- Annex I on high-risks machines to include escalators.
- The appropriateness of the provision of instructions for use in electronic form instead of in paper form to be subject to a specific risk assessment by the manufacturer.
- CE marking to be relegated to the technical file/documentation

¹ <https://www.anec.eu/publications/position-papers/795-revision-of-the-machinery-directive-2006-42-ec-anec-reply-to-the-ec-inception-impact-assessment>

1 | A Regulation will ensure a uniform level of safety in the Internal Market

ANEC welcomes that the proposal takes the form of a Regulation. A Regulation imposes rules and requirements that are applicable at the same time throughout the Union, and which do not give room for divergent transposition by Member States. Experience has shown that a Directive can lead to different interpretation and deadlines, creating different level of safety for consumers and burden for economic operators in the single market.

2 | Scope and definitions

We welcome the reference to the concept of **substantial modifications**. However, we believe that maintenance and repair operations by third parties are not to be considered as substantial modifications.

'Slow lifts' are not explicitly included in the scope of the draft Machinery Regulation. The Machinery Directive applies to slow lifts by default because the Lifts Directive excludes 'lifting appliances whose speed is not greater than 0.15 m/s'. Since there are specific requirements for slow lifts (section 6) in the Machinery legislation, it would make sense to list slow lifts in the scope along with a definition of a 'slow lift'.

3 | Exclusions

3.1 Means of transport

The exclusion of the **means of transport** on road is extended beyond the Union type approval legislation to increase the legal certainty. However, this exclusion will result in the absence of European legislation for several consumer products, like e-bikes, which are becoming more and more popular. Unfortunately this popularity carries a price as e-scooter accidents and injuries are on the rise. We refer e.g. to the Safety Gate notifications on e-scooters².

Absence of EU legislation for these products is of no benefit to manufacturers, consumers or standardisers.

- We call for the Regulation to include e-bikes, e-scooters and similar means of transport
- Alternatively, we urge the European Commission and the co-legislators to start developing dedicated legislation (or the elaboration of GPSD safety requirements and standards), to be in force by the time the Machinery Regulation exclusion applies.

It is crucial to have a legal basis for these products and no safety gap in the protection of consumers.

² <https://ec.europa.eu/safety-gate-alerts/screen/webReport>

3.2. Fairground and amusement park equipment

According to Article 2 (2) b), “specific equipment for use in fairgrounds and/or amusement parks” is excluded from the scope.

The outcome of the impact assessment study says: *The majority of interviewed stakeholders agreed that the specific equipment for use in fairgrounds and/or amusement parks and its use require clarification. For all stakeholder types (national authorities, notified bodies, manufacturers, consumer organisations, workers associations and market surveillance authorities), most agreed that the exclusion on specific equipment for use in fairgrounds and/or amusement parks should be removed.*

We regret this feedback is not reflected in the proposed Regulation.

In 2018, we welcomed adoption of three European standards for amusement rides and devices (EN 13814-1, EN 13814-2 and EN 13814-3). These standards are unfortunately not harmonised, as equipment for use in fairgrounds and amusement parks does not fall under any EU legislation.

Over the years, the concept and the design of this equipment has changed considerably into bigger, more exciting and more hazardous attractions. Although millions of consumers make use of this machinery (often when being on a holiday abroad), very serious accidents continue to happen.

- We call for the Regulation to include fairground and amusement park equipment in order to offer a high level of consumer protection and to reflect the outcome of the impact assessment study.

An exclusion will lead to continued absence of a European legal framework for fairground and amusement park equipment which is not acceptable.

3.3. Household appliances intended for domestic use

According to Article 2 (2) m) (i), “household appliances intended for domestic use which are not electrically operated furniture” are excluded from the scope.

Annex I of Directive 2014/35/EC (Low Voltage Directive), points 2 c) and 3 a) both refer to mechanical safety. This has created some problems in the standardisation work. The draft standard for electrical furniture under CENELEC TC 61 is also dealing with mechanical safety, e.g. stability. This has caused a lot of discussion, as furniture experts (CEN TC 207) do not want electrical experts to work on mechanical issues. According to the LVD, the electrical experts need to take mechanical safety into account. In Europe, there are furniture standards dealing with mechanical requirements which may not be identical to what has been put into the electrical standard. The same problem has occurred for hoverboards.

We might in future see other examples where CENELEC does not have the expertise to write mechanical requirements or where consumers will be better protected by the Machinery legislation.

Although we do not think the Machinery Regulation should cover for shortcomings in the Low Voltage Directive, we draw attention to cases where users of products covered by machinery legislation are being better protected than users of similar products

covered by the LVD. We think these additional safeguards need to be maintained in the Machinery Regulation.

4 | High-risk machinery (art 5)

We welcome the **provisions** on high-risk machinery and the list contained **in Annex I**.

However, in order to cover the consumer behaviours and what influences them (which might be different from workers behaviours), we suggest introducing the concept of **foreseeable use**, based on the following elements: the technical and functional characteristics of the machine, the factual and human behaviours and physical characteristics, the relation with other machines/products and the use with other machines/products.

- We call for the inclusion of the concept of foreseeable use in the determination on whether the machine poses a high risk, and not only the intended use.

We also think that it would be helpful for the Commission and the Member States to consult a pan European **accidents and injuries database** in order to assess whether a machine is posing a high risk for consumers. The need for specific injury surveillance systems on relevant external risk factors was recognised long ago in the occupational safety area. Due to the specific needs for information, this sector has developed its own systems to provide meaningful and statistically reliable information for evidence-based prevention policies. European consumer safety also needs solid injury data.

- We call³ for a revitalisation of the European Injury Database (EU-IDB): Parliament, Member States and the Commission should strive for a legal framework, which supports Member States in collecting and sharing data on injuries involving consumer products, based on a common methodology, with the aim of achieving a high quality, representative and up-to-date data sample for the entire Single Market.

We welcome the inclusion of **AI** products and components in Annex I as it is essential to ensure a high level of consumer protection with regards to autonomous systems. Because of the link of this proposal with the draft AI Regulation, we will further comment on the latter in terms of principles and requirements.

Escalators are machines with greater risk factor and potential for danger than comparable other machines. They have unrestricted, public access and are intended to be used by unskilled persons/laypersons (including children, older persons and persons with disabilities), without instructed personnel. They have crushing and shearing points. There are high risks in case of failure of the controls.

- We call for Annex I to include escalators.

³ European consumer safety needs solid injury data, ANEC-EuroSafe position paper (<https://bit.ly/352G2gQ>) and infographic (<https://bit.ly/3eIA3RL>), November 2020

5 | Presumption of conformity of machinery products

5.1 Implementing acts establishing technical specifications (Art. 17 (3)-(4))

The European legislators delegate to the European Commission the power to request the European Standardisation Organisations (ESOs) to develop standards in line with the principles of Regulation 1025/2012 (consensus, coherence, transparency, openness, independence of special interests, efficiency). However, as the ESOs can refuse to accept a standardisation request, which validity ceases if not accepted, it is opportune to foresee a fall-back solution in case of lack of Harmonised Standards.

However, we suggest that the Commission is invited to conduct extensive stakeholders consultations on the draft implementing acts containing the technical specifications, beyond the usual comitology procedures, in order to ensure that the views of all stakeholders are duly considered.

5.2 Conformity under a cybersecurity scheme

We wonder whether the reference to future **cybersecurity** scheme adopted to meet the essential safety requirements of the Machinery Regulation is appropriate, bearing in mind the uncertainty about the existence of such future schemes and the different scope of the two Regulations.

6 | Conformity assessment

We welcome that for **high-risk machinery** only third-party certification is foreseen, even when manufacturers apply the relevant Harmonised Standards, especially with regards to AI products. We are in favour of the principle '**the higher the risk, the higher the conformity assessment module**' such as for Medical Devices.

We also welcome the reference to the concept of **substantial modifications**. However, we believe that maintenance and repair operations by third parties are not to be considered as substantial modifications. This being said, a product that has been substantially modified by a third-party repairer should be considered as a new product. There is a new placing on the market and the third-party repairer is the producer.

It is important in this context to provide a clear regulatory framework so that the safety obligations for the producers are rolled out in a way that is compatible with the consumer right to repair, as well as the right to access by independent providers of maintenance or repair services.

In other words, it is key that the safety procedures set by the producer when designing the product do not lead to an automatic functional stop of that product or of its connected functions, where a "non-authorised" party engages in maintenance or repair. This also leads to the issue of the accessibility of codes by third parties for maintenance or repair reasons.

7 | Essential health and safety requirements (EHSRs) traditional machinery

7.1 Principles of safety integration (1.3. PROTECTION AGAINST MECHANICAL RISKS, 1.3.7. Risks related to moving parts)

As machine learning does not always stop with the putting into service, we welcome the new provisions which ensure safety of consumers in an unstructured environment. Consumer robots might interact with humans in an environment which is not controlled/structured, where parameters are not known/foreseeable (as it would happen in a factory). In addition, we also agree that the concept of safety risk might include mental/psychological risks induced by the interaction with the robot (eg: care robots), in light of the European approach to AI which is Trustworthy AI/ethical.

7.2 Digital documentation: instructions for use (Annex III - 1.7.4 Instructions - paper and/or digital, 1.7.4.2. Contents of the instructions)

Point 1.7.4 of Annex III indicates that *'The instructions may be provided in a digital format. However, upon purchaser's request at the time of the purchase of the machinery product, the instructions shall be provided in paper format free of charge'*.

It is important to offer both on-line and paper formats of all instructions for use (covering both safety but also maintenance for example), as not all consumers are regularly connected to the Internet.

The target audience (workers or consumers) and conditions under which the machinery is used must be the decisive factor when prescribing the manufacturers obligations about the content, media and format of the instructions.

The following criteria have to be taken into account:

- **accessibility** to information in all situations the instructions are needed e.g. in normal operation of the product as well as in exceptional and emergency situation. Manufacturers shall provide information on how to access the instructions for use in electronic form.
- **availability and legibility** of the instructions (for example the specific instructions related to the safe operation of the machinery shall be collated together in the front section of the user instructions. The height of the characters, measured on the capital letters, shall be at least 3 mm). The instructions for use shall be provided in a commonly used format that can be read with freely available software.

In order **for consumers** to safely operate a machine in all reasonable foreseeable circumstances, and to reduce potential risks as far as possible, the appropriateness of **the provision of instructions for use in electronic form instead of in paper form should be subject to a specific risk assessment by the manufacturer.**

The risk assessment shall demonstrate that providing instructions for use in electronic form maintains or improves the level of safety obtained by providing the instructions for use in paper form.

We suggest that especially **for machinery covered by Annex I**, manufacturers shall undertake a documented risk assessment which shall cover at least the following elements:

- (a) knowledge and experience of the intended users in particular regarding the use of the device and user needs;
- (b) characteristics of the environment in which the device will be used;
- (c) knowledge and experience of the intended user of the hardware and software needed to display the instructions for use in electronic form;
- (d) access of the user to the reasonably foreseeable electronic resources needed at the time of use;
- (e) performance of safeguards to ensure that the electronic data and content are protected from tampering;
- (f) safety and back-up mechanisms in the event of a hardware or software fault, particularly if the instructions for use in electronic form are integrated within the device;
- (h) impact caused by the temporary unavailability of the specific website or of the Internet in general, as well as the safety measures available to cope with such a situation.

7.3 EHSR 6.2 on control devices

We support the proposal about **control devices** as it allows the use of a control to summon the lift but it also demands a risk assessment to demonstrate that potential risks have been addressed. At the moment the fact that the EHSR is not satisfied is simply ignored/glossed over by all concerned parties, putting consumers at risk.

8 | Essential health and safety requirements machinery with new digital technologies:

8.1 Cybersecurity with impact on safety, machinery with evolving capacity

We welcome the proposed provisions to explicitly address aspects relating to emerging digital technologies, e.g. AI, cybersecurity, IoT. Most consumers connected products presently available in the Single Market are designed and manufactured without even the most basic security features embedded in their software. In order for consumers to trust the Internet of Things, consumers must be assured that the connected products they purchase, or services they use, are secure and protected from software and hardware vulnerabilities. For this to happen security by design and by default must become a priority.

8.2 Principles of safety integration (Annex I -1.1.2)

In order to cover the consumer behaviours and what influences them (which might be different from workers behaviours), we suggest introducing the concept of foreseeable use (in line with art. 7) and not only misuse, based on the following elements: normal

or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements.

9 | Other issues

9.1 CE marking (articles 19 & 20)

Even though CE Marking is not intended as a mark for consumers, its appearance on many machinery products (or their packaging) is misleading to consumers.

ANEC wants to see CE Marking relegated to the technical file of a product that European law also requires.

After over twenty years of the Internal Market for products, CE Marking should no longer be allowed to mislead and confuse European consumers, not only for products falling under the machinery legislation, but for all consumer products that require CE marking⁴.

9.2 Gender neutrality

We welcome the change of wording of the legal provision which refers to manufacturers/economic operators as 'he' to say 'she/he' or 'they'. In this age and time, it is not acceptable that European legislation refers to manufacturers as only males.

9.3 UN Convention on the Rights of Persons with disabilities

We think the new Regulation should make a reference to the UN Convention on the Rights of Persons with disabilities (as is the case for the Low Voltage Directive and Lifts Directive), in order to have accessibility safety requirements.

9.4 New consumption patterns/circular economy

Consumers do not always buy machinery products, but rather rent them as they do not need to use such machines very often. Many professional machinery products end up in the hands of consumers through renting shops/channels. We ask for the Machinery Regulation to consider the safety impact when consumers rent/exchange and do not purchase the machine.

ENDS.

⁴ <https://www.anec.eu/publications/position-papers/201-anec-position-paper-on-ce-marking-caveat-emptor-buyer-beware>



ANEC is the European consumer voice in standardisation, defending consumer interests in the processes of technical standardisation and the use of standards, as well as related legislation and public policies.

ANEC was established in 1995 as an international non-profit association under Belgian law and is open to the representation of national consumer organisations in 34 countries.

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