

CEN Identification number in the EC register: 63623305522-13 CENELEC Identification number in the EC register: 58258552517-56

Position Paper

On European Commission's legislative proposals for Regulation on consumer product safety and Regulation on market surveillance of products

April 2013

Executive summary

Following the publication of a Report on Implementation of directive 2001/95/EC the European Commission launched in 2010 a Public Consultation on revision of the General Product Safety Directive to which CEN and CENELEC made a comprehensive Contribution. In the report the Commission identified certain shortcomings in the provisions for standardization under the GPSD, particularly as regards complexity and lack of flexibility of the system as well as too lengthy procedures of mandating the European Standardization Organizations (ESOs).

These shortcomings were further emphasized by the European Parliament in a resolution from March 2011 on the revision of the General Product Safety Directive and Market Surveillance (P7 TA(2011)0076) that urged the Commission to **improve currently applicable procedures for establishing mandates** for development of European standards, and stressed the need for better and more systematic involvement of market surveillance authorities in the process of European standardization.

CEN and CENELEC agree fully with the need to simplify, clarify and render the procedures for preparation of standardization requests to the European Standardization Organizations **more transparent and flexible**. Therefore **CEN and CENELEC** welcome and in principle support the two legislative proposals from the European Commission for new regulations on Consumer Product Safety (2013/0049 (COD) and on Market Surveillance of Products (2013/0048 (COD) published earlier in 2013 since they propose a reform towards a more efficient system and an alignment of provisions regarding standardization with the Regulation on European Standardization (1025/2012) which came into force in January 2013.

However, **not all shortcomings** identified in the Report on Implementation of Directive 2001/95/EC **were addressed and further improvements are necessary**. This Position Paper aims at highlighting areas for improvement as regards three particular aspects: provisions for presumption of safety and its assessment; standardization requests (Mandates) to the ESOs and involvement of market surveillance authorities in the European standardization system.



1. Presumption of safety and its assessment (Art 6 of (2013/0049 (COD))

The main aim of the European Union consumer safety legislation is to ensure that only safe products are available on the European single market. Towards this end, according to the current General Product Safety Directive (2001/95/EC) a **product is presumed to be safe when it** "conforms to voluntary national standards transposing European standards whose references have been published in the Official Journal of the European Union (OJEU)".

Currently only some forty references to European Standards (ENs) have been listed in the OJEU even though CEN and CENELEC have developed several hundreds of ENs in this area covering a very wide range of products. This is mostly caused by the **lengthy and resource-intensive process of mandating by the European Commission** of the European Standardization Organizations (ESOs) under directive 2001/95/EC that received a lot of criticism during the Public Consultation to the revision of this directive and in a resolution from the European Parliament in reaction to it. Such a formal request (mandate) is necessary to allow the listing of the reference of the mandated EN in the OJEU.

In the absence of listed European Standards in the OJEU, the current directive (Article 3(3)) lays out provisions for assessment of "presumption of conformity of a product to the general safety requirement" by taking into account non-listed European Standards, national standards, Commission recommendations setting guidelines on product safety assessment; product safety codes of good practice in force in the sector concerned; the state of the art and technology and reasonable consumer expectations concerning safety, in this order.

Against this background, the current system for assessment of conformity with the safety requirement for consumer products (which has been functioning very well) is therefore based on a wide consensus among economic operators and market surveillance authorities to use both listed and not listed European Standards respectively, when assessing the safety of products.

The new legislative proposal for a Regulation on Consumer Product Safety (2013/0048 (COD)) in Article 5(b) maintains the current criteria for assessing product safety in the absence of Community legislation by referring to **European standards listed in the OJEU** developed by the European Standardization Organizations. However, a change is made with regard to "other elements giving presumption of conformity" by adding a **new Article 6** on "Aspects for assessing the safety of products" which, **instead of clarifying and simplifying** the current system, introduces new elements in a way that could confuse the economic operators and enforcement authorities.

CEN and CENELEC are particularly concerned about the form in which the new provisions for assessing the safety of product are presented and the consequences this might entail. **Article 6(1) lists new aspects** to be taken into account while **assessing the safety** of the product against such elements as characteristics of the product; effect on other products; presentation of the product; categories of consumers or appearance of the product **while Article 6(2) also lists aspects** to be taken into account while assessing the safety of the product against particular elements such as (in the following order):

- state of the art and technology;
- non-listed European standards;
- international standards;
- international agreements;
- Commission recommendations; national standards;



Changes proposed by CEN and CENELEC

- product safety codes of good practice and reasonable consumer expectations regarding safety.

It is unclear why both parts of article 6 include two lists under the same heading. Therefore an improvement of the text is needed, both for clarity and legal certainty reasons. Firstly, in order to allow for proper application of the future regulation, it should be stated that aspects listed in article 6(1) are of informative character and should not be confused with criteria for conformity assessment, also two separate lists should only be allowed if clearly distinguished from one another.

Secondly, it is the **role of the European Standards to provide specifications of products with regard to state of the art and technology**. This recognition of the role of the voluntary standards was made by the European Parliament in the resolution of 2011 on the revision of the General Product Safety Directive and Market Surveillance asking the European Commission to "consider other evolutionary ways to improve and integrate national and European standardization systems in the non-harmonised area". This is not reflected enough in the legislative proposal.

Against this background, CEN and CENELEC propose an amendment to the text by combining the well functioning provisions of the current 2001/95/EC directive and the legislative proposal to address these issues:

Proposal for amendment

Amendment 1 – Article 6(1) and (2)

Current content of 2013/0049(COD)

Article 6	Article 6
Aspects for assessing the safety of products	Aspects for assessing the safety of products
1. In the absence of Union harmonisation legislation, European standards or health and safety requirements laid down in the law of the Member State where the product is made available on the market as referred to in points (a), (b) and (c) of Article 5, the following aspects shall be taken into account when assessing whether a product is safe, in particular:	1. In the absence of Union harmonisation legislation, European standards or health and safety requirements laid down in the law of the Member State where the product is made available on the market as referred to in points (a), (b) and (c) of Article 5, the conformity of a product to the general safety requirement shall be
(a) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;	assessed by taking into account the following elements, in particular, where they exist: (a) European Standards other than those the references of which have been published in the
(b) the effect on other products, where it is reasonably foreseeable that it will be used with other products;	Official Journal of the European Union in accordance with Articles 16 and 17;
(c) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;	(b) national standards drawn up in the Member State in which the product is marketed; (c) Commission recommendations setting
(d) the categories of consumers at risk when using the product, in particular vulnerable consumers; (e) the appearance of the product and in particular	guidelines on product safety assessment; (d) product safety codes of good practice in force in the sector concerned;
where a product, although not foodstuff, resembles	



foodstuff and is likely to be confused with foodstuff due to its form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product not to be safe.

- 2. For the purpose of paragraph 1, when assessing whether a product is safe, the following aspects, when available, shall be taken into account, in particular:
- (a) the state of the art and technology;
- (b) European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Articles 16 and 17;
- (c) international standards;
- (d) international agreements;
- (e) Commission recommendations or guidelines on product safety assessment;
- (f) national standards drawn up in the Member State in which the product is made available;
- (g) product safety codes of good practice in force in the sector concerned;
- (h) reasonable consumer expectations concerning safety

(e) the state of the art and technology;

(f) reasonable consumer expectations concerning safety.

(Article 3 of 2001/95/EC)

- 2. In addition to elements listed in point (1), the following aspects relating to products and their use may be used as guidance when assessing whether a product is safe, in particular:
- (a) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- (b) the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- (c) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
- (d) the categories of consumers at risk when using the product, in particular vulnerable consumers;
- (e) the appearance of the product and in particular where a product, although not foodstuff, resembles foodstuff and is likely to be confused with foodstuff due to its form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product not to be safe.

(Article 6(1) of the new proposal)

2. Standardization requests to the European Standardization Organizations (Art 16 of 2013/0049 (COD))

CEN and CENELEC welcome continuous efforts of the European Commission to develop standardization mandates in order to allow the further citation of currently available or future European Standards. However, in order to speed up the current lengthy and resource-intensive procedures for issuing standardization requests to the ESOs and improve this process, the provisions in the European product safety legislation regarding standardization should be simplified to allow greater flexibility. The consultation launched in 2010 characterised the making of mandates as "a slow, bureaucratic and inefficient process".



CEN and CENELEC have expressed their concerns on numerous occasions about the fact, that obsolete references to European Standards already replaced by new versions are still listed in OJEU and are not replaced due to absence of related Mandates. In the past years, CEN and CENELEC have received a number of standardization requests to allow for regularisation of this situation, but this process has taken many years to deliver and is far from being finished.

CEN and CENELEC support the simplification made in the new legislative proposal for a Regulation on consumer product safety which in Article 16 lays down a much simpler procedure than the current one for issuing of standardization requests to ESOs that is in line with Regulation 1025/2012 on European Standardisation and which should ensure a quicker and more transparent process. The new procedure for adoption of Implementing Acts should also contribute to ensure better transparency and accountability of the process.

3. New Regulatory Framework for Market Surveillance of Products (2013/0048 (COD))

CEN and CENELEC welcome the effort of the European Commission to harmonise the fragmented rules for market surveillance for products and believe that the legislative proposal a new single Regulation on market surveillance of products (2013/0048 (COD)) is a step in the right direction, since by replacing several co-existing pieces of legislation it is expected to help to develop a better EU risk assessment methodology and thus a more efficient and effective market surveillance.

It deserves to be underlined that effective enforcement of European legislation plays a crucial role in guaranteeing safety but it cannot be entirely achieved if market surveillance authorities do not participate in the European standardization process. It is also crucial, that an adequate level of resources is made available to market surveillance authorities at a national level given the increasing range of activities they cover.

The Regulation 1015/2012/EC on European Standardization provides in Article 7 that "Member States shall, where appropriate, encourage participation of public authorities, including market surveillance authorities, in national standardisation activities aimed at the development or revision of standards requested by the Commission".

Moreover, in its resolution of March 2011 the European Parliament stressed the need for the market surveillance authorities to "systematically participate in the process of security-relevant standard development, as this is an appropriate means of ensuring that their knowledge informs the standardization process and of generating greater understanding for standards". CEN and CENELEC regret that this message was not reflected in the Commission legislative proposal

CEN and CENELEC welcome the active involvement of regulatory bodies and market surveillance authorities in the standardization process as reflected in the draft <u>European Standardization System Strategy 2020</u>. This however should be a two-way process in which the European Standardization Organizations are a consultation partner to the European Commission as regards consideration and interpretation of standards in the framework of notifications under the Union Rapid Information Exchange System – RAPEX. Article 19(4) provides for a possibility to participate in the Rapid Information Exchange System to international organizations – this is a development in the right direction.



Conclusions

To conclude, the legislative proposals for new regulations in the area of Consumer Safety are a step in the right direction towards simpler, clearer and less fragmented rules that should benefit all concerned parties. Some aspects however still remain unclear and shall be improved, especially as regards rules for presumption and assessment of safety, both in content and formulation present in the legislative proposals where the European Standards shall remain the main reference for this assessment. These aspects deserve further attention and development.

About CEN and CENELEC

CEN (European Committee for Standardization) and **CENELEC (European Committee for Electrotechnical Standardization)** are officially recognised organisations responsible for developing and defining standards at European level. These standards set out specifications and procedures in relation to a wide range of products and services.

The members of CEN and CENELEC are the National Standards Bodies and National Electrotechnical Committees of 33 European countries including all of the EU member states plus Croatia, Iceland, Norway, Switzerland and Turkey.

CEN and CENELEC also work to promote the international harmonisation of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission).

European Standards (ENs) are developed through a process of collaboration among technical experts nominated by business and industry, research institutes, consumer and environmental organisations and other societal stakeholders. These standards are recognised throughout all of the 33 countries covered by CEN and CENELEC.

For more information please see: www.cencenelec.eu