EUROPEAN PARLIAMENT 2009 – 2014

Consolidated legislative document

15.4.2014 EP-PE_TC1-COD(2013)0049

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POSITION OF THE EUROPEAN PARLIAMENT

adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC of the European Parliament and of the Council (EP-PE_TC1-COD(2013)0049)

PE 505.543

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure[2],

1 OJ C 271, 19.9.2013, p. 81.

2 Position of the European Parliament of 15 April 2014.

Whereas:

(1) Directive 2001/95/EC of the European Parliament and of the Council ~~of 3 December 2001 on general product safety~~[1] lays down the ***fundamental*** requirement ***for products on the internal market*** that consumer products must be safe and that Member States' market surveillance authorities must take ***efficient*** action against dangerous products as well as exchange information to that effect through the Community Rapid Information System (RAPEX). Directive 2001/95/EC needs to be fundamentally revised to improve its functioning and to ensure consistency with developments in Union legislation as regards market surveillance, obligations of economic operators and standardisation. In the interest of clarity, Directive 2001/95/EC should be repealed and replaced by this Regulation. **[Am. 1]**

(2) A regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for divergent transposition ***and application*** by Member States. A regulation ensures that legal requirements are applicable at the same time throughout the Union. **[Am. 2]**

[1] ***Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (***OL L 11, 15.1.2002, p. 4***)***.

(3) ~~This Regulation must contribute to the attainment of the objectives referred to in Article 169 of the TFEU. In particular it should aim at ensuring the functioning of the internal market as regards products intended for consumers by laying down uniform rules regarding a general~~ ***In order to ensure a high level of consumer protection, the Union should contribute to protecting the health and*** safety ~~requirement, assessment criteria and obligations of economic operators. Given that rules on market surveillance, including rules on RAPEX, are laid down in Regulation (EU) No […/…] […on market surveillance of products][1] which applies also to~~ ***of consumers. In that regard, this Regulation is essential to delivering the fundamental aim of an internal market for safe*** products ~~covered by this Regulation, no further provisions on market surveillance or RAPEX are needed in this Regulation~~***, whilst contributing to the attainment of the objectives referred to in Article 169 of the Treaty on the Functioning of the European Union (TFEU)***.
[Am. 3]

[1] ~~OJ L , , p. .~~

(3a) ***This Regulation should aim in particular to ensure the functioning of the internal market as regards products intended for consumers, by laying down uniform rules regarding a general safety requirement, assessment of the safety of products criteria and the obligations of economic operators. Given that rules on market surveillance, including rules on RAPEX, are laid down in Regulation (EU) No .../... of the European Parliament and of the Council[1+], no further provisions on market surveillance or RAPEX are necessary in this Regulation.*** **[Am. 4]**

(3b) ***The safety of consumers depends to a great extent on the active enforcement of Union product safety requirements. Market surveillance activities at national and Union level should be improved on an on-going basis and should be increasingly effective in order to meet the ever-changing challenges of a global market and a progressively complex supply chain. Failing market surveillance systems could generate a distortion of competition, jeopardise consumer safety and undermine citizens' trust in the internal market. The Member States should, therefore, establish systematic approaches to ensure the increasing effectiveness of market surveillance and other enforcement activities and should ensure their openness to the public and to interested parties.*** **[Am. 5]**

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1 ***Regulation (EU) No .../... of the European Parliament and of the Council of ... on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EC) No 764/2008, Regulation (EC) No 765/2008 and Regulation (EU) No 305/2011 of the European Parliament and of the Council (OJ L ...).***

\+ ***OJ: please insert the number of Regulation (2013/0048(COD)) in the recital and the number, date of adoption and publication reference of the Regulation in the footnote.***

(4) Union legislation on food, feed and related areas sets up a specific regime ensuring the safety of the products covered by it. This Regulation should therefore not apply to those products with the exception of materials and articles intended to come into contact with food insofar as risks are concerned that are not covered by Regulation (EC) No 1935/2004 of the European Parliament and of the Council[1] or by other food specific legislation which only covers chemical and biological food related risks.

(5) Medicinal products are subject to a pre-market assessment that includes a specific risk-benefit analysis. They should therefore be excluded from the scope of this Regulation.

(6) This Regulation should not cover services. However, in order to secure the attainment of the protection of health and safety of consumers, it should apply to ***all*** products that are ***used,*** supplied or made available to consumers in the context of the provision of services, including products to which consumers are directly exposed during the provision of a service~~. Equipment on which consumers ride or travel which is operated by a service provider should be excluded from the scope of this Regulation since it has to be dealt with in conjunction with the safety of the service provided~~ ***by a service provider***. **[Am. 6]**

[1] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

(6a) ***Products which are designed exclusively for professional use but which have subsequently migrated to the consumer market should be subject to this Regulation because they can pose risks to the health and safety of consumers when used under reasonably foreseeable conditions.*** **[Am. 7]**

(6b) ***Equipment on which consumers travel which is operated by a service provider should be excluded from the scope of this Regulation since it has to be dealt with in conjunction with the safety of the service provided.*** **[Am. 8]**

(7) Despite the development of sector-specific Union harmonisation legislation that addresses safety aspects of specific products or categories of products, it is practically impossible to adopt Union legislation for all consumer products that exist or may be developed. There is therefore still a need for a legislative framework of a horizontal nature to fill gaps and ensure consumer protection not otherwise ensured, in particular with a view to achieving a high level of protection of health and safety of consumers, as required by Articles 114 and 169 TFEU.

(8) In respect of the consumer products subject to this Regulation, the scope of application of the different parts of it should be clearly delimited from sector-specific Union harmonisation legislation. Whilst the general product safety requirement and related provisions ***of Chapter I of this Regulation*** should be applicable to all consumer products, the obligations of economic operators should not apply where Union harmonisation legislation includes equivalent obligations, such as Union legislation on cosmetics, toys, electrical appliances or construction products. **[Am. 9]**

(9) In order to ensure consistency between this Regulation and sector-specific Union harmonisation legislation with regard to specific obligations of economic operators, the provisions concerning manufacturers, authorised representatives, importers and distributors should be based on the reference provisions included in Decision No 768/2008/EC of the European Parliament and of the Council ~~of 9 July 2008 on a common framework for the marketing of products~~[1]. ***Nevertheless, Union harmonisation legislation should not impose unnecessary administrative burdens on economic operators***. **[Am. 10]**

[1] ***Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (***OJ L 218, 13.8.2008, p. 82***)***.

(10) The scope of this Regulation should not be limited to any selling technique of consumer products, and should therefore also cover distance selling***, such as electronic selling, online sales and sales platforms***. **[Am. 11]**

(11) This Regulation should apply to second hand products that re-enter the supply chain in the course of a commercial activity, ***provided that they have been placed on the market as such, and to second-hand products originally placed on the market after the entry into force of this Regulation,*** except for those second-hand products for which the consumer cannot reasonably expect that they fulfil state-of-the art safety standards, such as antiques. **[Am. 12]**

(12) This Regulation should also apply to, ***and thus prohibit the marketing, import, manufacture and export of,*** consumer products which, although not foodstuff, resemble foodstuff and are likely to ~~be confused with foodstuff in a way that consumers, especially~~ ***cause persons, in particular young*** children~~, may~~***, to confuse them with foodstuff and consequently to*** place them in their mouths, suck or ingest them, which ~~might~~ ***by doing so may*** cause~~, for example, suffocation, poisoning, the perforation or obstruction of the digestive tract~~ ***death or personal injury***. Those imitations of foodstuffs have so far been regulated by Council Directive 87/357/EEC ~~of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers~~[1] which should be repealed. **[Am. 13]**

(13) The safety of products should be assessed taking into account all the relevant aspects, in particular their characteristics***, composition, authenticity, materials, components,*** and presentation ***of the product and its packaging*** as well as the categories of consumers who are likely to use the products taking into account their vulnerability, in particular children, the elderly and the disabled. **[Am. 14]**

[1] ***Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers (***OJ L 192, 11.7.1987, p. 49***)***.

(13a) ***The precautionary principle, as laid down in Article 191(2) TFEU and outlined inter alia in the Commission Communication of 2 February 2000 entitled "On the precautionary principle", is a fundamental principle for the safety of products and for the safety of consumers and should be taken into due account when laying down the criteria for assessing the safety of a product.*** **[Am. 15]**

(13b) ***This Regulation should take into account "child-appealing products" whose design, packaging and characteristics in any way resemble a toy or an object appealing to or intended for use by children. Child-appealing products should furthermore be assessed for their levels of risk and appropriate action to mitigate that risk should be taken.*** **[Am. 16]**

(13c) ***When assessing the safety of a product, special consideration should be given if the product has caused injuries notified into the Pan-European Injury Database established pursuant to Regulation (EU) No .../...*** [+]**. [Am. 17]**

(14) To avoid overlapping safety requirements and conflicts with other Union legislation, a product which conforms to sector-specific Union harmonisation legislation that aims at the protection of health and safety of persons should be presumed to be safe under this Regulation.

[+] ***OJ: please insert the number of Regulation (2013/0048(COD)).***

(15) Economic operators should be responsible for the compliance of products, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of the health and safety of consumers. ***In that regard, there should be a strict alignment of the provisions regarding obligations of economic operators contained in Decision No 768/2008/EC, since this will provide a level playing field between the obligations on economic operators covered by Union harmonisation legislation and those covered by non-harmonised legislation under this Regulation.*** **[Am. 20]**

(15a) In the case of products that are not subject to Union harmonisation legislation, European standards or national legislation on health and safety requirements, economic operators should assess the safety of products in accordance with specific criteria, on which basis they should define the level of risk associated with a product. Market surveillance authorities may assist economic operators in carrying out the safety assessment. **[Am. 21]**

(15b) ***To make it easier to place safe products on the market, economic operators, in particular small and medium-sized enterprises (SMEs), should be able to meet their obligations under this Regulation by establishing consortia with the dual purpose of ensuring compliance with product safety requirements and high-quality standards and reducing the costs and "red tape" with which individual businesses are burdened.*** **[Am. 22]**

(16) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they only make available on the market products which are safe and in conformity with this Regulation. It is necessary to provide for a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution process.

(16a) ***Manufacturers should ensure that the products they place on the market have been designed and manufactured in accordance with the safety requirements laid down in this Regulation. In order to clarify the obligations of the manufacturer and to minimise the related administrative burdens, the Commission should establish a Union general risk assessment methodology for products and create user-friendly electronic tools for analysing risks. That methodology should establish an efficient tool for risk assessment that the manufacturers can use when designing products, by building on best practices and input from stakeholders.*** **[Am. 23]**

(16b) ***In order to facilitate communication between economic operators, market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.*** **[Am. 24]**

(17) Importers bear the responsibility that products originating from third countries that they place on the Union market comply with the requirements of this Regulation. The specific obligations of importers should therefore be included in this Regulation.

(18) Distributors make products available on the market after they have been placed on the market by the manufacturer or the importer and should act with due care to ensure that their handling of the product does not adversely affect the compliance of the product with this Regulation.

(18a) The distributor should ensure that the manufacturer and the importer have complied with their obligations, that is to say verifying the indication on the product or on its packaging of the name, model name, brand name or address at which the manufacturer and the importer can be contacted and the affixing of the manufacturer's batch number, serial number or other element on the product for its identification. The distributor should not check each product individually, unless the distributor considers that the manufacturer or the importer have not fulfilled their obligations. **[Am. 25]**

(19) Any economic operator that either places a product on the market under his own name or trade mark or modifies a product in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(20) Ensuring product identification and the traceability of products throughout the entire supply chain helps to identify economic operators and to take effective corrective action against unsafe products, such as targeted recalls. Product identification and traceability thus ensure that consumers and economic operators obtain accurate information regarding unsafe products which enhances confidence in the market and avoids unnecessary disruption of trade. Products should therefore bear information allowing their identification and the identification of the manufacturer and, if applicable, of the importer. Manufacturers should also establish technical documentation regarding their products for which they may choose the most appropriate and cost-efficient way such as by electronic means. Moreover, economic operators should be required to identify the operators who supplied them and to whom they supplied a product. Directive 95/46/EC of the European Parliament and of the Council[1] is applicable to the processing of personal data for the purposes of this Regulation.

[1] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

(20a) ***Globalisation, increased outsourcing and the growth in international trade mean that more products are being traded on markets across the world, and in that regard a close cooperation between global regulators and other stakeholders in the area of consumer product safety is essential to addressing the challenges of complex supply chains and higher volumes of trade. In particular, the Commission should be encouraged to strengthen the attention to safety by design of products through bilateral cooperation with the market surveillance authorities of third countries.*** **[Am. 26]**

(20b) ***The current traceability systems and identification procedures already in place should be effectively enforced and improved. In that regard, assessments and evaluations on the use of the technologies in place are necessary to ensure better performance and lower the administrative burden on economic operators. One of the objectives of this Regulation is to constantly improve the traceability systems imposed on economic operators and products.*** **[Am. 27]**

(20c) ***In order to improve traceability in the future, the Commission should assess how to facilitate the application of specific track-and-trace technologies and product authentication technologies. In that assessment, the technologies assessed should ensure inter alia consumer product safety, improve tracing mechanisms and avoid putting unnecessary administrative burdens on economic operators in order to prevent the costs thereof from being passed on to consumers.*** **[Am. 28]**

(20d) ***Building on the establishment of national contact points pursuant to Regulation (EC) No 764/2008 of the European Parliament and of the Council[1], Product Safety Contact Points should function as information centres in the Member States for economic operators in order for those operators to receive guidance and training on product safety requirements and legislation.*** **[Am. 29]**

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1 ***Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC (OJ L 218, 13.8.2008, p. 21).***

(21) The indication of origin ~~supplements~~ ***is a necessary supplement to*** the basic traceability requirements ***laid down in this Regulation*** concerning the name and address of the manufacturer. ~~In particular~~ ***Furthermore***, the indication of the country of origin helps to identify the actual place of manufacture in all those cases where the manufacturer cannot be contacted ~~or~~***, in particular where*** its given address is different from the actual place of manufacture***, where the name and address of the manufacturer is missing altogether or where the address was on the packaging that has been lost***. Such information can facilitate the task of market surveillance authorities in tracing the product back to the actual place of manufacture and enable contacts with the authorities of the countries of origin in the framework of bilateral or multilateral cooperation on consumer product safety for appropriate follow-up actions. **[Am. 30]**

(21a) The indication of origin of the product would make it easier for consumers to access information about the product chain, thereby increasing their level of awareness. In particular, when indicating the name of the manufacturer fulfilling the obligations of the economic operators, there is a risk of misleading the consumers since an indication of the manufacturer does not necessarily enable the consumer to establish what the country of production is. Thus, the indication of origin should be the sole means by which the consumers would be able to establish the country of production of a product. **[Am. 31]**

(21b) In several jurisdictions of the trade partners of the Union, the indication of origin is mandatory in product labelling and custom declarations. The introduction of the indication of origin pursuant to this Regulation will bring the Union into line with the international trade regime. Furthermore, since the requirement to provide an indication of origin covers all non-food products on the territory of the Union, whether imported or not, it will comply with the international trade obligations of the Union. **[Am. 32]**

(22) In order to facilitate the effective and consistent application of the general safety requirement set out in this Regulation, it is important to make use of European standards covering certain products and risks in such a way that a product which conforms to such a European standard, the reference of which has been published in the *Official Journal of the European Union*, is to be presumed to be in compliance with that requirement.

(23) Where the Commission identifies a need for a European standard ensuring compliance of certain products with the general safety requirement under this Regulation, it should apply the relevant provisions of Regulation (EU) No 1025/2012 of the European Parliament and of the Council[1] to request one or several European standardisation organisations to either draft or identify a standard which is suitable to ensure that products which conform to it are presumed to be safe. The references of such European standards should be published in the *Official Journal of the European Union*.

[1] Regulation (EU) No 1025/2012 of the European Parliament and the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

(24) The procedures to request European standards in support of this Regulation, and on formal objections against them, should be laid down in this Regulation and be aligned with Regulation (EU) No 1025/2012. To ensure overall consistency in European standardisation issues, requests for European standards, or objections to a European standard, should therefore be brought before the committee set up by that Regulation, after appropriate consultation of experts of the Member States in the field of consumer product safety ***and of relevant stakeholders***. **[Am. 33]**

(25) European standards, the references of which have been published in accordance with Directive 2001/95/EC, should continue providing presumption of conformity with the general safety requirement. Standardisation mandates issued by the Commission in accordance with Directive 2001/95/EC should be deemed standardisation requests issued in accordance with this Regulation.

(26) Where no relevant European standards or other recognised means to assess the safety of products exist, the assessment of product safety should take into account Commission recommendations adopted for that purpose pursuant to Article 292 TFEU.

(26a) In order to maintain a high level of health and safety of consumers, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to determine the products, categories or groups of products for which the name, registered trade name or registered trade mark and address of the manufacturer and of the importer does not need to be indicated on the product itself due to the low level of risk related to such products, to determine the products, categories or groups of products bearing a potential serious risk to health and safety of persons and to specify the data which economic operators are to collect and store by means of traceability system. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(27) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards the exemption to the obligation to inform market surveillance authorities about products presenting a risk, as regards the type of data carrier and its placement on the product for the purposes of the traceability system, as regards standardisation requests to European standardisation organisations and as regards decisions on formal objections to European standards. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1].

(28) The advisory procedure should be used for the adoption of implementing acts as regards decisions on formal objections to European standards and where the references to the European standard concerned have not yet been published in the *Official Journal of the European Union*, given that the relevant standard has not yet led to the presumption of conformity with the general safety requirement laid down in this Regulation.

[1] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

(30) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive ***and depend on the seriousness, duration and intentional or recurring character of the infringement, as well as the size of the undertakings, in terms of the number of persons employed by and annual turnover of the economic operators concerned, with particular regard to SMEs. Infringements should entail administrative penalties that are harmonised at Union level. Member States should be encouraged to allocate the revenues collected from such penalties to market surveillance activities***. **[Am. 34]**

(30a) In order to enhance the deterrent effect of the penalties, the Commission should make them public. In addition, economic operators who are repeatedly found to have intentionally breached this Regulation should be placed on a public, Union-wide blacklist. **[Am. 35]**

(31) To allow economic operators, Member States and the Commission to adapt to the changes introduced by this Regulation, it is appropriate to provide for a sufficient transitional period until the requirements of this Regulation are applicable.

(32) Since the objective of this Regulation, namely to ensure the proper functioning of the internal market as regards products intended for consumers whilst maintaining a high level of health, safety and consumer protection, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(33) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union. In particular this Regulation seeks to ensure full respect for the obligation to ensure a high level of human health protection and consumer protection as well as full respect for the freedom to conduct business,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

General provisions

Article 1

Subject matter ***and objective*** **[Am. 36]**

The objective of this Regulation is to ensure the proper functioning of the internal market whilst maintaining a high level of health, safety and consumer protection. **[Am. 37]**

This Regulation lays down rules on the safety of consumer products placed or made available on the Union market.

The provisions of this Regulation are based on the precautionary principle. **[Am. 38]**

Article 2

Scope

1. This Regulation shall apply to products obtained through a manufacturing process placed or made available on the market, ***including the online market,*** whether new, used or reconditioned, and which comply with any of the following criteria: **[Am. 39]**

(a) which are intended for consumers;

(b) which are likely, under reasonably foreseeable conditions, to be used by consumers even if***, when placed on the market, they were*** not intended for them; ***products are not likely to be used by consumers if they are intended for the exclusive use by professionals and are explicitly labelled and presented as such;*** **[Am. 40]**

(c) ~~to~~ which ~~consumers are exposed~~ ***are provided to a consumer*** in the ~~context~~ ***course*** of a service ~~provided to them~~***, whether or not the product is used by the consumer himself***. **[Am. 41]**

2. This Regulation shall not apply to products to be repaired or reconditioned prior to being used where those products are made available on the market as such***, nor to second-hand products originally placed on the market before ...***[*]. **[Am. 42]**

3. This Regulation shall not apply to the following:

[*] ***OJ: please insert the date of entry into force of this Regulation.***

(a) medicinal products for human or veterinary use;

(b) food;

(c) materials and articles intended to come into contact with food insofar as risks related to those products are covered by Regulation (EC) No 1935/2004 or other Union legislation applicable to food;

(d) feed;

(da) medical devices as defined in Council Directive 90/385/EEC[1], Council Directive 93/42/EEC[2] and Directive 98/79/EC of the European Parliament and of the Council[3]; **[Am. 43]**

(e) living plants and animals, genetically modified organisms and genetically modified microorganisms in contained use, as well as products of plants and animals relating directly to their future reproduction;

(f) animal by-products and derived products;

(g) plant protection products;

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1 ***Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ*** *L 189, 20.7.1990, p. 17)**.***

2 ***Council Directive 93/42/EEC of 14 June 1993 concerning medicinal devices (OJ L 169, 12.7.1993, p. 1).***

3 ***Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ*** *L 331, 7.12.1998, p. 1).*

(h) equipment on which consumers ride or travel which is operated by a service provider within the context of a service provided to consumers;

(i) antiques;

(ia) construction products as defined in Regulation (EU) No 305/2011 of the European Parliament and of the Council[1]. **[Am. 44]**

4. Chapters II to IV of this Regulation shall not apply to products subject to requirements designed to protect human health and safety laid down in Union harmonisation legislation or pursuant to it.

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

[1] ***Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC*** *(OJ L 88, 4.4.2011, p. 5).*

(1) ‘safe product’ means any ***authentic*** product which ***is compliant with Union harmonisation legislation relating to health and safety. In the absence of such legislation it means any product which***, under normal or reasonably foreseeable conditions of use of the product concerned, including the duration of ***the*** use and, where applicable, its putting into service, installation ~~and~~**,** maintenance***, training and supervision*** requirements, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of health and safety of persons; **[Am. 45]**

(1a) 'product model' means products that are considered to be distinct in terms of presenting identical or similar essential characteristics, with differences, if any, having no impact on their safety level unless otherwise proven by the manufacturer or the importer; **[Am. 46]**

(2) ‘making available on the market’ means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(3) ‘placing on the market’ means the first making available of a product on the Union market;

(4) ‘manufacturer’ means any natural or legal person who manufactures a product or has a product designed or manufactured and markets that product under his name or trade mark;

(5) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(6) ‘importer’ means any natural or legal person established within the Union who places a product from a third country on the Union market;

(7) ‘distributor’ means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

(8) ‘economic operators’ means the manufacturer, the authorised representative, the importer and the distributor;

(9) ‘international standard’ means an international standard as defined in point (a) of Article 2(1) of Regulation (EU) No 1025/2012;

(10) ‘European standard’ means a European standard as defined in point (b) of Article 2(1) of Regulation (EU) No 1025/2012;

(11) ‘national standard’ means a national standard as defined in point (d) of Article 2(1) of Regulation (EU) No 1025/2012;

(12) ‘European standardisation organisation’ means a European standardisation organisation as defined in Article 2(8) of Regulation (EU) No 1025/2012;

(13) ‘market surveillance authority’ means a market surveillance authority as defined in point 12 of Article 3 of Regulation (EU) No …/…[+];

(14) ‘recall’ means any measure aimed at achieving the return of a product that has already been made available to the end user;

(15) ‘withdrawal’ means any measure aimed at preventing a product in the supply chain from being further made available on the market;

[+] ***OJ: please insert the number of Regulation (2013/0048(COD)).***

(16) ‘Union harmonisation legislation’ means any Union legislation harmonising the conditions for the marketing of products;

(17) ‘serious risk’ means ~~a~~ ***any serious*** risk ~~requiring rapid intervention and follow-up~~, including ~~cases where~~ ***those*** the effects ~~may~~ ***of which are*** not ~~be~~ immediate***, requiring rapid intervention by the public authorities***. **[Am. 47]**

Article 4

General safety requirement

Economic operators shall place or make available on the Union market only safe consumer products.

Article 4a

Prohibition of marketing, import, manufacture and export of imitations of foodstuffs

Member States shall take all the measures necessary to prohibit the marketing, import, manufacture and export of consumer products which, although not foodstuff, resemble foodstuff and are likely to be confused with foodstuff due to their form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics, thereby endangering the health or safety of consumers. **[Am. 48]**

Article 5

Presumption of safety

For the purposes of this Regulation, a product shall be presumed to be in compliance with the general safety requirement laid down in Article 4 in the following cases:

(a) as regards the risks covered by requirements designed to protect human health and safety laid down in or pursuant to Union harmonisation legislation, if it conforms to those requirements;

(aa) if it is authentic, meaning that the product or any presentation of the product does not bear a trade mark without the authorisation of the trade mark owner that is identical or similar to a registered trade mark for that product, thereby misleading consumers as to the true identity of the product; **[Am. 49]**

(b) in the absence of requirements laid down in or pursuant to Union harmonisation legislation referred to in point (a) of this Article, as regards the risks covered by European standards, if it conforms to relevant European standards or parts thereof, the references of which have been published in the *Official Journal of the European Union* in accordance with Articles 16 and 17;

(c) in the absence of requirements laid down in or pursuant to Union harmonisation legislation referred to in point (a) and European standards referred to in point (b), as regards the risks covered by health and safety requirements laid down in the law of the Member State where the product is made available on the market, if it ~~conforms to~~ ***complies with*** such national ~~requirements~~ ***rules provided that they comply with Union law***. **[Am. 50]**

Article 6

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), (aa), (b) and (c) of Article 5, the following aspects shall be taken into account when assessing whether a product is safe, in particular:

(a) the characteristics of the product, including its ***authenticity,*** composition, packaging, instructions for assembly and, where applicable, for installation and maintenance; **[Am. 51]**

(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~~ ***characteristics*** of consumers at risk when using the product ***under reasonably foreseeable conditions***, in particular vulnerable consumers; **[Am. 52]**

(e) the appearance of the product and in particular where a product:

(i) 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***; or***

(ii) ***although not designed or not intended for use by children, resembles an object commonly recognised as appealing to or intended for use by children, because of its design, packaging and characteristics***. **[Am. 53]**

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 of this Article, 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;~~ **[Am. 54]**

(aa) reasonable consumer expectations concerning safety in terms of the nature, composition and intended use of the product; **[Am. 55]**

(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;

(ba) the essential requirements contained in the standardisation requests to European standardisation organisations in accordance with Article 16 as long as the Commission has not yet published the references of the harmonised standards in the Official Journal of the European Union; **[Am. 56]**

(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;

(ga) if the product, categories or groups of products, have caused injuries notified into the Pan-European Injury Database established pursuant to Regulation (EU) No .../...[+]; [Am. 57]

~~(h) reasonable consumer expectations concerning safety.~~ **[Am. 58]**

(ha) the state of the art and technology. **[Am. 59]**

[+] ***OJ: please insert the number of Regulation (2013/0048(COD)).***

Article 7

Indication of the origin

1. Manufacturers and importers shall ensure that products bear an indication of the country of origin of the product or, where the size or nature of the product does not allow it, that indication is to be provided on the packaging or in a document accompanying the product.

2. For the purpose of determination of the country of origin within the meaning of paragraph 1 ***of this Article***, non-preferential origin rules set out in Articles ~~23 to 25 of Council~~ ***59 to 62 of*** Regulation ~~(EEC) No 2913/92 establishing a Community Customs Code~~[1] ***(EU) No 952/2013 of the European Parliament and of the Council[1], including delegated acts to be adopted pursuant to Article 62 of that Regulation,*** shall apply. **[Am. 61]**

3. Where the country of origin determined in accordance with paragraph 2 is a Member State of the Union, manufacturers and importers may refer to the Union or to a particular Member State.

3a. Manufacturers shall be authorised to indicate the country of origin in English only ('Made in [country]'), since this is readily comprehensible for consumers. **[Am. 62]**

[1] ~~OJ L 302, 19.10.1992, p. 1.~~ ***Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).***

CHAPTER II

Obligations of economic operators

Article 8

Obligations of manufacturers

1. When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the general safety requirement laid down in Article 4.

2. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with the general safety requirement laid down in Article 4.

3. Proportionate to the possible risks of a product, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of ***randomly picked*** products made available on the market ***chosen under the control of a judicial officer or any qualified person designated by each Member State***, investigate complaints and keep a register of complaints, non-conforming products and product recalls, and shall keep distributors informed of any such monitoring. ***That information shall be made available to the market surveillance authorities on request.*** **[Am. 63]**

3a. ***When the products made available on the market have been subject to a Commission decision adopted under Article 12 of Regulation (EU) No .../....[+], manufacturers or, where appropriate, importers, shall, in order to protect the health and safety of consumers and proportionate to the possible risks of a product, carry out at least once a year representative sample testing of products made available on the market chosen under the control of a judicial officer or any qualified person designated by each Member State.*** **[Am. 64]**

4. Proportionate to the possible risks of a product, manufacturers shall draw up a technical documentation.The technical documentation shall contain~~, as appropriate~~: **[Am. 65]**

(a) a general description of the product and its essential properties relevant for assessing the product's safety;

(b) an analysis of the possible risks related to the product and the solutions adopted to eliminate or mitigate such risks, including the outcome of any tests conducted by the manufacturer or by another party on his behalf;

[+] ***OJ: please insert the number of Regulation (2013/0048(COD)).***

(c) where applicable, a list of the European standards referred to in point (b) of Article 5 or health and safety requirements laid down in the law of the Member State where the product is made available on the market referred to in point (c) of Article 5, or other aspects referred to in Article 6(2), applied to meet the general safety requirement laid down in Article 4.

Where any of the European standards, health and safety requirements or other aspects referred to in point (c) of the first subparagraph have been only partly applied, the parts which have been applied shall be identified.

5. Manufacturers shall keep, for a period of 10 years after the product has been placed on the market, the technical documentation ~~and make it available to~~ ***in paper or electronic form at the disposal of*** the market surveillance authorities ***and provide it to those authorities***, upon ***reasoned*** request. **[Am. 66]**

6. Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing the identification of the product which is easily visible and legible for consumers, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

Where the information allowing the identification of a product is not provided directly on the product, manufacturers shall indicate in a sufficiently visible manner that the medium containing that information should be retained. **[Am. 67]**

6a. ***Manufacturers of products that are the subject of a Commission decision adopted under Article 12 of Regulation (EU) No .../....[+] shall draw up a list of product models, accompanied by a photograph, and make it available to the public and other economic operators by any appropriate means.***

The manufacturer shall provide, upon request, the market surveillance authorities as well as any economic operator to whom he distributes his products with evidence supporting the existence of different essential characteristics between its models within the meaning of the definition set out in point 1a of Article 3 of this Regulation. **[Am. 68]**

7. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.

[+] ***OJ: please insert the number of Regulation (2013/0048(COD)).***

8. Manufacturers shall ensure that their product is accompanied by instructions and safety information ***addressed to the consumer in a clear and comprehensible manner*** in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available, except where the product can be used safely and as intended by the manufacturer without such instructions and safety information. **[Am. 69]**

Member States shall inform the Commission about any provisions adopted by them determining the required language(s).

9. ***Manufacturers shall ensure that they have procedures in place for taking corrective action, withdrawing or recalling their products***. Manufacturers who consider or have reason to believe that a product which they have placed on the market is not safe or is otherwise not in conformity with this Regulation shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, if appropriate***, and to warn consumers who are at risk caused by the non-conformity of the product***. Furthermore, where the product is not safe, manufacturers shall immediately inform the market surveillance authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the risk to health and safety and of any corrective action taken, ***and of the results of such corrective action***. **[Am. 70]**

Article 9

Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 8(1) and (4) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) further to a ***reasoned*** request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product; **[Am. 71]**

(b) cooperate with the market surveillance authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate.

Article 10

Obligations of importers

1. Before placing a product on the market importers shall ensure that the product is compliant with the general safety requirement laid down in Article 4 and that the manufacturer has complied with the requirements set out in Article 8(4), (6) and (7).

2. Where an importer considers or has reason to believe that a product is not in conformity with this Regulation, he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product is not safe, the importer shall inform the manufacturer and the market surveillance authorities of the Member State in which he is established to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. They shall ~~ensure that any additional label does~~ not obscure any ***compulsory*** information ~~on the label~~ ***or safety-related information*** provided by the manufacturer. **[Am. 72]**

4. Importers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers, as determined by the Member State in which the product is made available, except where the product can be used safely and as intended by the manufacturer without such instructions and safety information.

   Member States shall inform the Commission about any provisions adopted by them determining the required language(s).

5. Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety requirement laid down in Article 4 and its conformity with Article 8(6).

6. Proportionate to the possible risks presented by a product, importers shall, to protect the health and safety of persons, carry out sample testing of ***randomly picked*** marketed products, investigate complaints, and keep a register of complaints, of non-conforming products and of product recalls, and shall keep the manufacturer and distributors informed of such monitoring. **[Am. 73]**

7. Importers who consider or have reason to believe that a product which they have placed on the market is not safe or is otherwise not in conformity with this Regulation shall immediately take the corrective action necessary to bring that product into conformity, to withdraw it or recall it, ~~if~~ ***as*** appropriate. Furthermore, where the product is not safe, importers shall immediately inform the market surveillance authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the risk to health and safety and of any corrective action taken***, and of the results of such corrective action***. **[Am. 74]**

8. Importers shall keep, for a period of 10 years after the product has been placed on the market, the technical documentation ~~and make it available to~~ ***in paper or electronic form at the disposal of*** the market surveillance ***authorities and provide it to those*** authorities, upon ***reasoned*** request. **[Am. 75]**

Article 11

Obligations of distributors

1. When making a product available on the market, a distributor shall act with due care in relation to the requirements of this Regulation.

2. Before making a product available on the market distributors shall verify that the ~~manufacturer and the importer have complied with the requirements~~ ***product bears the required information,*** set out in Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable. ***Distributors shall not obscure any compulsory information or safety-related information provided by the manufacturer or the importer.*** **[Am. 76]**

3. Where a distributor considers or has a reason to believe that a product is not in conformity with this Regulation, he shall not make the product available on the market until it has been brought into conformity. Furthermore, where the product is not safe, the distributor shall inform the manufacturer or the importer, as applicable, to that effect as well as the market surveillance authority of the Member State in which the distributor is established.

4. Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety requirement laid down in Article 4 and its conformity with Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable.

4a. ***Depending on the risks that a product is likely to pose, distributors may, in order to protect the health and safety of consumers, test products made available on the market, taking random samples.*** **[Am. 77]**

5. Distributors who consider or have reason to believe that a product which they have made available on the market is not safe or is not in conformity with Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable, shall ***immediately*** make sure that the corrective action necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, is taken. Furthermore, where the product is not safe, distributors shall immediately inform the manufacturer or importer, as applicable as well as market surveillance authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the risk to health and safety and of any corrective action taken, ***and of the results of such corrective action***. **[Am. 78]**

Article 12

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and shall be subject to the obligations of the manufacturer under Article 8, where he places a product on the market under his name or trade mark or modifies a product already placed on the market in such a way that compliance with the requirements of this Regulation may be affected.

Article 13

Exemption from certain obligations of manufacturers, importers and distributors

1. Obligation to inform the market surveillance authorities in accordance with Article 8(9), Article 10(2) and (7) and Article 11(3) and (5) shall not apply where the following conditions are fulfilled:

(a) only a limited number of well-identified products are not safe;

(b) the manufacturer, importer or distributor can demonstrate that the risk has been ~~fully~~ ***effectively*** controlled ~~and cannot any more endanger~~ ***so as to prevent any dangers to*** the health and safety of persons; **[Am. 79]**

~~(c) the cause of the risk of the product is such that knowledge of it does not represent useful information for the authorities or the public.~~ **[Am. 80]**

2. The Commission may by means of implementing acts determine the situations which meet the conditions of paragraph 1 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(3).

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 18a determining the products, categories or groups of products for which, due to their low level of risk, the information referred to in Article 8(7) and Article 10(3) does not need to be indicated on the product itself.

Article 14

Identification of economic operators

1. Economic operators shall, on request, ~~identify the following to~~ ***provide*** the market surveillance authorities ***with the following information***: **[Am. 81]**

(a) any economic operator who has supplied them with the product;

(b) any economic operator to whom they have supplied the product.

2. Economic operators shall be able to present the information referred to in paragraph 1 for a period of 10 years after they have been supplied with the product and for a period of 10 years after they have supplied the product.

2a. Where economic operators provide the information referred to in paragraph 1, the market surveillance authorities shall treat that information as confidential.
[Am. 82]

Article 15

Traceability of products

1. For certain products, categories or groups of products which, due to their specific characteristics or specific conditions of distribution or usage, ***are*** susceptible to bear a serious risk to health and safety of persons ***and***, ***after consulting relevant stakeholders, as appropriate***, the Commission may require economic operators who place and make available those products on the market to establish or adhere to a system of traceability. **[Am. 83]**

2. The system of traceability shall consist of the collection and storage of data by electronic means enabling the identification of the product and of the economic operators involved in its supply chain as well as of the placement of a data carrier on the product, its packaging or accompanying documents enabling access to that data.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 18a:

(a) determining the products, categories or groups of products susceptible to bear a serious risk to health and safety of persons as referred to in paragraph 1 of this Article. ***The Commission shall state in the delegated acts concerned if it has used the risk analysis methodology provided for in Commission Decision 2010/15/EU[1] or, if that methodology is not appropriate for the product concerned, it shall give a detailed description of the methodology used***; **[Am. 84]**

(b) specifying the data which economic operators shall collect and store by means of the traceability system referred to in paragraph 2 of this Article.

4. The Commission may by means of implementing acts determine the type of data carrier and its placement as referred to in paragraph 2 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(3).

5. When adopting the acts referred to in paragraphs 3 and 4, the Commission shall take into account the following:

[1] ***Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System RAPEX established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive) (****OJ L 22, 26.1.2010, p. 1***).**

(a) the cost-effectiveness of the acts, including their impact on businesses in particular SMEs;

(b) the compatibility with traceability systems available at international level.

Article 15a

Product Safety Contact Points

1. Member States shall designate Product Safety Contact Points in their territories and shall communicate their contact details to the other Member States and to the Commission.

2. The Commission shall draw up and regularly update a list of Product Safety Contact Points and publish it in the Official Journal of the European Union. The Commission shall also make that information available on its website. **[Am. 85]**

Article 15b

Tasks of Product Safety Contact Points

1. ***Product Safety Contact Points shall, at the request of inter alia an economic operator or a competent authority of another Member State, provide the following information:***

(a) ***the technical rules applicable to a specific type of product on the territory in which those Product Safety Contact Points are established and information as to whether that type of product is subject to a requirement for prior authorisation under the laws of their Member State, together with information concerning the principle of mutual recognition as provided for in Regulation (EC) No 764/2008 and the application of that Regulation in the territory of that Member State;***

(b) ***the contact details of the competent authorities within that Member State by means of which they may be contacted directly, including the particulars of the authorities responsible for supervising the implementation of the technical rules in question in the territory of that Member State;***

(c) the remedies generally available in the territory of that Member State in the event of a dispute between the competent authorities and an economic operator.

2. Product Safety Contact Points shall respond within 15 working days of receiving any request referred to in paragraph 1.

3. Product Safety Contact Points in the Member State in which the economic operator concerned has lawfully marketed the product in question may provide the economic operator or the competent authority as referred to in Article 6 of Regulation (EC) No 764/2008 with any relevant information or observations.

4. The Member States shall establish offices in the framework of the Product Safety Contact Points in order to facilitate training on product safety legislation and requirements in general and transfer information across industries in order to support education of economic operators on product safety requirements.

5. Product Safety Contact Points shall not charge any fee for the provision of the information referred to in paragraph 1. **[Am. 86]**

CHAPTER III

European standards providing presumption of conformity

Article 16

Standardisation requests to European standardisation organisations

1. The Commission may request one or more European standardisation organisations to draft or identify a European standard, which aims at ensuring that products that conform to such standard or parts thereof comply with the general safety requirement laid down in Article 4. ~~The~~ ***Taking into account the views of relevant stakeholders, as appropriate, the*** Commission shall determine the requirements as to the content to be met by the requested European standard and a deadline for its adoption. **[Am. 87]**

   The Commission shall adopt the request referred to in the first subparagraph of this paragraph by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(3).

2. The relevant European standardisation organisation shall indicate, within one month following receipt of the request referred to in paragraph 1, if it accepts it.

3. Where a request for funding is made, the Commission shall inform the relevant European standardisation organisations, within two months following the receipt of the acceptance referred to in paragraph 2, about the award of a grant for drafting a European standard.

4. The European standardisation organisations shall inform the Commission about the activities undertaken for the development of the European standard referred to in paragraph 1. The Commission together with the European standardisation organisations shall assess the compliance of the European standards drafted or identified by the European standardisation organisations with its initial request.

5. Where the European standard satisfies the requirements it aims to cover and the general safety requirement laid down in Article 4, the Commission shall publish a reference to such European standard without delay in the *Official Journal of the European Union*.

Article 17

Formal objections to European standards

1. When a Member State or the European Parliament considers that a European standard referred to in Article 16 does not entirely satisfy the requirements it aims to cover and the general safety requirement laid down in Article 4, it shall inform the Commission thereof with a detailed explanation and the Commission shall decide by means of implementing acts:

   (a) to publish, not to publish or to publish with restriction the references to the European standard concerned in the *Official Journal of the European Union*;

   (b) to maintain, to maintain with restriction or to withdraw the references to the European standard concerned in or from the *Official Journal of the European Union*.

2. The Commission shall publish information on its website on the European standards that have been subject to a decision referred to in paragraph 1.

3. The Commission shall inform the European standardisation organisation concerned of the decision referred to in paragraph 1 and, if necessary, request the revision of the European standard concerned.

4. The decision referred to in point (a) of paragraph 1 of this Article shall be adopted in accordance with the advisory procedure referred to in Article 19(2).

5. The decision referred to in point (b) of paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 19(3).

CHAPTER IV

Final provisions

Article 18

Penalties

1. The Member States shall lay down the rules ~~on~~ ***establishing appropriate*** penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. ~~The penalties provided for must be effective, proportionate and dissuasive.~~ Member States shall notify those provisions to the Commission by…[*] ~~[~~*~~insert date - 3 months prior to the date of application of this Regulation~~*~~]~~ and shall notify it without delay of any subsequent amendment affecting them. **[Am. 88]**

[*] ***OJ: please insert the date: three months prior to the date of application of this Regulation.***

2. ***The penalties provided for shall be effective, proportionate and dissuasive.*** The penalties ~~referred to in paragraph 1~~ shall have regard to the ~~size of the undertakings and in particular to the situation of small and medium-sized enterprises~~ ***seriousness, the duration and, where applicable, the intentional character of the infringement***. ***In addition,*** the penalties ~~may be increased if~~ ***shall take into account whether*** the relevant economic operator has previously committed a similar infringement ~~and may include criminal sanctions for serious infringements~~. **[Am. 89]**

2a. ***Administrative penalties applicable to infringements shall at least offset the economic advantage sought through the infringement, but shall not exceed 10 % of the annual turnover or an estimate thereof. The penalties imposed may be higher than 10 % of the annual turnover or an estimate thereof, where necessary to offset the economic advantage sought through the infringement. The penalties may include criminal sanctions for serious infringements.*** **[Am. 90]**

2b. ***The Member States shall inform the Commission of the type and the size of the penalties imposed under this Regulation, identify the actual infringements of this Regulation, and indicate the identity of economic operators upon which penalties have been imposed. The Commission shall make that information available to the public without undue delay, electronically and, where appropriate, by other means.***

The Commission shall, on the basis of the information received under the first subparagraph, publish and update a Union-wide blacklist of economic operators who are repeatedly found to intentionally infringe this Regulation. **[Am. 91]**

Article 18a

Exercise of the delegation

1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 13(3) and Article 15(3) shall be conferred on the Commission for an indeterminate period of time from ...[*].

3. The delegation of power referred to in Article 13(3) and Article 15(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

[*] OJ: please insert the date: the date of entry into force of this Regulation.

5. A delegated act adopted pursuant to Article 13(3) and Article 15(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by two months at the initiative of the European Parliament or of the Council.

Article 19

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

   However, for the purposes of Articles 16 and 17 of this Regulation the Commission shall be assisted by the committee established by Regulation (EU) No 1025/2012. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4. Where the opinion of the committee referred to in the second subparagraph of paragraph 1 is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a simple majority of committee members so request.

Article 21

Evaluation

No later than ...* ***and every five years thereafter,*** the Commission shall assess the application of this Regulation and transmit an evaluation report to the European Parliament and the Council. That report shall assess whether this Regulation has achieved its objectives, in particular with regard to enhancing the protection of consumers against unsafe products ***within the meaning of Article 4 of this Regulation***, taking into account its impact on business and in particular on ~~small and medium-sized enterprises~~ ***SMEs***. ***That report shall also assess the implications and contributions of Regulation (EU) No 1025/2012 within the scope of this Regulation***. **[Am. 92]**

* OJ: please insert the date: [five] years after the date of application of this Regulation.

Article 22

Repeal

1. Directive 2001/95/EC is repealed with effect from ...*.

2. Directive 87/357/EEC is repealed with effect from ...*.

3. References to Directive 2001/95/EC and Directive 87/357/EEC shall be construed as references to this Regulation and shall be read in accordance with the correlation table set out in the Annex.

Article 23

Transitional provisions

1. Member States shall not impede the making available on the market of products covered by Directive 2001/95/EC which are in conformity with that Directive and which were placed on the market before ...*.

* OJ: please insert the date: date of application of this Regulation.

2. European standards the references of which have been published in the *Official Journal of the European Union* in accordance with Directive 2001/95/EC shall be deemed to be European standards referred to in point (b) of Article 5 of this Regulation.

3. Standardisation mandates issued by the Commission to a European standardisation organisation in accordance with Directive 2001/95/EC shall be deemed standardisation requests referred to in Article 15(1) of this Regulation.

Article 24

Entry into force

1. This Regulation shall enter into force on ..... [*]..

2. It shall apply from ... [**].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at …,

For the European Parliament	*For the Council*
The President	*The President*

[*] OJ: Please insert the date of entry into force of Regulation (2013/0048(COD)).

[**] OJ: Please insert the date of application of Regulation (2013/0048(COD)).

ANNEX

Correlation table

Directive 2001/95/EC	Directive 87/357/EEC	This Regulation
Article 1(1)		Article 1
First subparagraph of Article 1(2)		Article 2(1)
Second subparagraph of Article 1(2)		Article 2(4)
Article 2		Article 3
Points (b)(i)-(iv) of Article 2		Article 6(1)
Article 3(1)		Article 4
Article 3(2)		Article 5
Article 3(3)		Article 6(2)
Article 3(4)		-
Article 4		Articles 16 and 17
First subparagraph of Article 5(1)		Article 8(8)
Second subparagraph of Article 5(1)		-
Third subparagraph of Article 5(1)		Article 8(9)
Fourth subparagraph of Article 5(1)		Article 8(3), (6) and (7)
Fifth subparagraph of Article		-

5(1)		
Article 5(2)		Article 11
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