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Subject:	Proposal for a Regulation of the European Parliament and of the Council on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC - *General approach*

Please find attached the Presidency compromise text for the proposal on Product Safety as amended following the Coreper on 20 May 2015. Changes following the COREPER meeting compared to document 16901/13 are indicated.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC

(Text with EEA relevance)

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,

Whereas:

(1) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[2] lays down the requirement that consumer products must be safe and that Member States' market surveillance authorities must take action against dangerous products as well as exchange information to that effect through the Community rapid information exchange 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 In the interest of clarity, Directive 2001/95/EC should be repealed and replaced by this Regulation.

[1] OJ C , , p. .
[2] OL L 11, 15.1.2002, p. 4.

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

(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 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*][3] which applies also to products covered by this Regulation, no further provisions on market surveillance or RAPEX are needed in this Regulation.

(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 of 27 October 2004 on materials and articles to come into contact with food[4] or by other food specific legislation which only covers chemical and biological food related risks.

(5) Medicinal products and medical devices 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.

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3 OJ L , , p. .

4 OJ L 338, 13.11.2004, p. 4.

(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 products that are provided to consumers in the course of the provision of services. Equipment used for transport by consumers 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. This regulation does not affect the Member State's right to issue requirements to the operation and the use of these products within the framework of a service provided to consumers.

(6a) This Regulation does not affect the application of the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiations within the meaning of Article 30 of the Treaty establishing the European Atomic Energy Community.

(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 safety and health of consumers, as required by Article 114 and Article 169 of the 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 should be applicable to all consumer products, the obligations of economic operators under Chapter II of this Regulation should not apply where Union harmonisation legislation includes equivalent obligations, such as Union legislation on cosmetics, toys, electrical appliances or construction products. For reasons of transparency, the Commission should provide guidance regarding the relevant Union harmonisation legislation.

(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[5].

(10) This Regulation should apply to all forms of supply of consumer products, including distance selling.

(11) This Regulation should apply to second hand products that re-enter the supply chain in the course of a commercial activity, 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.

(12) This Regulation should also apply to consumer products which, although not foodstuff, resemble foodstuff and are likely to be confused with foodstuff in a way that consumers, especially children, may place them in their mouths, suck or ingest them, which might cause, for example, suffocation, poisoning, the perforation or obstruction of the digestive tract. Those food-imitating products 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[6] which should be repealed. (12a) This Regulation should also address safety aspects related to products that, although not designed for use to by children, due to their design or characteristics resemble objects commonly recognised as appealing to, or intended for use by children and therefore has direct impact on product safety.

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5 OJ L 218, 13.8.2008, p. 82.

6 OJ L 192, 11.7.1987, p. 42.

(13) The safety of products should be assessed taking into account all of the relevant aspects, in particular the product's characteristics and presentation 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.

(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. However, this presumption could be rebutted when there is evidence that the product presents a risk. This presumption should not prevent market surveillance authorities from taking action as appropriate where there is evidence that, despite such conformity or compliance, the product presents a risk .

(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.

(15a) Economic operators when fulfilling their obligations under this Regulation should cooperate closely with the market surveillance authorities of the Member States, where necessary. Furthermore, economic operators should be encouraged on request of a market surveillance authority of the Member State to notify to the authority a contact person on product safety issues.

(15b) Effective market surveillance is necessary in order to ensure that the provisions of this Regulation are respected. To this end market surveillance authorities should be able to request economic operators to provide documentation necessary to demonstrate compliance of a product where there are doubts in respect of such compliance. Requests of the market surveillance authorities of the Member States to economic operators in connection to the fulfilment of their obligations under this Regulation should reasoned, as appropriate, in accordance with national rules of the Member States of these market surveillance authorities, in conformity with Union law.

(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 operator in the supply and distribution process.

(16a) Products should be accompanied by instructions and safety information where needed due to the products' inherent risks throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings. The relevant information should inform the consumers about those risks and the precautions to be taken to allow the safe use of the product. They should be written and provided in such a way that they as to be are easily visible, clearly legible and understandable for the consumer. Safety information should always accompany a product when it is assumed that without such safety information consumers will not recognise a risk and therefore cannot use a product safely.

(16b) Manufacturers should monitor their products by carrying out sample testing, investigating complaints and maintaining records of complaints, non-conforming products and product recalls. Manufacturers of low-risk products should only act in a manner proportionate to the risks presented by their products.

(17) Importers bear the responsibility that products 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. Importers, *inter alia*, should ensure that the technical documentation can be made available within a reasonable period of time to the market surveillance authorities of the Member States, upon request, for a period of ten years after the product has been placed on the market.

(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.

(19) Any economic operator that either places a product on the market under his own name or trademark 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 measures 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 documentations 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 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[7] is applicable to the processing of personal data for the purposes of this Regulation.

[7] OJ L 281, 23.11.1995, p. 31.

(20a) The manufacturer and the importer should indicate on the product his name, registered trade name or registered trade mark, and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the product does not allow it or where the importer would have to open the packaging to put the required information on the product itself.

[(21) The indication of origin supplements the basic traceability requirements concerning the name and address of the manufacturer. In particular, 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 its given address is different from the actual place of manufacture. 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.]

(21a) Certain products or categories or groups of products, due to their specific characteristics or specific conditions of usage, bear a serious risk to health and safety of consumers. Their traceability is therefore of particular importance and it is relevant to examine if the traceability could be enhanced by way of specific traceability systems. Pilot projects are useful to assess whether system of traceability would be effective to improve the traceability of certain products or categories or groups of products. The Commission should submit an evaluation of the outcome of the pilot project, if appropriate, accompanied by a legislative proposal to amend this Regulation with a view to provide for specific rules requiring economic operators to establish or adhere to a system of traceability by electronic or other appropriate means.

(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 is published in the *Official Journal of the European Union*, is to be presumed to be in compliance with that requirement. European standard should retain its voluntary nature and economic operators should be allowed to take other measures than following European standard in order to comply with the general safety 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 of 25 October 2012 on European standardisation[8] 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*.

(23a) ~~(27)~~ **In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission 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 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[9].**

8 OJ L 316, 14.11.2012, p. 12.

9 OJ L 55, 28.2.2011, p. 13.

(23aa) ~~(28)~~ **The advisory procedure should be used for the adoption of implementing acts with respect to the 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 compliance with the general safety requirement laid down in this Regulation.**

(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** ~~taking into account the provisions of~~ Regulation (EU) No 1025/2012. **However, in order to ensure that the Commission can rely on adequate expertise in the field of consumer product safety, requests for European standards, or objections to a European standard, should be brought before the committee set up by this Regulation.** ~~The Commission should be assisted by the Committee set up by this Regulation. Formal objections to European standards developed under this Regulation should be dealt with in the same manner as formal objections to harmonized standards as provided for in Article 11 of Regulation (EU) No 1025/2012.~~

(25) European standards, the references of which have been published in accordance with Directive 2001/95/EC, should continue providing presumption of compliance 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 this purpose pursuant to Article 292 TFEU.

(26a) The Commission should be assisted by the Committee set up by this Regulation also in cases where other Union legislation requires so, for example, ~~on the basis of the Regulation (EU) No … [on Market Surveillance]~~ when taking Union action against certain consumer products presenting a serious risk~~, as provided for in that Regulation~~ **on the basis of the Regulation (EU) No … [on Market Surveillance].**

~~(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 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[10].~~

~~(28) The advisory procedure should be used for the adoption of implementing acts with respect to the 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 compliance with the general safety requirement laid down in this Regulation..~~

~~10~~ 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.

(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 functioning of the internal market as regards products intended for consumers while guaranteeing a high level of health and safety protection of consumers, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the measure, 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 the freedom to conduct business.

(33a) The precautionary principle has been taken into account in the drafting of this Regulation and ~~must~~ should be taken into account in its application.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

General provisions

Article 1

Subject matter and objective

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

2. The objective of this Regulation is to ensure a high level of protection of health and safety of consumers as well as to contribute to the proper functioning of the internal market.

3. The provisions of this Regulation are based on the precautionary principle.

Article 2

Scope

1. This Regulation shall apply to products placed or made available on the market, irrespective of the form of supply, whether new, used or reconditioned, and which comply with any of the following criteria:

   (a) which are intended for consumers;

   (b) which are likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them;

   (c) which are provided to consumers in the course of a service provision, whether or not the product is operated by the consumer himself.

3. This Regulation shall not apply to the following:

(a) medicinal products for human or veterinary use covered by Directive 2001/83/EC or Directive 2001/82/EC;

(aa) medical devices and in vitro diagnostic medical devices covered by Directives 90/385/EEC, 93/42/EEC and 98/79/EC;

(b) food and feed within the meaning of Regulation (EC) No 178/2002;

(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;

(e) genetically modified organisms covered by Directive 2001/18/EC;

(f) animal by-products and derived products covered by Regulation (EC) No 1069/2009;

(g) plant protection products covered by Regulation (EC) No 1107/2009;

(h) equipment used for transport which is operated by a service provider within the context of a service provided to consumers;

(i) antiques or products to be repaired or reconditioned prior to being used provided that the economic operator clearly informs to that effect;

(j) human blood, blood components and blood products covered by Directive 2002/98/EC;

(k) human tissue and cells covered by Directive 2004/23/EC.

4. Chapters II and III of this Regulation shall apply to products subject to requirements designed to protect human health and safety laid down in Union harmonisation legislation or pursuant to it in so far as there are no equivalent requirements in such legislation. Where products are subject to requirements designed to protect human health and safety laid down in Union harmonisation legislation or pursuant to it, Chapters II and III of this Regulation shall apply only to the aspects and risks or categories of risks not covered by those requirements.

Article 3

Definitions

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

(0) ‘product’ means a substance, mixture or a good produced through a manufacturing process;

(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 trademark;

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

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

(11) ‘national standard’ means a national standard as defined in Article 2(1)(d) 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 Article [*3(12) of Regulation (EU) No […/…] [on market surveillance of products*];[11]

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11 It is suggested amending Recital 12 of Market Surveillance Regulation as follows: "This Regulation should establish a comprehensive framework for market surveillance in the Union. It should define the scope of the products covered and those excluded **and** impose an obligation on Member States to organise and carry out market surveillance**. This Regulation should** require Member States to appoint market surveillance authorities **in line with the organisational structure of administration of Member States,** to specify the **market surveillance authorities’** powers and duties, and make Member States responsible for setting up general and sector-specific market surveillance programmes. **Market surveillance authority should mean any authority deemed competent by the relevant Member State for the purposes of this Regulation and may include any competent authority which verifies compliance with the general safety requirement for the purposes of Regulation (EU) No […/…] *[on consumer product safety].***"

(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 made available on the market;

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

(16a) ‘risk’ means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm.

Article 4

General safety requirement

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

2. A product shall be considered safe if, under normal or reasonably foreseeable conditions of use, it 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. The conditions of use include the duration of use and where applicable, putting into service of the product, its installation and its maintenance requirements.

Article 5

Presumption of compliance with the general safety requirement

For the purpose of this Regulation, a product shall be presumed to be in compliance with the general safety requirement in the following cases:

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

(b) in the absence of requirements laid down in or pursuant to Union harmonisation legislation referred to in point (a), 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), as regards the risks covered by national requirements designed to protect against risks to human health and safety laid down in the law of the Member State where the product is made available on the market, if it conforms to such national requirements.

Article 6

Aspects for assessing the compliance with the general safety requirement

1. In the absence of requirements designed to protect against risks to human health and safety laid down in or pursuant to 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 in compliance with the general safety requirement, in particular:

   (a) the characteristics and presentation of the product, including its composition, labelling, packaging, any warnings, and instructions for assembly, installation, use, maintenance and/or disposal and any other indication or information regarding the product;

(b) the effect on other products and the effect on that product from its interaction with other products, where it is reasonably foreseeable that it will be used with other products;

(d) the categories of consumers at risk when using the product, in particular vulnerable consumers;

(ea) the appearance of the product, in particular where a product, 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 and characteristics.

1a. So far as the risk is not covered by requirements designed to protect against risks to human health and safety laid down in or pursuant to Union harmonisation legislation, when a product, although not foodstuff, resembles foodstuff and is likely to be confused with foodstuff which can reasonably result in serious severity of harm, the following aspects, in particular, shall be taken into account when assessing whether a that product is in compliance with the general safety requirement:

(a) form,
(b) odour,
(c) colour,
(d) appearance,
(e) packaging,
(f) labelling,
(g) volume, or
(h) size.

1b. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds, in itself, for considering a product not to be a product in compliance with the general safety requirement.

2. For the purpose of paragraphs 1, 1a and 1b, when assessing whether a product is in compliance with the general safety requirement, 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;

(ba) safety requirements to be met by European standards laid down in measures adopted by the Commission in accordance with Article 4 of Directive 2001/95/EC or Article 16 of this Regulation;

(c) international standards;

(d) international agreements;

(e) Commission recommendations or guidelines on product safety ;

(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.

Article 7

Indication of the origin

1. This Article shall apply only to the following product categories:

(a) footwear as defined in Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer;

(b) ceramic articles as defined in Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuff;

1~~2~~. Manufacturers and importers shall ensure that the products referred to in the first paragraph 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

3~~2~~. For the purpose of determination of the country of origin within the meaning of paragraph 1, non-preferential origin rules set out in Articles ~~23 to 25 of Council Regulation (EEC) No 2913/92 establishing a Community Customs Code[12]~~ **60 to 63 of Regulation (EU) No 952/2013 laying down the Union Customs Code** shall apply.

4~~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.

~~[12] OJ L 302, 19.10.1992, 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 compliance with the general safety requirement .

2. Manufacturers shall ensure that procedures are in place for series production to remain in compliance with the general safety requirement.

3. When deemed appropriate with regard to the risks presented by a product, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of products made available on the market, investigate complaints and keep a register of complaints, non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.

4. Manufacturers shall draw up a technical documentation. The technical documentation shall contain, proportionate to the possible risks of the product, as appropriate:

   (a0) name and postal address of the manufacturer;

   (a) a general description of the product which enables the technical documentation to be clearly attributed to the product;

   (aa) the essential properties of the product 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;

(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.

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 and details shall be given on how risks related to parts which have not been applied have been taken into account.

5. Manufacturers shall keep in paper or electronic form, for a period of ten years after the product has been placed on the market, the technical documentation and make it available to the market surveillance authorities, upon request.

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.

7. Manufacturers shall indicate on the product their name, registered trade name or registered trade mark and the postal address at which they can be contacted 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.

8. Manufacturers shall ensure that their product is accompanied by instructions and safety information which are clear and easily legible, 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 without such instructions and safety information.

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

9. 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. 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.

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 request from a market surveillance authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product with this Regulation;

   (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 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 on the product their name, registered trade name or registered trade mark and the postal address at which they can be contacted 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 mandatory information provided by the manufacturer.

4. Importers shall ensure that the product is accompanied by instructions and safety information which are clear and easily legible, 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 and its conformity with Article 8(6) and (7).

6. When deemed appropriate with regard to the risks presented by a product, importers shall, to protect the health and safety of persons, carry out sample testing of 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.

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 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.

8. Importers shall ensure that the technical documentation can be made available to the market surveillance authorities, upon request, for a period of ten years after the product has been placed on the market.

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 set out in Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable. Distributors shall ensure that any additional label does not obscure any mandatory information provided by the manufacturer or the importer.

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 and its conformity with Article 8(6), (7) and (8) and Article 10(3) and (4), as applicable.

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 make sure that the corrective action necessary to bring that product into conformity is taken, to withdraw it or recall it, if appropriate. 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.

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 trademark 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 notification obligations of economic operators in specific cases

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 in the following specific cases where well-identified products are affected, the severity of harm which can reasonably result from the hazard presented by the product is low and one of the following conditions are fulfilled:

(aa) the market surveillance authority has been informed about the identification of the product, the relevant economic operator(s) and the risks presented by the product concerned, and corrective actions taken, or

(ba) the product has not yet been made available to consumers and the economic operator has taken all necessary corrective action to remove the risk presented by the product concerned.

1a. Economic operators shall make available on request by the market surveillance authority the information that proves demonstrates the fulfilment of the conditions referred to in paragraph 1.

Article 14

Identification of economic operators and products

1. Economic operators shall, on request, provide the following information to the market surveillance authorities:

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

(b) the identity of 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.

Article 15

Traceability of certain products

The Commission may carry out pilot projects in order to assess whether a system of traceability by electronic or other appropriate means would be an effective tool to improve the traceability of certain products or categories or groups of products.

The Commission shall submit an evaluation of the outcome of the pilot project to the European Parliament and the Council. If appropriate, that evaluation may be accompanied by a legislative proposal to amend this Regulation with a view to provide for rules requiring economic operators to establish or adhere to a system of traceability by specified means

CHAPTER III

European standards providing presumption of compliance with the general safety requirement

Article 16

Standardisation requests to European standardisation organisations

1. The Commission may request one or several 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. The Commission shall determine the requirements as to the content to be met by the requested European standard and a deadline for its adoption

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

~~1. Where the Commission considers that a European standard, which aims at ensuring that products that conform to such standard or parts thereof comply with the general safety requirement, should be drafted or identified, it shall make a request to one or several European standardisation organisations in accordance with Articles 10(1) to 10(5) of Regulation (EU) No 1025/2012.~~

~~For such a request the Commission shall determine the requirements as to the content to be met by the requested European standard and a deadline for its adoption on the basis of the opinion of the committee referred to in the first subparagraph of Article 19(1), first subparagraph and in accordance with the procedure referred to in Article 19(3).~~

5. Where the European standard satisfies the requirements it aims to cover and the general safety requirement, 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*~~

~~Article 11 of Regulation (EU) No 1025/2012 shall apply in the case of formal objections by the Member States or the European Parliament to European standards referred to in Article 16.~~

CHAPTER IV

Final provisions

Article 18

Penalties

1. The Member States shall lay down the rules on 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.

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.

~~Without prejudice to the second subparagraph of Article 16(1), the Committee shall be consulted by the Commission on any matter to which the provisions of this Regulation apply and for which consultation of sectorial experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.~~

~~However, for the purposes of Articles 16 and 17 of this Regulation except the second subparagraph of Article 16(1), 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.

Article 21

Evaluation

No later than [five] years after the date of application, the Commission shall assess the application of this Regulation and transmit an evaluation report to the European Parliament and the Council. This report shall assess if this Regulation achieved its objectives, in particular with regard to enhancing the protection of consumers against unsafe products, taking into account its impact on business and in particular on small and medium-sized enterprises.

No later than [three] years after the date of application, the Commission shall prepare an evaluation report in order to assess whether Article 7 of this Regulation has achieved its objectives, in particular with regard to enhancing the protection of consumers against unsafe products and improving product traceability, taking into account its impact on businesses and in particular on small and medium-sized enterprises. The Commission shall transmit the evaluation report to the European Parliament and the Council.

Article 22

Repeal

1. Directive 2001/95/EC is repealed with effect from [*insert date - day of application of this Regulation*].

2. Directive 87/357/EEC is repealed with effect from [*insert date - day of application of this Regulation*].

3. References to Directive 2001/95/EC and Directive 87/357/EEC shall be construed as references to this Regulation or to Regulation (EU) N° […/…][on market surveillance of products] and shall be read in accordance with the correlation table 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 [*insert date - day of application of this Regulation*].

2. European standards the reference of which is 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. Mandates given by the Commission to a European standardisation organisation in accordance with Directive 2001/95/EC shall be deemed standardisation requests referred to in Article 16(1) of this Regulation.

Article 24

Entry into force

1. This Regulation shall enter into force on [insert date - the same day as entry into force of Regulation (EU) No […/…][on market surveillance of products].

2. It shall apply from [insert date - the same day as date of application of Regulation (EU) No […/…][on market surveillance of products].

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

Done at Brussels,

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

Annex

Correlation table

Directive 2001/95/EC	Directive 87/357/EEC	This Regulation
Article 1(1)		Article 1
Article 1(2), 1st subparagraph		Article 2(1)
Article 1(2), 2nd subparagraph		Article 2(4)
Article 2		Article 3
Article 2(b)(i)-(iv)		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
Article 5(1), 1st subparagraph		Article 8(8)
Article 5(1), 2nd subparagraph		-
Article 5(1), 3rd subparagraph		Article 8(9)
Article 5(1), 4th subparagraph		Article 8(3), (6) and (7)
Article 5(1), 5th subparagraph		-
Article 5(2)		Article 11
Article 5(3), 1st subparagraph		Article 8(9) and Article 11(5)

Article 5(3), 2nd subparagraph		-
Article 5(4)		-
Article 6(1)		-
Article 6(2) and (3)		-
Article 7		Article 18
Article 8(1)(a)		-
Article 8(1)(b) – (f)		-
Article 8(2), 1st subparagraph		-
Article 8(2), 2nd subparagraph		-
Article 8(2), 3rd subparagraph		-
Article 8(3)		-
Article 8(4)		-
Article 9(1)		-
Article 9(2)		-
Article 10		-
Article 11		-
Article 12		-
Article 13		-
Article 14		-

Article 15		Article 19
Article 16		-
Article 17		-
Article 18(1)		-
Article 18(2)		-
Article 18(3)		-
Article 19(1)		-
Article 19(2)		Article 21
Article 20		-
Article 21		-
Article 22		Article 22
Article 23		Article 24
Annex I, section 1		Article 8(9) and Article 11(5)
Annex I, section 2, first sentence		-
Annex I, section 2, second sentence		Article 13(1) and (2)
Annex I, section 3		-
Annex II		-
Annex III		-

Annex IV		Annex
	Article 1	Article 6(1)(e)
	Articles 2 to 7	-