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PRODUCT SAFETY AND MARKET SURVEILLANCE PACKAGE

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)

{SWD(2013) 33 final}
{SWD(2013) 34 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

The free movement of safe consumer products is one of the cornerstones of the European Union. It is an important pillar of the single market and gives consumers confidence when purchasing products.

This proposal for a Regulation on consumer product safety, which will replace Directive 2001/95/EC of the European Parliament and of the Council on general product safety[1] (the "General Product Safety Directive" or simply GPSD), concerns manufactured non-food consumer products. Like the GPSD also the proposed Regulation requires that consumer products must be "safe", sets certain obligations on economic operators and contains provisions for the development of standards in support of the general safety requirement.

However, the operation of the proposed Regulation and its interface with other Union legislation will be significantly streamlined and simplified whilst maintaining a high level of protection of the health and safety of consumers.

Overlaps of market surveillance rules and obligations of economic operators laid down in various pieces of Union legislation (the GPSD, the Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[2] and sector-specific Union harmonisation legislation that also covers consumer products) has led to confusion on the part of both economic operators and national authorities and has seriously hampered the effectiveness of market surveillance activity in the Union.

This proposal aims at clarifying the regulatory framework for consumer products taking into account legislative developments in recent years such as the New Legislative Framework on the Marketing of Products adopted in 2008[3], the alignment of sector-specific Union harmonisation legislation to that new framework[4] and the entry into application on 1 January 2013 of a new Regulation on European standardisation[5].

The proposal is part of the "Product Safety and Market Surveillance Package" which also includes a proposal for a single market surveillance regulation and a multi-annual action plan for market surveillance covering the period 2013-2015. The Single Market Act (2011)[6] identified the revision of the GPSD and the drawing up of a market surveillance plan as initiatives that will contribute to boosting growth and creating jobs. The Single Market Act II[7], adopted in 2012, confirms the "Product Safety and Market Surveillance Package" as a key action "to improve the safety of

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1 OJ L 11, 15.1.2002, p. 4.

2 OJ L 218, 13.8.2008, p. 30.

3 Consisting of Regulation (EC) No 765/2008 and 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, OJ L 218, 13.8.2008, p. 82.

4 Adopted by the Commission on 21 November 2011, http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/new-legislative-framework/index_en.htm.

5 Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012, OJ L 316, 14.11.2012, p. 12.

6 COM(2011)206 final.

7 COM(2012)573 final.

products circulating in the EU through better coherence and enforcement of product safety and market surveillance rules".

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENTS

From 2009 to 2011, the Commission held extensive public consultations on the revision of the GPSD concerning the scope of the impact assessment. Following the definition of the scope of the impact assessment, the Commission proceeded to the second round of public consultation which concentrated on four main substantive areas for improvement in the EU product safety regime: (i) procedures for mandating standards under the GPSD for non-harmonised products, (ii) harmonisation of safety evaluations, (iii) market surveillance cooperation and coordination, including the functioning of the EU Rapid Information System (RAPEX) and on-line distribution channels, and (iv) alignment with the Free Movement of Goods Package.

The second round of public consultation on problems identified and the solutions proposed by the Commission took place between May and December 2010. Between 18 May and 20 August 2010, the Commission held an internet public consultation focussing on those four areas. The Commission sought feedback through four consultation papers and nine online questionnaires targeting various groups of stakeholders. 55 national authorities responded, from all EU Member States except one and from Norway, Iceland and Switzerland. Various other stakeholders, including more than thirty business associations, seventeen consumer organisations, and over fifty individual economic operators (including several SMEs) contributed to the consultation. In total, 305 replies were received to the nine online questionnaires. In addition, thirteen business and consumer organisations provided separate position papers. A number of presentations and direct exchanges with stakeholders (with both business and consumer organisations) were also held during the consultation period.

The second round of public consultation ended with an international stakeholder conference on the "Revision of the General Product Safety Directive" on 1 December 2010 during which the Commission received feedback from the stakeholders on key conclusions of the public internet consultation.

The third round of public consultation took place between January and March 2011. It took the form of targeted stakeholder meetings with the participation of experts in the relevant areas. These meetings covered structural topics, including the organisation of market surveillance coordination, the impact of the new definitions of obligations of economic operators (in particular traceability obligations), procedures for establishing mandates leading to the establishment of European standards under the GPSD and ways to establish a clear and understandable structure for non-food product safety rules.

One of the outcomes of the public consultation process and the dialogue with interested parties was to transfer the market surveillance rules from the current GPSD into a new stand-alone Market Surveillance Regulation to be developed and adopted hand in hand with the present proposal for the revision of the GPSD.

The impact assessment prepared by the Commission thus covers aspects related to both this proposal and the proposal for a new Market Surveillance Regulation. The Commission's Impact Assessment Board delivered a favourable opinion in September 2012.

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Scope and definitions**

  The proposed Regulation clearly delimits its scope of application compared to sectoral Union harmonisation legislation. Whilst the general principle that all non-food consumer products must be safe applies across the board, the more detailed obligations on economic operators only apply to those operators that are not subject to corresponding obligations laid down in harmonising legislation covering a specific product sector. The Commission envisages drawing up guidance which will help businesses, in particular small and medium-size enterprises, to identify which legislation applies to the consumer products they manufacture or distribute.

  The definitions section has been updated and, where applicable aligned with the New Legislative Framework for the Marketing of Products[8].

- **General safety requirement and obligations of economic operators**

  The requirement that all consumer products must be safe when placed or made available on the Union market is a fundamental pillar of EU legislation in the field of product safety. This general product safety requirement, laid down already in the GPSD, has been kept. However, its operation in practice will be significantly simplified due to the introduction of a clear link with sector-specific legislation and a simplification of the rules on standards.

  Consumer products that comply with sector-specific Union harmonisation legislation that aims at ensuring the health and safety of persons shall be presumed to be safe also under this proposed Regulation. If they do not comply with the applicable harmonisation legislation, they would not benefit from the safety presumption but correction of such situation would be governed by the sector-specific legislation in conjunction with the future single market surveillance regulation.

  Moreover, the proposal lays down the elementary obligations of economic operators (manufacturers, importers, distributors) involved in the supply chain of consumer products insofar as they are not subject to corresponding requirements under sector-specific Union harmonisation legislation. The obligations are based on the reference provisions set out 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[9] and address, among others, issues related to labelling, product identification, corrective actions to be taken in case of unsafe products and information of the competent authorities. Proportionate to the potential risks of their products, manufacturers will be obliged to establish a technical documentation regarding their products which shall contain the necessary information to prove that their product is safe.

  Equally based on Decision No 768/2008/EC, the proposal requires economic operators to be able to identify the operators who supplied them with the product and to whom they supplied it. Where justified due to the risks inherent to specific types of products, the Commission should be empowered to adopt measures requiring economic operators to establish or adhere to an electronic traceability system.

- **Use of European standards**

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8 See footnote 3.

9 OJ L 218, 13.8.2008, p. 82.

Like the GPSD, also the proposal for the new Regulation favours the use of standards in support of the implementation of the general safety requirement. However, the process to identify existing European standards or to ask for the development of European standards that would give rise to presume that a product is safe has been significantly simplified and aligned to Regulation (EU) No 1025/2012 that sets a new overarching framework for European standardisation[10]. This underlines the importance the Commission gives to an approach of co-regulation and will enhance the use of European standards in support of the proposed Regulation.

- **Transfer of rules on market surveillance and RAPEX to a new Market Surveillance Regulation**

  In line with the objective to strengthen and streamline market surveillance for all products, whether harmonised or not and whether intended for consumers or for professionals, the provisions regarding market surveillance and RAPEX that are currently contained in the GPSD have been transferred to the proposal for a new single Market Surveillance Regulation. That new Regulation would produce a one-tier system in which all market surveillance rules are brought together in a single instrument and in which RAPEX will be the single alert system regarding products presenting a risk. Further information is given in the proposal for a Regulation on market surveillance of products.

- **Union competence, subsidiarity, proportionality and legal form**

  The proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU) which provides for the same legal base for the establishment and functioning of the internal market on which the current GPSD was adopted. In regulating product safety, the Union is exercising its shared powers under Article 4(2) of the TFEU.

  Within the internal market where products can circulate freely, the rules on product safety can effectively be adopted only at Union level. This is necessary in order to guarantee a high level of consumer protection (in line with Article 169 TFEU) and also to prevent Member States from adopting diverging product regulations which would result in fragmentation of the single market. In accordance with the principles of proportionality and subsidiarity, as set out in Article 5 of the Treaty on European Union, this proposal does not go beyond what is necessary in order to achieve those objectives.

  The proposal takes the form of a Regulation. This is the appropriate legal instrument as it imposes clear and detailed rules which will become applicable in a uniform manner and at the same time throughout the Union. It will avoid diverging transposition by Member States which is liable to lead to different levels of health and safety protection and to create obstacles to the internal market. Replacing the national transposition measures also has a strong simplification effect since it allows economic operators to conduct their business on the basis of a single regulatory framework, rather than a 'patchwork' of Member States' national laws.

- **Fundamental rights**

  In line with the Charter of Fundamental Rights of the EU, this proposal seeks to ensure a high level of human health protection (Article 35 of the Charter) and consumer protection (Article 38) by assuring a high level of safety of consumer

[10] See footnote 5.

products made available on the Union market. The proposal affects the freedom of economic operators to conduct business (Article 16) but the obligations imposed on manufacturers, importers and distributors of consumer products are necessary to guarantee a high level of safety of those products.

4. BUDGETARY IMPLICATION

The proposal does not have other budgetary implications than those related to the proper management of the Regulation which, in form of the GPSD, is already part of the Union law *acquis*. The budgetary implications are already foreseen in the existing or proposed programmes and respect the Commission proposal for the new multiannual financial framework. The details are set out in the financial statement attached to this proposal.

5. SIMPLIFICATION AND SMART REGULATION

This proposal contributes to the simplification of EU legislation and adheres to the principles of smart regulation. When preparing this proposal the Commission has taken stock of the important advancement of sector-specific legislation that aims at ensuring the safety of products and which usually does not make a distinction whether the products covered are intended for consumers or professional users. Contrary to the situation 10 or 15 years ago, it is not necessary any more to apply a second layer of obligations to economic operators who are already appropriately regulated by sector-specific legislation. At the same time, the obligations for those who produce, import or distribute consumer products that are not covered by specific legislation are to a large extent aligned with those applicable to harmonised products.

This approach will reduce administrative burdens and compliance costs for businesses, in particular for small and medium-sized enterprises. In the future, they can easily identify the set of rules applicable to their commercial activity so that they will save on costs caused by legal uncertainty.

Due to the subject-matter and objective of the proposed Regulation, micro-enterprises as defined in Commission Recommendation 2003/361/EC[11] cannot be exempted from its requirements because rules aiming at protecting the health and safety of persons must apply regardless of the size of the economic operator. But micro-enterprises are likely to benefit most from the simplification that the new piece of legislation will bring about which is fit for purpose and replaces two directives that have become out of date. The Commission is committed to providing further guidance to businesses, in particular to small and medium-sized enterprises, and consumers to help them to easily identify their respective rights and obligations.

[11] OJ L 124, 20.5.2003, p. 36.

2013/0049 (COD)

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[12],

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[13] 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.

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

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12 OJ C , , p. .

13 OL L 11, 15.1.2002, p. 4.

14 OJ L , , p. .

(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[15] 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 products that are supplied or made available to consumers in the context of the provision of services, including products to which consumers are directly exposed during a service provision. 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.

(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 should not apply where Union harmonisation legislation includes equivalent obligations, such as Union legislation on cosmetics, toys, electrical appliances or construction products.

(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[16].

(10) The scope of this Regulation should not be limited to any selling technique of consumer products, and thus also cover 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

[15] OJ L 338, 13.11.2004, p. 4.
[16] OJ L 218, 13.8.2008, p. 82.

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[17] which should be repealed.

(13) The safety of products should be assessed taking into account all the relevant aspects, in particular their 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.

(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.

(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.

(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.

(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

[17] OJ L 192, 11.7.1987, p. 42.

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[18] is applicable to the processing of personal data for the purposes of this Regulation.

(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.

(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.

(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[19] 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.*

(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.

(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 this purpose pursuant to Article 292 TFEU.

(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

[18] OJ L 281, 23.11.1995, p. 31.
[19] OJ L 316, 14.11.2012, p. 12.

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[20].

(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 with the general safety requirement laid down in this Regulation.

(29) 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 in respect of products for which the name 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, and in respect of the identification and traceability of products bearing a potential serious risk to health and safety. 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.

(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.

[20] OJ L 55, 28.2.2011, p. 13.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

General provisions

Article 1

Subject matter

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

Article 2

Scope

1. This Regulation shall apply to products obtained through a manufacturing process placed or made available on the market, 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) to which consumers are exposed in the context of a service provided to them.
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.
3. This Regulation shall not apply to the following:
   (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;
   (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;
   (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.
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 shall apply:

(1) ‘safe product’ means any product which, under normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance 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;

(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*];

(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;

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

(17) ‘serious risk’ means a risk requiring rapid intervention and follow-up, including cases where the effects may not be immediate.

Article 4

General safety requirement

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

Article 5

Presumption of safety

For the purpose 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;

(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) 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 such national requirements.

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), (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 composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;

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

   (c) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;

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

   (e) the appearance of the product and in particular where a product, although not foodstuff, resembles foodstuff and is likely to be confused with foodstuff due

to its form, odour, colour, appearance, packaging, labelling, volume, size or other characteristics.

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

2. For the purpose of paragraph 1, when assessing whether a product is safe, the following aspects, when available, shall be taken into account, in particular:

(a) the state of the art and technology;

(b) European standards other than those the references of which have been published in the *Official Journal of the European Union* in accordance with Articles 16 and 17;

(c) international standards;

(d) international agreements;

(e) Commission recommendations or guidelines on product safety assessment;

(f) national standards drawn up in the Member State in which the product is made available;

(g) product safety codes of good practice in force in the sector concerned;

(h) reasonable consumer expectations concerning safety.

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, non-preferential origin rules set out in Articles 23 to 25 of Council Regulation (EEC) No 2913/92 establishing a Community Customs Code[21] shall apply.

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.

CHAPTER II

Obligations of economic operators

Article 8

Obligations of manufacturers

[21] OJ L 302, 19.10.1992, p. 1.

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 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. Proportionate to the possible risks of a product, manufacturers shall draw up a technical documentation.The technical documentation shall contain, as appropriate:

   (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;

   (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 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 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.

8. Manufacturers shall ensure that their 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).

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;

   (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 information on the label provided by the manufacturer.

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 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 keep, 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.

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.

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.

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 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 controlled and cannot any more endanger the health and safety of persons;

   (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.

2. The Commission may by means of implementing acts determine the situations which meet the conditions of paragraph 1. 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 20 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 the market surveillance authorities:

   (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 the first paragraph 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 products

1. For certain products, categories or groups of products which, due to their specific characteristics or specific conditions of distribution or usage, susceptible to bear a serious risk to health and safety of persons, 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.

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 20:

   (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;

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

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

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

   (a) the cost-effectiveness of the measures, including their impact on businesses in particular small and medium-sized enterprises;

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

CHAPTER III

European standards providing presumption of conformity

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 laid down in Article 4. 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).

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:

   (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 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.

2. 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. The penalties may be increased if the relevant economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringements.

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 20

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 Articles 13(3) and 15(3) shall be conferred on the Commission for an indeterminate period of time from [*insert date* - the date of entry into force of this Regulation].

3. The delegation of power referred to in Articles 13(3) and 15(3) may be revoked at any time by the European Parliament or by the Council. A decision of revocation 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.

5. A delegated act adopted pursuant to Articles 13(3) and 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 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.

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 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 15(1) of this Regulation.

Article 24

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	-

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

1.2. Policy area(s) concerned in the ABM/ABB structure

1.3. Nature of the proposal/initiative

1.4. Objective(s)

1.5. Grounds for the proposal/initiative

1.6. Duration and financial impact

1.7. Management method(s) envisaged

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

2.2. Management and control system

2.3. Measures to prevent fraud and irregularities

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

3.2.2. Estimated impact on operational appropriations

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.4. Compatibility with the current multiannual financial framework

3.2.5. Third-party participation in financing

3.3. Estimated impact on revenue

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council on consumer product safety

1.2. Policy area(s) concerned in the ABM/ABB structure[22]

Title 17 – Health and consumer protection – Chapter 17 02: Consumer policy

1.3. Nature of the proposal/initiative

☐ The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[23]

X The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objectives

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

The proposal contributes to the European Union's ten-year growth strategy "Europe 2020" by enhancing consumer confidence in the safety of products and improving the functioning of the single market.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

SANCO specific objective: To consolidate and enhance product safety through effective market surveillance throughout the Union

[22] ABM: Activity-Based Management – ABB: Activity-Based Budgeting.

[23] As referred to in Article 49(6)(a) or (b) of the Financial Regulation.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

On consumers: Reinforced confidence that consumer products made available on the single market are safe.

On economic operators: Clearer rules as regards the respective obligation incumbent on manufacturers, importers and distributors.

On authorities: Clear legal framework to enforce general safety requirement and obligations on economic operators and better identification of (dangerous) consumer products.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

Ratio of traceable/non-traceable consumer products covered by this Regulation notified under RAPEX.

Number of mandates to European standardisation organisations and number of European standards referenced in the OJ pursuant to the new Regulation.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The objective is to build a consistent regulatory framework for safe products in the single market. This shall overcome the fragmentation of market surveillance rules and obligations of economic operators among various pieces of Union legislation (Directive 2001/95/EC, Regulation (EC) No 765/2008 and sector-specific Union harmonisation legislation) which has led to confusion on the part of both economic operators and national authorities and has seriously hampered the effectiveness of market surveillance activity in the Union.

Along with a series of other actions, the Single Market Act I and II identified the revision of the General Product Safety Directive as part of the Product Safety Market Surveillance Package as important initiatives to contribute to boosting growth and creating jobs.

1.5.2. Added value of EU involvement

The proposed revision of Directive 2001/95/EC, which will integrate the modifications of the Lisbon Treaty, can only be achieved at Union level. The proposal is based on Article 114 Treaty on the Functioning of the European Union (TFEU), to which also Article 169 TFEU refers, in order to ensure a high level of protection of health and safety of all European consumers and establish an internal market for consumer goods.

In accordance with the principles of proportionality and subsidiarity, as set out in Article 5 of the Treaty on European Union, this proposal does not go beyond what is necessary to achieve those objectives.

1.5.3. Lessons learned from similar experiences in the past

The use of European standards in support of Directive 2001/95/EC is cumbersome and resource-intensive. The proposal aims at simplifying the procedures.

The application of Directive 2001/95/EC in terms of market surveillance measures to consumer products covered also by sector-specific legislation was not always clear which will be clarified.

1.5.4. Coherence and possible synergy with other relevant instruments

This proposal is part of the Product Safety and Market Surveillance Package and thus fully coherent with the proposal for a Regulation of the European parliament and of the Council on market surveillance of products.

This proposal aligns definitions and economic operators' obligations with the New Legislative Framework adopted in 2008. It is therefore coherent with the "Alignment Package" of sectoral Union harmonisation legislation currently negotiated in the European Parliament and in the Council.

The provisions on European standards are coherent with the recently adopted Regulation (EU) No 1025/2012 on European standardisation.

1.6. Duration and financial impact

☐ Proposal/initiative of **limited duration**

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

X Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

1.7. Management mode(s) envisaged[24]

X **Centralised direct management** by the Commission

X **Centralised indirect management** with the delegation of implementation tasks to:

– x executive agencies

– ☐ bodies set up by the Communities[25]

– ☐ national public-sector bodies/bodies with public-service mission

– ☐ persons entrusted with the implementation of specific actions pursuant to Title V of the Treaty on European Union and identified in the relevant basic act within the meaning of Article 49 of the Financial Regulation

☐ **Shared management** with the Member States

☐ **Decentralised management** with third countries

☐ **Joint management** with international organisations ***(to be specified)***

If more than one management mode is indicated, please provide details in the "Comments" section.

Comments:

Implementation of the proposed Regulation should be ensured through centralised direct management by the Commission.

The management of the proposed Regulation may be complemented by actions with the involvement of the Executive Agency on Health and Consumers (EAHC) that, in accordance with Council Regulation (EC) No 58/2003 of 19 December 2002[26], can be entrusted with certain tasks in the management of Community programmes. The Commission has entrusted[27] the Executive Agency for Health and Consumers with implementation tasks for the management of the Programme of Community Action in the field of Consumer policy for 2007-2013. The Commission may therefore decide to entrust the Executive Agency for Health and Consumers also with implementation tasks for the management of the Consumers Programme 2014-2020, which, once adopted, should be the legal basis for procurement and grants in the field of product safety.

[24] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

[25] As referred to in Article 185 of the Financial Regulation.

[26] OJ L 11, 16.1.2003, p. 1.

[27] Commission Decision C(2008)4943 of 9 September 2008.

The envisaged programme delegation will be the extension of tasks already externalised to the Executive Agency for Health and Consumers (EAHC).

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

The GPSD committee (which the proposed Regulation will transform into a committee within the meaning of Regulation (EU) No 182/2011) and existing expert groups and/or the European Market Surveillance Forum foreseen in the proposal for a single market surveillance regulation will provide a regular platform to discuss issues related to the implementation of the new Regulation.

The proposal suggests that the Commission should review its implementation and submit a report theron to the European parliamnet and to the Council.

2.2. Management and control system

2.2.1. Risk(s) identified

The two proposals (on general product safety and on market surveillance) forming part of the Package are separated from each other during the legislative negotiations and do not progress in parallel.

2.2.2. Control method(s) envisaged

The provisions on entry into force are interlinked in both proposals.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

In addition to the application of all regulatory control mechanisms, DG SANCO will devise an anti-fraud strategy in line with the Commission's new anti-fraud strategy (CAFS; adopted on 24 June 2011) in order to ensure inter alia that its internal anti-fraud related controls are fully aligned with the CASF and that its fraud risk management approach is geared to identify fraud risk areas and adequate responses. Where necessary, networking groups and adequate IT tools dedicated to analysing fraud cases related to the Consumer Programme will be set up. In particular a series of measures will be put in place such as:

- decisions, agreements and contracts resulting from the implementation of the Consumer Programme will expressly entitle the Commission, including OLAF, and the Court of Auditors to conduct audits, on-the-spot checks and inspections;

- during the evaluation phase of a call for proposals/tender, the proposers and tenderers are checked against the published exclusion criteria based on declarations and the Early Warning System (EWS);

- the rules governing the eligibility of costs will be simplified in accordance with the provisions of the Financial Regulation.

- regular training on issues related to fraud and irregularities is given to all staff involved in contract management as well as to auditors and controllers who verify the beneficiaries' declarations on the spot.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Description……...…….]	Diff./non-diff. (28)	from EFTA[29] countries	from candidate countries[30]	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
N° 3: Security and citizenship	17.01.04.01 Administrative expenditure in support of the Consumer Programme 2014 - 2020	Non-diff.	YES	NO	NO	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number [Heading……..]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
N° 3: Security and citizenship	17 02 01 Consumer Programme 2014 - 2020	Diff.	YES	YES	NO	NO

28 Diff. = Differentiated appropriations / Non-diff. = Non-Differentiated Appropriations

29 EFTA: European Free Trade Association.

30 Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure[31]

EUR million in current prices (to 3 decimal places)

Heading of multiannual financial framework:	3	Security and citizenship

DG: SANCO			2015	2016	2017	2018	2019	2020	**TOTAL**
• Operational appropriations									
Number of budget line 17.02.01	Commitments	(1)	1,107	1,189	1,272	1,356	1,443	1,530	**7,897**
	Payments	(2)	0,554	1,148	1,230	1,314	1,400	2,251	**7,897**
Appropriations of an administrative nature financed from the envelope for specific programmes[32]									
Number of budget line: 17.01.04.01	Commitments	(1a)	0,094	0,094	0,094	0,094	0,094	0,094	**0,564**
	Payments	(2a)	0,094	0,094	0,094	0,094	0,094	0,094	**0,564**
TOTAL appropriations for DG SANCO	Commitments	=1+1a	1,201	1,283	1,366	1,450	1,537	1,624	**8,461**
	Payments	=2+2a	0,648	1,242	1,324	1,408	1,494	2,345	**8,461**

• TOTAL operational appropriations	Commitments	(3)	1,107	1,189	1,272	1,356	1,443	1,530	**7,897**

31 Amounts subject to the outcome of the legislative process based on the Commission proposal for the new Multiannual Financial Framework 2014-2020.

32 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

	Payments	(4)	0,554	1,148	1,230	1,314	1,400	2,251	**7,897**
•TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(5)	0,094	0,094	0,094	0,094	0,094	0,094	**0,564**
TOTAL appropriations under HEADING 3 of the multiannual financial framework	Commitments	=3+ 5	1,201	1,283	1,366	1,450	1,537	1,624	**8,461**
	Payments	=4+ 5	0,648	1,242	1,324	1,408	1,494	2,345	**8,461**

Heading of multiannual financial framework:	**5**	" Administrative expenditure "

EUR million in current prices (to 3 decimal places)

		2015	2016	2017	2018	2019	2020	**TOTAL**
• Human resources		0,524	0,524	0,524	0,524	0,524	0,524	**3,144**
• Other administrative expenditure (missions, meetings)		0,069	0,069	0,069	0,069	0,069	0,069	**0,414**
TOTAL	Appropriations	0,593	0,593	0,593	0,593	0,593	0,593	**3,558**

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	0,593	0,593	0,593	0,593	0,593	0,593	**3,558**

EUR million in current prices (to 3 decimal places)

		2015	2016	2017	2018	2019	2020	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	1,794	1,876	1,959	2,043	2,130	2,217	12,019
	Payments	1,241	1,835	1,917	2,001	2,087	2,938	12,019

3.2.2. Estimated impact on operational appropriations

– The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million in current prices (to 3 decimal places)

Indicate objectives and outputs ⇩			2015		2016		2017		2018		2019		2020		TOTAL	
	Type of output[33]	Average cost of the output	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Number of outputs	Cost	Total number of outputs	Total cost
SPECIFIC OBJECTIVE: To consolidate and enhance product safety through effective market surveillance throughout the Union																
- Output																
Product safety: scientific advice, international cooperation, monitoring and assessing of the safety of products, knowledge base		1,316	4	1,107	4	1,189	4	1,272	4	1,356	4	1,443	4	1,530	**24**	**7,897**
Sub-total for specific objective: To consolidate and enhance product safety through effective market surveillance throughout the Union			4	1,107	4	1,189	4	1,272	4	1,356	4	1,443	4	1,530	**24**	**7,897**

[33] The output consists in ensuring a high level of consumer product safety. It would be difficult to further break it down in quantitative outputs because, due to lack of reliable data, it is not possible to indicate in absolute or relative terms a target number for fewer unsafe products on the market. The number of RAPEX notifications does not necessarily reflect the number of unsafe products on the market. An increased number of RAPEX notifications can mean more effective market surveillance but less unsafe products and vice versa.

TOTAL COST	4	1,107	4	1,189	4	1,272	4	1,356	4	1,443	4	1,530	**24**	**7,897**

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

– The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million in current prices (to 3 decimal places)

	2015	2016	2017	2018	2019	2020	**TOTAL**
HEADING 5 of the multiannual financial framework							
Human resources	0,524	0,524	0,524	0,524	0,524	0,524	**3,144**
Other administrative expenditure	0,069	0,069	0,069	0,069	0,069	0,069	**0,414**
Subtotal HEADING 5 of the multiannual financial framework	0,593	0,593	0,593	0,593	0,593	0,593	**3,558**
Outside HEADING 5[34] of the multiannual financial framework							
Human resources	0	0	0	0	0		0
Other expenditure of an administrative nature	0,094	0,094	0,094	0,094	0,094	0,094	**0,564**
Subtotal outside HEADING 5 of the multiannual financial framework	0,094	0,094	0,094	0,094	0,094	0,094	**0,564**
TOTAL	0,687	0,687	0,687	0,687	0,687	0,687	**4,122**

[34] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

3.2.3.2. Estimated requirements of human resources

– The proposal/initiative requires the use of human resources, as explained below:

EUR million in current prices (to 3 decimal places)

		2015	2016	2017	2018	2019	2020	TOTAL
17 01 01 01 (Headquarters and Commission's Representation Offices)		0,524	0,524	0,524	0,524	0,524	0,524	**3,144**
XX 01 01 02 (Delegations)		0	0	0	0	0		
XX 01 05 01 (Indirect research)		0	0	0	0	0		
10 01 05 01 (Direct research)		0	0	0	0	0		
XX 01 02 01 (CA, INT, SNE from the "global envelope")		0	0	0	0	0		
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)		0	0	0	0	0		
XX 01 04 ***yy*** [35]	- at Headquarters[36]	0	0	0	0	0		
	- in delegations	0	0	0	0	0		
XX 01 05 02 (CA, INT, SNE - Indirect research)		0	0	0	0	0		
10 01 05 02 (CA, INT, SNE - Direct research)		0	0	0	0	0		
Other budget lines (specify)		0	0	0	0	0		
TOTAL		0,524	0,524	0,524	0,524	0,524	0,524	**3,144**

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints. The resources required are indicated without taking account of the tasks which will be implemented by an executive agency. The proposal does not lead to an increase of the resources already involved in the executive agency.

Description of tasks to be carried out:

Officials and temporary agents	Administrators: • Ensure, monitor and report on the proper implementation and application of EU policies in the area of product safety. • Follow policy developments in the area of product safety and information exchange between Member States. • Participate and represent the Commission in comitology meetings and expert groups linked to product safety. • Identify and prepare initiatives within the framework of the Consumer Product Safety Regulation to ensure a consistent and high level of consumer product safety, in particular standardisation mandates and assessment of standards and specifications to support the application of the Regulation.

35 Under the ceiling for external personnel from operational appropriations (former "BA" lines).

36 Essentially for Structural Funds, European Agricultural Fund for Rural Development (EAFRD) and European Fisheries Fund (EFF).

	Assistants: • Ensure the administrative support with the operation of the comitology committee and expert groups. • Carry out various tasks related to the interface with internal and external correspondents and stakeholders in the area of product safety. • Assist in launching, managing and monitoring calls for tenders and the implementation of contracts.

3.2.4. Compatibility with the current multiannual financial framework

– X Proposal/initiative is compatible with the new multiannual financial framework 2014-2020 as proposed by the Commission.

– ☐ Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts. NA

– ☐ Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[37].

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts. NA

3.2.5. Third-party contributions

– The proposal does not provide for co-financing by third parties

3.3. Estimated impact on revenue

– X The proposal has no financial impact on revenue.

[37] See points 19 and 24 of the Interinstitutional Agreement.