EUROPEAN
COMMISSION

Brussels, 13.2.2013
COM(2013) 75 final

2013/0048 (COD)

PRODUCT SAFETY AND MARKET SURVEILLANCE PACKAGE

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

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

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

The European Union needs a Single Market that is operating at maximum efficiency to help get its economy back on track. The free movement of goods is the most developed and best established of the four fundamental freedoms laid down in the Treaty on the Functioning of the European Union (TFEU) that make up the internal market. But it would be complacent to believe that the job is done. True, harmonisation rules[1] have now been put in place for most products and the free movement provisions of the TFEU, supplemented by the mutual recognition principle, are sufficient for the rest. But even a good legislative framework is only as effective as those using it allow it to be. Alongside responsible economic operators, prepared to adapt their methods and incur the costs necessary to comply with the law, there will always be those traders who cut corners or deliberately flout the rules to 'make a fast buck' or gain a competitive edge.

These sharp practices not only skew the single market against the type of trader we wish to encourage, damaging its effectiveness and causing detriment to consumers and business, they also threaten the public interests that our legislation is designed to protect. In addition to financial burden, the European citizen is exposed to potentially dangerous products. The environment is put at risk. Public security may even be undermined.

Market surveillance is the answer. If high quality legislation, based on a sound evaluation of market needs is one side of the coin, market surveillance is the other. It should enable unsafe or otherwise harmful products to be identified and kept or taken off the market and unscrupulous or even criminal operators punished. It should also act as a powerful deterrent.

Market surveillance has not kept pace with developments in the Union regulatory framework. In a single market in which products circulate freely throughout 27 (and in some sectors up to 32)[2] national territories, market surveillance needs to be highly coordinated and capable of reacting rapidly over a huge area. Advances have been made over the last decade, in particular with the implementation of Directive 2001/95/EC of the European Parliament and of the Council on general product safety[3] (the "General Product Safety Directive" or simply GPSD) which had to be transposed by 2004 and with the coming into application in 2010 of Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance[4]. However, overlap of market surveillance rules and obligations of economic operators laid down in various pieces of Union legislation (the GPSD, the Regulation (EC) 765/2008 and sector-specific Union harmonisation legislation) 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.

---

1 Harmonisation rules seek to achieve free movement by protecting at a high level public interests that Member States might otherwise invoke to justify imposing restrictions on trade in products.

2 In accordance with international agreements of the EU with the EFTA countries and Turkey.

3 OJ L 11, 15.1.2002, p. 4.

4 OJ L 218, 13.8.2008, p. 30.

This proposal aims at clarifying the regulatory framework for market surveillance in the field of non-food products. It merges the rules on market surveillance of the GPSD, Regulation (EC) 765/2008 and many sector-specific pieces of Union harmonisation legislation into a single legal instrument that applies horizontally across all sectors.

Market surveillance action by national authorities has important implications for small and medium-sized enterprises. Consequently, their situation should be taken into account particularly in relation to action that could impose additional administrative burdens.

The proposal is part of the "Product Safety and Market Surveillance Package" which also includes a proposal for a regulation on consumer product safety (replacing the GPSD) and a multi-annual action plan for market surveillance covering the period 2013-2015. After the Single Market Act (2011)[5] had identified the revision of the GPSD and the drawing up of a multi-annual action plan for market surveillance as initiatives that will contribute to boosting growth and creating jobs, the Commission added this proposal for a single market surveillance regulation to the other two initiatives in response to calls from the European Parliament and from stakeholders in industry and public administrations. The Single Market Act II[6], adopted in 2012, confirms the "Product Safety and Market Surveillance Package" as a key action "to improve the safety of 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 (for more details see the Proposal for a Consumer Product Safety Regulation). One of the main substantive areas related to the improvement of market surveillance cooperation and coordination, including the functioning of RAPEX.

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 standalone Market Surveillance Regulation to be developed and adopted hand in hand with the proposal for the revision of the GPSD.

The impact assessment prepared by the Commission thus covers aspects related to both the GPSD revision and this proposal.

The Commission's Impact Assessment Board delivered a favourable opinion in September 2012.

3. LEGAL ELEMENTS OF THE PROPOSAL

Main elements

[5] COM(2011)206 final.
[6] COM(2012)573 final.

The overarching objective of this new regulation is to simplify the Union market surveillance framework fundamentally so that it works better for its main users: market surveillance authorities and economic operators. At present, different product evaluation requirements and procedures apply depending on the category of product involved. Market surveillance authorities should be able to do their job of evaluating the risk presented by products without being hindered by unnecessary complexities and to share the results of their work efficiently.

The new Regulation will get rid of overlaps, close gaps, reduce the need to categorise products to a minimum and assimilate as far as possible the rules and procedures applicable to all products. This will result in a more even application of market surveillance rules across the Member States, providing better protection for consumers and other users, more uniform trading conditions for economic operators, reduced administrative burdens and enhanced information- and work-sharing between market surveillance authorities. This is particularly important in the context of the economic crisis and responds to the need to make the internal market for goods more efficient and competitive.

- **Reducing the number of pieces of legislation containing market surveillance rules**

At first sight, this might seem to be a rather cosmetic objective but the current set of market surveillance rules is spread across the GPSD, Regulation 765/2008 and a range of sector-specific legislation (which is increasingly based on the reference provisions of Decision 768/2008). This '3-tier' system causes problems for market surveillance authorities and economic operators alike and was expressly targeted for criticism by the European Parliament. The new Regulation would produce a one tier system in which all of those rules are brought together in a single instrument. It may be complemented by sector-specific rules laid down in the relevant Union harmonisation legislation.

- **Eliminating overlaps in the current system**

Regulation 765/2008 and sector-specific legislation apply to all harmonised products regardless whether they are intended (or likely) to be used by consumers or professionals. The GPSD applies to all consumer products regardless whether they are non-harmonised or harmonised. This obviously creates overlaps in relation to harmonised products intended or likely to be used by consumers. The current system tries to deal with this by means of complicated *lex specialis* provisions but this is universally regarded as unsatisfactory.

The new market surveillance Regulation would dispense with the distinction between consumer and professional products for market surveillance purposes. It would also avoid making a distinction between harmonised products and non-harmonised products except where this is unavoidable in applying certain specific provisions. To the greatest extent possible the applicable rules are the same for all products.

- **Dovetailing the RAPEX and Union evaluation procedures**

At present, two separate procedures operate, sometimes in parallel, which require the Member States to notify to the Commission and the other Member States certain

market surveillance action taken at national level. This is an especially problematic aspect of the overlapping categories of products mentioned above. Under the new Regulation the two procedures become a single procedural flow with certain events triggering a single notification to the other Member States and the Commission (made using either the proven RAPEX rapid alert system or the Information and Communication System for Market Surveillance in accordance with the distinction made in this Regulation).

In the case of products which are subject to sector-specific Union harmonisation legislation, in the event of disagreement among Member States about action taken by one of their number, the proposal would empower the Commission to decide whether the measures taken by the original notifying Member State are reasonable, necessary and proportionate and should be followed by all Member States in the interests of the single market. In this way, the market surveillance process may be brought to a definite close. This is not extended to products not subject to sector-specific Union harmonisation legislation as such a decision cannot be taken in the absence of the essential requirements for products that are laid down in that legislation.

In urgent situations the Commission is empowered to adopt temporary or permanent measures requiring consistent action across the EU against products presenting a serious risk where the risk cannot be satisfactorily addressed by one or several individual Member States.

- **Making the legislation more accessible and user-friendly**

Apart from being spread across three tiers of EU legislation (and in the case of directives, also in national implementing measures), current market surveillance provisions are not based around a chronological flow of events - from the identification by market surveillance authorities of a product that may present a risk, through risk assessment, involvement of the economic operators, action by the national authorities, notification to the other Member States, up to possible action across the Union by all Member States and, where necessary, evaluation and decision by the Commission at Union level. Instead, market surveillance authorities and economic operators must hunt around in the legislation for the provisions that affect them directly.

The new Regulation sets out the whole process of a market surveillance exercise in a chronological, sequential manner. It presents a chain of events, incorporating relevant provisions on natural justice aspects, publication of information, notification etc. at each stage of the procedure. This approach substantially improves the accessibility and user-friendliness of the legislation, and hence its effectiveness.

Legal basis

The proposal is based on Articles 33, 114 and 207 of the Treaty on the Functioning of the European Union.

Subsidiarity

Market surveillance is an activity which is carried out by the authorities of the Member States of the Union. This will not change. However, in order to be effective, the market surveillance effort must be uniform across the Union. If market

surveillance is ‘softer’ in some parts of the Union than others, weak spots are created which threaten the public interest and create unfair trading conditions. Furthermore, much of the risk presented by products to the various public interests that Union legislation tries to protect derives from products entering the Union from third countries. There must be effective market surveillance along the entire length of the Union’s external borders.

There is therefore a need for Union legislation which creates uniform obligations in relation to the activities to be carried out, the resources to be attributed and the powers and duties of market surveillance authorities. Equally, there must be an obligation to cooperate and to coordinate market surveillance and mechanisms and tools must be established to make possible and facilitate these endeavours. Penalties, financing and reporting also all need to be addressed at Union level.

Proportionality

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set. The modifications introduced by the Regulation do not impose unnecessary burdens or costs on industry, having particular regard to small and medium-sized enterprises, or administrations. Many modifications to the existing legislative framework relate to improving its clarity and workability without introducing significant new requirements with cost implication. Where a modification has an impact on burdens or costs, the impact analysis indicated that it represents the most proportionate response to the problem identified.

4. BUDGETARY IMPLICATION

The budgetary implications are already envisaged in existing or proposed programmes and respect the Commission proposal for the new multiannual financial framework. This initiative will be financed through redeployment of existing resources. The details are set out in the financial statement attached to this proposal.

2013/0048 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(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 Articles 33, 114 and 207 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[7],

After consulting the European Data Protection Supervisor,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) In order to guarantee the free movement of products within the Union, it is necessary to ensure that they fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment and public security. Robust enforcement of these requirements is essential to the proper protection of these interests and to create the conditions in which fair competition in the Union goods market can thrive. Rules are therefore necessary on market surveillance and on controls of products entering the Union from third countries.

(2) Market surveillance activities covered by this Regulation should not be directed exclusively towards the protection of health and safety but should also be applicable to

[7] OJ C , , p. .

the enforcement of Union legislation which seeks to safeguard other public interests, for example, by means of regulating the accuracy of measurement, electromagnetic compatibility and energy efficiency.

(3) It is necessary to establish an overall framework of rules and principles in relation to market surveillance which should not affect the substantive rules of existing Union legislation designed to protect public interests such as health and safety, consumer protection and the protection of the environment, but should aim at enhancing their operation.

(4) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products[8] was adopted to establish a framework for market surveillance to complement and strengthen existing provisions in Union harmonisation legislation relating to market surveillance and the enforcement of such provisions.

(5) For the purpose of ensuring the equivalent and consistent enforcement of Union harmonisation legislation, Regulation (EC) No 765/2008 introduced a Union market surveillance framework, defining minimum requirements against the background of the objectives to be achieved by Member States and a framework for administrative cooperation including the exchange of information among Member States.

(6) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[9] established rules to ensure the safety of products intended for or likely to be used by consumers. Regulation (EC) No 765/2008 maintained the possibility for market surveillance authorities to take the more specific measures available to them under that Directive.

(7) In its Resolution of 8 March 2011 on the revision of the General Product Safety Directive and market surveillance[10] the European Parliament states that having one single regulation is the only way to have one single market surveillance system for all products and therefore urges the Commission to establish a single market surveillance system for all products, based on one act covering both Directive 2001/95/EC and Regulation (EC) No 765/2008.

(8) This Regulation should therefore integrate the provisions of Regulation 765/2008, Directive 2001/95/EC and several sector-specific acts of Union harmonisation legislation relating to market surveillance into a single regulation which covers products in both the harmonised and non-harmonised areas of the Union legislation, regardless whether they are intended for use, or are likely to be used, by consumers or professionals.

(9) Union legislation applicable to products and processes of the food chain, and in particular Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[11], establishes a comprehensive framework for the performance of official controls and

---

8 OJ L 218, 13.8.2008, p.30.
9 OJ L 11, 15.1.2002, p. 4.
10 2010/2085(INI).
11 OJ L 165, 30.4.2004, p. 1.

other official activities to verify compliance with feed and food law, rules on animal health and welfare, genetically modified organisms, plant health and plant reproductive material, plant protection products, and pesticides. These areas should therefore be excluded from the scope of this Regulation.

(10) Union legislation concerning medicinal products, medical devices, in vitro diagnostic medical devices and substances of human origin contain special provisions to ensure post-market safety based in particular on sector-specific vigilance and market surveillance systems. Those products should therefore also be excluded from the scope of this Regulation, with the exception of its provisions on control of products entering the Union market which should apply insofar as the relevant Union legislation does not contain specific rules relating to the organisation of border controls.

(11) Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment[12] applies not only to new transportable pressure equipment for the purpose of making it available on the market but also to certain other transportable pressure equipment for the purposes of its periodic inspections, intermediate inspections, exceptional checks and use. It provides for the specific Pi-marking and for a Union safeguard procedure and particular procedures for dealing with transportable pressure equipment presenting a risk at national level, with compliant transportable pressure equipment which presents a risk to health and safety and with formal non-compliance. Therefore, the procedures for the controls of products within the Union laid down in this Regulation should not apply to transportable pressure equipment subject to Directive 2010/35/EU.

(12) 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, impose an obligation on Member States to organise and carry out market surveillance, require Member States to appoint market surveillance authorities and to specify their powers and duties, and make Member States responsible for setting up general and sector-specific market surveillance programmes.

(13) Some Union harmonisation legislation contains provisions on market surveillance and safeguard clauses. These may be based on the reference provisions on market surveillance and safeguard clauses contained 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[13]. This Regulation should contain all of the market surveillance provisions applicable to the products falling within its scope. This Regulation should therefore include the reference provisions on market surveillance and safeguard clauses contained in Decision No 768/2008/EC. Provisions in existing Union harmonisation legislation that relate to market surveillance and safeguard clauses, whether drafted before the adoption of Decision No 768/2008/EC or based on its reference provisions, should be removed from that harmonisation legislation unless there are specific sectoral reasons for retaining them. Exemptions from the safeguard provisions should be made in relation to products subject to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), certain fittings subject to Directive 2009/142/EC of the European

[12] OJ L165, 30.6.2010, p.1.
[13] OJ L 218, 13.8.2008, p.82.

Parliament and of the Council of 30 November 2009, certain pressure equipment subject to Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 and certain pressure vessels subject to Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009.

(14) In order to make the entire market surveillance process transparent and easy to follow for both market surveillance authorities and economic operators, the Regulation should clearly set out the chronological steps of that process, from the moment when market surveillance authorities identify a product which they believe may present a risk, to the assessment of the risk presented, the corrective action to be taken by the relevant economic operator within a specified period and the measures to be taken by market surveillance authorities themselves if economic operators do not comply or in cases of urgency.

(15) Market surveillance should be based on the assessment of the risk presented by a product taking all relevant data into account. A product that is subject to Union harmonisation legislation which lays down essential requirements relating to protection of certain public interests should be presumed not to present a risk to those public interests if it complies with those essential requirements.

(16) Products subject to Union harmonisation legislation that does not lay down essential requirements but which is designed to ensure the protection of certain public interests should be presumed not to present a risk to those public interests provided that they comply with that legislation.

(17) Similarly, a product that is not subject to Union harmonisation legislation but which complies with national rules on the health and safety of persons or with European standards referenced in the *Official Journal of the European Union* should be presumed not to present a risk to health and safety.

(18) For the purposes of this Regulation risk assessment should be carried out to identify products which have the potential to affect adversely the public interests protected by [Regulation (EU) No xxxx (on consumer product safety)], sector-specific Union harmonisation legislation and other Union legislation on products that are subject to this Regulation. It should include, where available, data on risks that have materialised previously with respect to the product in question. Account should also be taken of any measures that may have been taken by the economic operators concerned to alleviate the risks. The particular potential vulnerability of consumers, as opposed to professional users, should be taken into account as should the increased vulnerability of certain categories of consumer such as children, the elderly or the disabled.

(19) Both new and second hand products originating outside the Union may be placed on the market only after they have been released for free circulation. Effective controls are required at the external borders of the Union to suspend the release of products that may present a risk if placed on the market in the Union pending evaluation and a final decision by market surveillance authorities.

(20) Obliging the authorities responsible for the control of products entering the Union market to carry out checks on an adequate scale therefore contributes to a safer Union market for products. In order to increase the effectiveness of such checks, cooperation

and exchange of information between those authorities and market surveillance authorities concerning products presenting a risk should be enhanced.

(21) Market surveillance authorities should be given the power to destroy products, render inoperable or order their destruction by the relevant economic operator, if they deem it necessary and proportionate to ensure that such goods cannot pose any further threats.

(22) The release for free circulation of products that are imported in the physical possession of persons entering the Union for their personal, non-commercial use should not be suspended or refused under this Regulation by the authorities responsible for the control of products entering the Union market.

(23) There should be effective, speedy and accurate exchange of information among the Member States and between the Member States and the Commission. It is therefore necessary to provide for effective tools for such exchange. The Union rapid information system (RAPEX) has proved its effectiveness and efficiency. RAPEX enables measures to be taken across the Union in relation to products that present a risk beyond the territory of a single Member State. To avoid unnecessary duplication, this system should be used for all alert notifications required by this Regulation relating to products presenting a risk.

(24) Coherent and cost-effective market surveillance activity throughout the Union also requires well-structured, comprehensive archiving and sharing among Member States of all pertinent information on national activities in this context, including a reference to notifications required by this Regulation, to form a complete database of market surveillance information. The Commission has established a database called 'Information and Communication System for Market Surveillance' which is suited for this purpose and should therefore be used.

(25) Given the size of the Union market for goods and as there are no internal borders, it is imperative that the market surveillance authorities of the Member States are willing and able to cooperate with each other effectively and to coordinate joint support and action. Accordingly, mechanisms for mutual assistance should be established.

(26) In order to facilitate market surveillance of products entering the Union market from third countries, this Regulation should provide a basis for cooperation between market surveillance authorities of Member States and the authorities of those countries.

(27) A European Market Surveillance Forum composed of representatives from market surveillance authorities should be established. The Forum should provide a means of involving all stakeholders concerned, including professional organisations and consumer organisations, in order to take advantage of available information relevant for market surveillance when establishing, implementing and updating market surveillance programmes.

(28) The Commission should provide support for cooperation between market surveillance authorities and participate in the Forum. The Regulation should set out a list of tasks to be performed by the Forum. An executive secretariat should organise the Forum's meetings and provide other operational support for the accomplishment of its tasks.

(29) Where appropriate, reference laboratories should be established with a view to providing expert, impartial technical advice and conducting tests on products required in relation to market surveillance activities.

(30) This Regulation should strike a balance between transparency through the release of the maximum possible amount of information to the public and maintaining confidentiality, for example for reasons of personal data protection, commercial secrecy or the protection of investigations, in accordance with rules on confidentiality pursuant to applicable national law or, as regards the Commission, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[14]. 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[15] and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data[16] apply in the context of this Regulation.

(31) Information exchanged between competent authorities should be subject to the strictest guarantees of confidentiality and professional secrecy and be handled in a way that investigations are not compromised and that the reputations of economic operators are not prejudiced.

(32) Member States should provide means of redress in the competent courts and tribunals in respect of restrictive measures taken by their authorities.

(33) 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.

(34) Market surveillance should be financed at least in part by fees charged to economic operators where they are required by market surveillance authorities to take corrective action or where those authorities are obliged to take action themselves.

(35) In order to achieve the objectives of this Regulation, the Union should contribute to the financing of activities required to implement policies in the field of market surveillance such as the drawing-up and updating of guidelines, preliminary or ancillary activities in connection with the implementation of Union legislation and programmes of technical assistance and cooperation with third countries as well as the enhancement of policies at Union and international level.

(36) Union financing should be made available in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union[17], depending on the nature of the activity to be financed, in particular for support to the executive secretariat of the EMSF.

---

14 OJ L 145, 31.5.2001, p. 43.
15 OJ L 281, 23.11.1995, p. 31.
16 OJ L 8, 12.1.2001, p. 1.
17 OJ L 298, 26.10.2012, p. 1.

(37) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards national measures taken and notified by a Member State in relation to products subject to Union harmonisation legislation and the establishment of Union reference laboratories.

(38) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission as regards uniform conditions for the carrying out of checks by reference to particular product categories or sectors, including the scale of checks to be carried out and the adequacy of samples to be checked. Implementing powers should also be conferred as regards the modalities for the provision of information to market surveillance authorities by economic operators, as regards establishing uniform conditions for determining cases in which such information need not be provided. Implementing powers should also be conferred as regards the modalities and procedures for the exchange of information through RAPEX and as regards the adoption of temporary or permanent marketing restrictions on products presenting a serious risk, where appropriate, specifying the necessary control measures to be taken by the Member States for their effective implementation where other Union legislation does not provide a specific procedure to address the risks in question. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of its implementing powers[18].

(39) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to restrictive measures relating to products that present a serious risk, imperative grounds of urgency so require.

(40) The market surveillance provisions of Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment[19], Directive 93/15/EEC of 5 April 1993 on the harmonization of the provisions relating to the placing on the market and supervision of explosives for civil uses[20], Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres[21], Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft[22], European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts[23], Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment[24], Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their

18 OJ L 55, 28.2.2011, p. 11.
19 OJ L 399, 30.12.1989, p. 18.
20 OJ L 121, 15.5.1993, p. 20.
21 OJ L 100, 19.4.1994, p. 1.
22 OJ L 164, 30.6.1994, p. 15.
23 OJ L 213, 7.9.1995, p. 1.
24 OJ L 181, 9.7.1997, p. 1.

conformity[25], Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons[26], Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors[27], Directive 2001/95/EC, Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility[28], Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery[29], Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits[30], Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles[31], Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community[32], Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys[33], Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels[34], Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels[35], Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment[36], Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products[37], and Regulation (EC) No 765/2008 overlap with the provisions of this Regulation. Therefore, these provisions should be deleted. Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC should be amended accordingly[38].

(41) Since the objective of this Regulation, namely to ensure that products on the market covered by Union legislation fulfil the requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market by providing a framework for coherent market surveillance in the Union, cannot be sufficiently achieved by the Member States as the attainment of this objective requires a very high degree of cooperation, interaction and uniformity of operation among all of the competent authorities of all Member States, and can therefore, by reason of its scale and effects, be better achieved at Union level,

25 OJ L 91, 7.4.1999, p. 10.
26 OJ L 106, 3.5.2000, p. 21.
27 OJ L 162, 3.7.2000, p. 1.
28 OJ L 390, 31.12.2004, p. 24.
29 OJ L 157, 9.6.2006, p. 24.
30 OJ L 374, 27.12.2006, p. 10.
31 OJ L 154, 14.6.2007, p. 1.
32 OJ L 191, 18.7.2008, p. 1.
33 OJ L 170, 30.6.2009, p. 1.
34 OJ L 264, 8.10.2009, p. 12.
35 OJ L 330, 16.12.2009, p. 10.
36 OJ L 174, 1.7.2011, p. 88.
37 OJ L 88, 4.4.2011, p. 5.
38 OJ L 218, 13.8.2008, p. 21.

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.

(42) 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 obligation to ensure a high level of human health protection and consumer protection as well as full respect of the freedom to conduct a business and the right to property,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

General provisions

Article 1

Subject matter

This Regulation lays down a framework for verifying that products meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests.

Article 2

Scope

1. Chapters I, II, III, V and VI of this Regulation shall apply to all products that are subject to Regulation (EU) No [… on Consumer Product Safety] or Union harmonisation legislation, including to products assembled or manufactured for the manufacturer's own use, and to the extent that Union harmonisation legislation does not contain a specific provision with the same objective.

2. Chapters I and IV and Article 23 shall apply to all products covered by Union legislation to the extent that other Union legislation does not contain specific provisions relating to the organisation of external border controls or to cooperation between authorities in charge of external border controls.

3. Chapters II, III, V and VI shall not apply to the following products:

   (a) medicinal products for human or veterinary use;

   (b) medical devices and in vitro diagnostic medical devices;

   (c) blood, tissues, cells, organs and other substances of human origin.

4. Chapter III of this Regulation shall not apply to transportable pressure equipment subject to Directive 2010/35/EU.

5. Articles 11 and 18 of this Regulation shall not apply to the following products:

   (a) products subject to Regulation (EC) No 1907/2006;

   (b) fittings as defined in Article 1(2)(b) of Directive 2009/142/EC;

   (c) pressure equipment subject to the provisions of Article 3(3) of Directive 97/23/EC;

   (d) simple pressure vessels subject to the provisions of Article 3(2) of Directive 2009/105/EC.

6. This Regulation shall not apply in the areas governed by Union legislation on official controls and other official activities carried out for the verification of compliance with the following rules:

   (a) rules governing food and food safety, at any stage of production, processing and distribution of food, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information;

   (b) rules governing the manufacture and use of materials and articles intended to come into contact with food;

   (c) rules governing the deliberate release into the environment of genetically modified organisms;

   (d) rules governing feed and feed safety, at all stages of production, processing and distribution of feed and the use of feed, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information;

   (e) rules laying down animal health requirements;

   (f) rules aiming at preventing and minimising risks to human and animal health arising from animal by-products and derived products;

   (g) rules laying down welfare requirements for animals;

   (h) rules on protective measures against pests of plants;

   (i) rules on the production, with a view to placing on the market, and placing on the market of plant reproductive material;

   (j) rules laying down the requirements for placing on the market and the use of plant protection products and the sustainable use of pesticides;

   (k) rules governing organic production and labelling of organic products;

   (l) rules on the use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.

Article 3

Definitions

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

(1) ‘product’ means a product obtained 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 a manufacturer or importer, who makes a product available on the market;

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

(9) ‘conformity assessment’ means conformity assessment as defined in Regulation (EC) No 765/2008;

(10) ‘conformity assessment body’ means conformity assessment body as defined in Regulation (EC) No 765/2008;

(11) ‘market surveillance’ means the activities carried out and measures taken by public authorities to ensure that products do not endanger health, safety or any other aspect of public interest protection and, in the case of products falling within the scope of Union harmonisation legislation, that they comply with the requirements set out in that legislation;

(12) ‘market surveillance authority’ means an authority of a Member State responsible for carrying out market surveillance on its territory;

(13) ‘product presenting a risk’ means a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security as well as other public interests to a degree which goes beyond that considered reasonable and acceptable under the 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;

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

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

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

(17) ‘release for free circulation’ means the procedure laid down in Article 79 of Council Regulation (EEC) No 2913/92[39];

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

(19) ‘European standard’ means a European standard as defined in Article 2(1)(b) of Regulation (EU) No 1025/2012 of the European Parliament and the Council[40];

(20) ‘harmonised standard’ means a harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012.

CHAPTER II

Union market surveillance framework

Article 4

Market surveillance obligation

1. Member States shall carry out market surveillance in respect of products covered by this Regulation.

2. Market surveillance shall be organised and carried out in accordance with this Regulation with a view to ensuring that products presenting a risk are not made available on the Union market and, where such products have been made available, effective measures are taken to remove the risk presented by the product.

3. The implementation of market surveillance activities and external border controls shall be monitored by the Member States which shall report on these activities and controls to the Commission every year. The information reported shall include statistics regarding the number of controls carried out and shall be communicated to all Member States. Member States may make a summary of the results accessible to the public.

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

[40] OJ L 316, 14.11.2012, p. 12.

4. The results of the monitoring and assessment of market surveillance activities carried out pursuant to paragraph 3 shall be made available to the public, electronically and, where appropriate, by other means.

Article 5

Market surveillance authorities

1. Each Member State shall establish or designate market surveillance authorities and define their duties, powers and organisation.

2. Market surveillance authorities shall be given the powers and entrusted with the resources and means necessary for the proper performance of their tasks.

3. Each Member State shall establish appropriate mechanisms to ensure that the market surveillance authorities that it has established or designated exchange information, cooperate and coordinate their activities both among themselves and with the authorities in charge of controls of products at the external borders of the Union.

4. Each Member State shall inform the Commission about its market surveillance authorities and their areas of competence, providing the necessary contact details, and the Commission shall transmit this information to the other Member States and publish a list of market surveillance authorities.

5. Member States shall inform the public of the existence, responsibilities and identity of national market surveillance authorities and how those authorities may be contacted.

Article 6

General obligations of market surveillance authorities

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale and with adequate frequency, by means of a documentary check and, where necessary, a physical and laboratory check on the basis of an adequate sample. They shall record these checks in the information and communication system for market surveillance referred to in Article 21.

   In cases of known or emerging risk related to the objectives set out in Article 1 of this Regulation and concerning a particular product or a category of products, the Commission may adopt implementing acts to establish uniform conditions for the carrying out of the checks performed by one or several market surveillance authorities in relation to that particular product or category of products and the characteristics of that known or emerging risk. These conditions may include requirements for a temporary increase of the scale and frequency of checks to be carried out and the adequacy of samples to be checked. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).

2. Where appropriate, market surveillance authorities shall alert users in their territories within an adequate timeframe of products that those authorities have identified as presenting a risk.

They shall cooperate with economic operators to prevent or reduce risks caused by products made available by those operators. For this purpose, they shall encourage and promote voluntary action by economic operators including, where applicable, through the development of and adherence to codes of good practice.

3. Market surveillance authorities shall carry out their duties independently, impartially and without bias and shall fulfil their obligations under this Regulation; they shall exercise their powers in relation to economic operators in accordance with the principle of proportionality.

4. Where it is necessary and justified for carrying out their duties, market surveillance authorities may enter the premises of economic operators and take any necessary samples of products.

5. Market surveillance authorities shall:

(a) provide consumers and other interested parties with the opportunity to submit complaints on issues relating to product safety, market surveillance activities and risks arising in connection with products and follow up those complaints as appropriate;

(b) verify that corrective action has been taken;

(c) follow and keep up to date with developments in scientific and technical knowledge concerning the safety of products.

6. Adequate procedures shall be established and made known to the public to enable market surveillance authorities to fulfil these obligations.

7. Without prejudice to national legislation in the area of confidentiality, the safeguarding of confidentiality with regard to information received and collated by market surveillance authorities shall be ensured. Information exchanged between national market surveillance authorities and between them and the Commission on condition of confidentiality shall remain confidential unless the originating authority has agreed to its disclosure.

8. The protection of confidentiality shall not prevent the dissemination to market surveillance authorities of information necessary to ensure effective market surveillance.

Article 7

Market surveillance programmes

1. Each Member State shall draw up a general market surveillance programme and shall review that programme, and update it if necessary, at least every four years. The programme shall cover market surveillance organisation and related activities and

take into account the specific needs of business generally, and SMEs in particular, when implementing Union harmonisation legislation and Regulation (EU) No […/…] [on consumer product safety], and provide for guidance and assistance. It shall include the following:

(a) the sectoral and geographical competence of the authorities designated under Article 5(1);

(b) the financial resources, staff, technical and other means attributed to the authorities;

(c) an indication of the priority areas of work of the different authorities;

(d) the mechanisms of coordination among the different authorities and with customs authorities;

(e) the participation of the authorities in the exchange of information under Chapter V;

(f) the participation of the authorities in sectoral or project-oriented cooperation at Union level;

(g) the means to fulfil the requirements of Article 6(5).

2. Each Member State shall draw up sector-specific programmes and shall review these programmes, and update them if necessary, every year. These programmes shall cover all sectors in which authorities conduct market surveillance activities.

3. The general and sector-specific programmes and their updates shall be communicated to the other Member States and the Commission and, subject to Article 6(6), shall be made accessible to the public electronically and, where appropriate, by other means.

Article 8

General obligations of economic operators

1. On request, economic operators and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities any documentation and information that those authorities require for the purpose of carrying out their activities, in a language which can be easily understood by them.

2. Economic operators shall provide all necessary information to market surveillance authorities including information that enables the precise identification of the product and facilitates the tracing of the product.

CHAPTER III

Control of products within the Union

Article 9

Products presenting a risk

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market or is used in the course of the provision of a service may present a risk, they shall carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13.

   Market surveillance authorities shall take due consideration of any readily available test result and risk assessment that has already been carried out or issued in relation to the product by an economic operator or any other person or authority including the authorities of other Member States.

2. In relation to a product that is subject to Union harmonisation legislation, formal non-compliance with that legislation shall give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases:

   (a) the CE marking or other markings required by Union harmonisation legislation have not been affixed or have been affixed incorrectly;

   (b) the EU declaration of conformity, where required, has not been drawn up or has been drawn up incorrectly;

   (c) the technical documentation is incomplete or unavailable;

   (d) the required labelling or instructions for use are incomplete or missing.

   Regardless whether the risk assessment shows that the product in fact presents a risk, market surveillance authorities shall require the economic operator to rectify the formal non-compliance. If the economic operator fails to do so, market surveillance authorities shall ensure that the product is withdrawn or recalled.

3. Without prejudice to Article 10(4), where market surveillance authorities find that a product does present a risk they shall without delay specify the necessary corrective action to be taken by the relevant economic operator to address the risk within a specified period. Market surveillance authorities may recommend or agree with the relevant economic operator the corrective action to be taken.

   The economic operator shall ensure that all necessary corrective action is taken in respect of all the products concerned that it has made available on the market throughout the Union.

   The economic operator shall provide all necessary information to market surveillance authorities pursuant to Article 8, and in particular the following information:

   (a) a full description of the risk presented by the product;

   (b) a description of any corrective action undertaken to address the risk.

Where possible, market surveillance authorities shall identify the manufacturer or importer of the product and take action in relation to that economic operator in addition to the distributor.

4. Corrective action to be taken by economic operators in relation to a product presenting a risk may include:

(a) in the case of a product subject to the requirements laid down in or pursuant to Union harmonisation legislation, taking the measures necessary to bring the product into compliance with those requirements;

(b) in the case of a product that is liable to present a risk only in certain conditions or only to certain persons and where such risk is not addressed by requirements of Union harmonisation legislation:

(i) affixing to the product suitable, clearly worded, easily comprehensible warnings of the risks it may present, in the official language or languages of the Member State in which the product is made available on the market ;

(ii) making the marketing of the product subject to prior conditions;

(iii) alerting the persons at risk to the risk, in good time and in an appropriate form, including by publication of special warnings;

(c) in the case of a product that may present a serious risk, temporarily preventing the product from being placed or made available on the market pending a risk assessment;

(d) in the case of a product that presents a serious risk:

(i) preventing the product from being placed or made available on the market;

(ii) withdrawing or recalling the product and alerting the public to the risk presented;

(iii) destroying the product or otherwise rendering it inoperable.

5. The Commission may adopt implementing acts establishing the modalities for the provision of information in accordance with the third subparagraph of paragraph 3, while ensuring the effectiveness and proper functioning of the system. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).

Article 10

Measures taken by market surveillance authorities

1. Where the identity of the relevant economic operator cannot be ascertained by the market surveillance authorities or where an economic operator has not taken the necessary corrective action pursuant to Article 9(3) within the period specified,

market surveillance authorities shall take all necessary measures to deal with the risk presented by the product.

2. For the purpose of paragraph 1, market surveillance authorities may oblige the relevant economic operators to take, inter alia, any of the corrective action referred to in Article 9(4) or take such measures themselves, as appropriate.

Market surveillance authorities may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. They may require the relevant economic operator to bear the cost of such action.

The first subparagraph shall not prevent Member States from enabling market surveillance authorities to take other, supplementary measures.

3. Prior to taking any measure under paragraph 1 in relation to an economic operator who has failed to take the necessary corrective action, market surveillance authorities shall allow him at least 10 days within which to be heard.

4. Where market surveillance authorities consider that a product presents a serious risk, they shall take all necessary measures and may do so without first requiring the economic operator to take corrective action pursuant to Article 9(3) and without giving the operator the opportunity to be heard beforehand. In such cases the economic operator shall be heard as soon as practicable.

5. Any measure taken pursuant to paragraphs 1 or 4 shall:

(a) be communicated without delay to the economic operator together with information about the remedies available under the law of the Member State concerned;

(b) state the exact grounds on which it is based;

(c) be lifted without delay where the economic operator has demonstrated that he has taken the required action.

For the purposes of point (a) of the first subparagraph, where the economic operator to whom the measure has been communicated is not the economic operator concerned, the manufacturer located within the Union or the importer shall be informed of the measure, provided market surveillance authorities know his identity.

6. Market surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. This information shall not be published where it is imperative to observe confidentiality in order to protect commercial secrets, preserve personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.

7. Any measure taken in accordance with paragraphs 1 or 4 shall be subject to legal remedies, including recourse to the competent national courts.

8. Market surveillance authorities may charge fees on economic operators which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraphs 1 or 4.

Article 11

Union assessment for products controlled within the Union and subject to harmonisation legislation

1. Within 60 days of communication by the Commission to the Member States, pursuant to Article 20(4), of measures taken pursuant to paragraphs 1 or 4 of Article 10 by the original notifying Member State, a Member State may object to those measures where they relate to a product subject to Union harmonisation legislation. The Member State shall state its reasons for objecting, indicate any difference in its assessment of the risk presented by the product and mention any special circumstances and any additional information relating to the product in question.

2. If no objection is raised by a Member State pursuant to paragraph 1 and the Commission does not consider that the national measures are contrary to Union legislation, the measures taken by the original notifying Member State shall be deemed justified and each Member State shall ensure that restrictive measures are taken without delay in respect of the product concerned.

3. Where an objection is raised by a Member State pursuant to paragraph 1 or the Commission considers that the national measures may be contrary to Union legislation, the Commission shall without delay enter into consultation with the relevant economic operator(s) and shall evaluate the national measures, taking account of all available scientific or technical evidence.

4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission may decide by implementing acts whether the national measures are justified and similar measures should be taken by all Member States that have not already done so. In this case, it shall address the decision to the Member States concerned and immediately communicate it to all Member States and the relevant economic operator or operators.

5. If the Commission decides that the national measures are justified, each Member State shall take the necessary restrictive measures without delay. If it decides that the national measure is not justified, the original notifying Member State and any other Member State that has taken a similar measure shall withdraw the measure and the notification made under the rapid information exchange system pursuant to Article 20.

6. Where a national measure is considered justified and the product is found not to be in compliance with Union harmonisation legislation because of shortcomings in the relevant harmonised standards, the Commission shall inform the relevant European standardisation organisation and may make an appropriate request pursuant to Article 11 of Regulation (EU) No 1025/2012.

Article 12

Union action against products presenting a serious risk

1. Where it is evident that a product, or a specific category or group of products, when used in accordance with the product's intended purpose or under conditions which can be reasonably foreseeable, presents a serious risk the Commission may, by means of implementing acts, take any appropriate measures depending on the gravity of the situation, including measures prohibiting, suspending or restricting the placing or making available on the market of such products or laying down special conditions for their marketing, in order to ensure a high level of protection of the public interest, provided that the risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned or by any other procedure under Union legislation. By those implementing acts, the Commission may lay down the appropriate control measures to be taken by Member States to ensure their effective implementation.

   The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 32(2).

   On duly justified imperative grounds of urgency relating to the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment and public security and other public interests, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 32(3).

2. For products and risks subject to Regulation (EC) No 1907/2006, a decision taken by the Commission pursuant to paragraph 1 of this Article shall be valid for up to two years and may be extended for additional periods of up to two years. Such a decision shall be without prejudice to procedures provided in that Regulation.

3. The exportation from the Union of a product that has been prohibited to be placed or made available on the Union market pursuant to a measure adopted in accordance with paragraph 1 shall be prohibited, unless the measure expressly so permits.

4. Any Member State may submit a substantiated request to the Commission to examine the need for the adoption of a measure referred to in paragraph 1.

Article 13

Risk assessment

1. Risk assessment shall be based on available scientific or technical evidence.

   For products subject to Regulation (EC) No 1907/2006, risk assessment shall be carried out as appropriate in accordance with the relevant parts of Annex I to that Regulation.

2. In the context of the risk assessment, market surveillance authorities shall take into account the extent to which the product complies with the following:

(a) any requirements laid down in or pursuant to Union harmonisation legislation that apply to the product and relate to the potential risk under consideration, taking full account of test reports or certificates attesting conformity and issued by a conformity assessment body;

(b) in the absence of requirements laid down in or pursuant to Union harmonisation legislation, specific rules laying down health and safety requirements for such products in the national law of the Member State where it is made available on the market, provided that such rules are in accordance with Union law;

(c) any European standards the references of which have been published in the *Official Journal of the European Union*.

3. Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is new evidence that, despite such conformity or compliance, the product presents a risk.

4. The feasibility of obtaining higher levels of protection of the public interest concerned and the availability of other products presenting a lesser risk shall not be a reason to consider that a product presents a risk.

CHAPTER IV

Control of products entering the Union

Article 14

Checks and suspension of release

1. The authorities of the Member States in charge of the control of products at the external borders of the Union shall have the powers and resources necessary for the proper performance of their tasks. They shall carry out appropriate documentary and, where necessary, physical and laboratory checks on products before those products are released for free circulation.

2. Where more than one authority is responsible for market surveillance or external border controls in a Member State, those authorities shall cooperate with each other, by sharing information relevant to their functions.

3. Subject to Article 17, the authorities in charge of external border controls shall suspend release of a product for free circulation on the Union market when, in the course of the checks referred to in paragraph 1, they have reason to believe that the product may present a risk.

In relation to a product which must comply with Union harmonisation legislation when it is released for free circulation, formal non-compliance with that legislation

shall give the authorities of Member States sufficient reason to believe that the product may present a risk in any of the following cases:

(a) is not accompanied by the documentation required by the legislation;

(b) is not marked or labelled in accordance with that legislation;

(c) bears a CE marking or other marking required by Union harmonisation legislation which has been affixed in a false or misleading manner.

4. The authorities in charge of external border controls shall immediately notify the market surveillance authorities of any suspension under paragraph 3.

5. In the case of perishable products, the authorities in charge of external border controls shall, as far as possible, seek to ensure that any requirements they may impose with regard to the storage of products or the parking of vehicles used for transport are not incompatible with the preservation of those products.

6. Where, in relation to products that are not declared for free circulation, the authorities in charge of external border controls have reason to believe that those products present a risk, they shall transmit all relevant information to the authorities in charge of external border controls in the Member State of final destination.

Article 15

Release

1. A product the release of which has been suspended by the authorities in charge of external border controls pursuant to Article 14 shall be released if, within three working days of the suspension of release, those authorities have not been requested by the market surveillance authorities to continue the suspension or they have been informed by the market surveillance authorities that the product does not present a risk, and provided that all the other requirements and formalities pertaining to such release have been fulfilled.

2. If the market surveillance authorities conclude that a product the release of which was suspended due to formal non-compliance in accordance with the second sub-paragraph of paragraph 3 of Article 14 does not in fact present a risk, the economic operator shall nevertheless rectify the formal non-compliance before the product is released.

3. Compliance with the requirements of any Union harmonisation legislation that apply to the product upon its release which relate to the potential risk under consideration, taking full account of test reports or certificates attesting conformity and issued by a conformity assessment body, shall raise a presumption on the part of market surveillance authorities that the product does not present a risk. However, this shall not prevent those authorities from instructing the authorities in charge of external border controls not to release the product where there is evidence that, despite such compliance, the product does in fact present a risk.

Article 16

Refusal to release

1. Where the market surveillance authorities conclude that a product does present a risk, they shall instruct the authorities in charge of external border controls not to release the product for free circulation and to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document:

   "Product presents a risk — release for free circulation not authorised — Regulation (EU) No XXX/XXXX".

2. Where that product is subsequently declared for a customs procedure other than release for free circulation and provided that the market surveillance authorities do not object, the endorsement set out in paragraph 1 shall also be included, under the conditions set out in paragraph 1, on the documents used in connection with that procedure.

3. Market surveillance authorities or the authorities in charge of external border controls, as the case may be, may destroy or otherwise render inoperable a product presenting a risk where they deem it necessary and proportionate. The cost of such action shall be borne by the person declaring the product for free circulation.

4. Market surveillance authorities shall provide the authorities in charge of external border controls with information on product categories in which a risk has been identified pursuant to paragraph 1.

5. Any measure taken in accordance with paragraphs 1 or 3 shall be subject to legal remedies, including recourse to the competent national courts.

6. Market surveillance authorities may charge fees which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraph 1.

Article 17

Personal imports

1. Where a product enters the Union accompanied by, and in the physical possession of, a natural person and reasonably appears to be destined for the personal use of that person, its release shall not be suspended pursuant to Article 14(3) except where the use of the product can endanger the health and life of persons, animals or plants.

2. A product shall be deemed to be destined for the personal use of a natural person bringing it into the Union if it is of an occasional nature and exclusively intended for use by that person or his family and does not by its nature or quantity indicate any commercial intent.

Article 18

Union assessment for products entering the Union and subject to harmonisation legislation

1. Within 60 days of communication by the Commission to the Member States, pursuant to Article 20(4), of any refusal to release a product for free circulation by the original notifying Member State, a Member State may object to that refusal where it relates to a product subject to Union harmonisation legislation. The Member State shall state its reasons for objecting, indicate any difference in its assessment of the risk presented by the product and mention any special circumstances and any additional information relating to the product in question.

2. If no objection is raised by a Member State under paragraph 1 and the Commission does not consider that the national measures are contrary to Union legislation, the refusal by the original notifying Member State shall be deemed justified and each Member State shall ensure that restrictive measures are taken without delay in respect of the product concerned.

3. Where an objection is raised by a Member State under paragraph 1 or the Commission considers that the refusal may be contrary to Union legislation, the Commission shall without delay enter into consultation with the relevant economic operator(s) and shall evaluate the refusal, taking account of all available scientific or technical evidence.

4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission may decide by implementing acts whether the refusal is justified and similar action should be taken by all Member States that have not already done so. In this case, it shall address the decision to the Member States concerned and immediately communicate it to all Member States and the relevant economic operator or operators.

5. If the Commission decides that the refusal is justified, each Member State shall take the necessary restrictive measures without delay. If it decides that the refusal is not justified, the original notifying Member State and any other Member State that has taken a similar measure shall withdraw it and the notification made under RAPEX pursuant to Article 20.

6. Where a refusal is considered justified and the product is found not to be in compliance with Union harmonisation legislation because of shortcomings in the relevant harmonised standards, the Commission shall inform the relevant European standardisation organisation and may make an appropriate request pursuant to Article 11 of Regulation (EU) No. 1025/2012.

CHAPTER V

Exchange of information

Article 19

Union Rapid Information Exchange System - RAPEX

1. The Commission shall maintain the system for rapid exchange of information (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a risk in accordance with this Regulation.

2. Each Member State shall designate a single contact point for RAPEX.

3. The Commission may, by means of implementing acts, prescribe the modalities and procedures for the exchange of information through RAPEX. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).

4. Participation in RAPEX shall be open to applicant countries, third countries or international organisations within the framework of and in accordance with agreements between the Union and those countries or organisations. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Union.

Article 20

Notification through RAPEX of products presenting a risk

1. The RAPEX contact point shall immediately notify to the Commission information on any of the following:

   (a) any corrective action taken by economic operators pursuant to Article 9(3);

   (b) any measure taken by market surveillance authorities pursuant to Article 10(1) or (4), unless it concerns a product subject to a notification pursuant to point (a);

   (c) any refusal to release a product for free circulation pursuant to Article 16.

   The first subparagraph shall not apply where the RAPEX contact point has reason to believe that the effects of the risk presented by a product do not go beyond the territory of its Member State.

   The RAPEX contact point shall inform the Commission without delay of any relevant update, modification or withdrawal of the corrective action or measures referred to in the first subparagraph.

2. The information provided in accordance with paragraph 1 shall include all available details relating to the risk and at least the following information:

   (a) the nature and level of the risk, including a summary of the results of the risk assessment;

   (b) the nature of any non-compliance with Union harmonisation legislation;

(c) the data necessary to identify the product;

(d) the origin and the supply chain of the product;

(e) the date on which the measure or corrective action was taken and its duration;

(f) the nature of the measure or corrective action taken and whether voluntary, approved, required;

(g) whether the economic operator has been given the opportunity to be heard.

The information referred to in the first subparagraph shall be transmitted using the standard notification form made available by the Commission in the RAPEX system.

3. Where a notification relates to a product found not to comply with Union harmonisation legislation, the information provided shall also indicate whether the non-compliance is due to any of the following:

(a) the failure of the product to satisfy the requirements of the applicable legislation;

(b) shortcomings in the harmonised standards referred to in that legislation which confer a presumption of conformity with those requirements.

Where a measure or corrective action referred to in paragraph 1 relates to a product that has undergone conformity assessment by a notified body, the market surveillance authorities shall ensure that the relevant notified body is informed of the corrective action or measures taken.

4. On receiving a notification, the Commission shall communicate it to the other Member States. If the notification does not satisfy the requirements set out in paragraphs 1, 2 and 3, the Commission may suspend it.

5. The Member States shall immediately inform the Commission of the action or measures taken following receipt of a notification and shall provide any supplementary information, including the results of any tests or analyses carried out or possible differences in views. The Commission shall immediately transmit this information to other Member States.

Article 21

Information and communication system for market surveillance

1. The Commission shall maintain an information and communication system for market surveillance (ICSMS) for the collection and structured storage of information on issues relating to market surveillance, in particular the following information:

(a) market surveillance authorities and their areas of competence;

(b) market surveillance programmes;

(c) the monitoring, review and assessment of market surveillance activities;

(d) complaints or reports about issues relating to risks arising from products;

(e) any non-compliance with Union harmonisation legislation other than measures or corrective action notified under RAPEX in accordance with Article 20;

(f) any objection raised by a Member State in accordance with Articles 11(1) or 18(1) and the follow-up.

ICSMS shall contain a record of references to the notifications of measures or corrective action made under RAPEX in accordance with Article 20.

ICSMS may also be made available, where necessary or appropriate, for use by the authorities in charge of controls at the external borders.

2. For the purposes of paragraph 1, Member States shall enter into ICSMS any information at their disposal and not already notified under Article 20 about products presenting a risk regarding, in particular, the identification of risks, results of testing carried out, restrictive measures taken, contacts with the economic operators concerned and justification for action or inaction.

3. Market surveillance authorities shall recognise the validity and make use of test reports prepared by or for their counterparts in other Member States and entered into ICSMS.

Article 22

International exchange of confidential information

The Commission and Member States may exchange confidential information, including information exchanged through RAPEX, with regulatory authorities of third countries or international organisations with which the Commission and the Member State or group of Member States have concluded bilateral or multilateral confidentiality arrangements based on reciprocity.

CHAPTER VI

Cooperation

Article 23

Mutual assistance

1. There shall be efficient cooperation and exchange of information among the market surveillance authorities of the Member States, among the different authorities within each Member State and between market surveillance authorities and the Commission and the relevant Union agencies regarding market surveillance programmes and all issues relating to products presenting a risk.

2. Market surveillance authorities shall, on receipt of a duly motivated request from a market surveillance authority in another Member State, provide any relevant information or documentation and carry out checks, inspections or investigations and report on them and on any follow-up action taken to the requesting authority.

The information, documentation and reporting referred to in the first subparagraph shall be used only in respect of the matter for which it was requested and shall be processed as quickly as possible, by electronic means.

Article 24

Cooperation with the competent authorities of third countries

1. Market surveillance authorities may cooperate with the competent authorities of third countries with a view to exchanging information and technical support, promoting and facilitating access to Union information exchange systems including the RAPEX system in accordance with Article 19(4), and promoting activities relating to conformity assessment and market surveillance.

2. Cooperation with the competent authorities of third countries shall take the form of, inter alia, the types of activities referred to in Article 27. Member States shall ensure that their competent authorities participate in those activities.

Article 25

European Market Surveillance Forum

1. A European Market Surveillance Forum (EMSF) is established.

2. Each Member State shall be represented in meetings of the EMSF by a person or persons selected by the Member State having the particular knowledge and experience required in accordance with the subject matter of the meeting in question.

3. The EMSF shall meet at regular intervals and, where necessary, at the request of the Commission or a Member State.

4. The EMSF shall use its best endeavours to reach consensus. If consensus cannot be reached, the EMSF shall adopt its position by a simple majority of its members. Members may request that their positions and the grounds on which they are based are officially recorded.

5. The EMSF may invite experts and other third parties to attend meetings or provide written contributions.

6. The EMSF may establish standing or temporary sub-groups which shall include the administrative cooperation groups for market surveillance set up for the implementation of Union harmonisation legislation. Organisations representing the interests of industry, small and medium-sized enterprises, consumers, laboratories and conformity assessment bodies at Union level may be invited to participate in such sub-groups as observers.

7. The EMSF shall establish its rules of procedure which shall enter into force after receiving a favourable opinion from the Commission.

8. The EMSF shall cooperate with the Forum for Exchange of Information on Enforcement established by Regulation (EC) No 1907/2006.

Article 26

Commission support and executive secretariat

1. The Commission shall support cooperation between market surveillance authorities. It shall participate in the meetings of the EMSF and its sub-groups.

2. To perform the tasks set out in Article 27, the EMSF shall be assisted by an executive secretariat that provides technical and logistic support to the EMSF and its sub-groups.

Article 27

Tasks of the EMSF

The EMSF shall have the following tasks:

(a) to facilitate the exchange of information on products presenting a risk, risk assessment, test methods and results, recent scientific developments and other aspects relevant to control activities;

(b) to coordinate the preparation and implementation of the general and sector-specific market surveillance programmes referred to in Article 7;

(c) to organise joint market surveillance and joint testing projects;

(d) to exchange expertise and best practices;

(e) to organise training programmes and exchanges of national officials;

(f) to assist in monitoring activities as described in Article 4(3);

(g) to organise information campaigns and joint visit programmes;

(h) to improve cooperation at Union level with regard to the tracing, withdrawal and recall of products presenting a risk;

(i) to ensure the easy access, retrieval and sharing of product safety information collected by market surveillance authorities, including information on complaints, accidents, injury reports and investigation and test results;

(j) to contribute to the development of guidance to ensure the effective and uniform implementation of this Regulation, taking due account of the interests of business, in particular small and medium-sized enterprises, and other stakeholders;

(k) to provide advice and assist the Commission, at its request, in its assessment of any issue relating to the implementation of this Regulation;

(l) to contribute to uniform administrative practices with regard to market surveillance in the Member States.

Article 28

European Union reference laboratories

1. For specific products or a category or group of products or for specific risks related to a category or group of products, the Commission may by means of implementing acts designate Union reference laboratories that satisfy the criteria set out in paragraph 2.

2. Each Union reference laboratory shall satisfy the following criteria:

(a) have suitably qualified staff with adequate training in the analytical techniques used in their area of competence and an adequate knowledge of standards and practices;

(b) possess the equipment and reference material needed to carry out the tasks assigned to them;

(c) act in the public interest in an impartial and independent manner;

(d) ensure that the staff respect the confidential nature of certain subjects, results or communications.

3. Within the area of their designation, Union reference laboratories shall where appropriate have the following tasks:

(a) carrying out product testing in relation to market surveillance activities and investigations;

(b) contributing to the resolution of disputes between the authorities of Member States, economic operators and conformity assessment bodies;

(c) providing independent technical or scientific advice to the Commission and the Member States;

(d) developing new techniques and methods of analysis;

(e) disseminating information and providing training.

CHAPTER VII

Financing

Article 29

Financing activities

1. The Union may finance the following activities in relation to the application of this Regulation:

   (a) the drawing up and updating of contributions to guidelines on market surveillance;

   (b) the making available to the Commission of technical or scientific expertise for the purpose of assisting the Commission in its implementation of market surveillance administrative cooperation and the Union assessment procedures referred to in Articles 11 and 18;

   (c) the performance of preliminary or ancillary work in connection with the implementation of market surveillance activities linked to the application of Union legislation such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits, research work, the development and maintenance of databases, training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work, and European market surveillance campaigns and similar activities;

   (d) activities carried out under programmes of technical assistance, cooperation with third countries and the promotion and enhancement of European market surveillance policies and systems among interested parties at European and international levels;

   (e) the functioning of cooperation among market surveillance authorities and the technical and logistic support by the Executive Secretariat to the EMSF and its sub-groups.

2. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012, either directly, or indirectly by delegating budget implementation tasks to the entities listed in Article 58(1)(c) of Regulation (EU, Euratom) No 966/2012.

3. The appropriations allocated to activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the financial framework in force.

4. The appropriations determined by the budgetary authority for the financing of market surveillance activities may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities which are required for the management of the activities pursuant to this Regulation and the achievement of their objectives; in particular, studies, meetings of experts, information and communication actions, including corporate communication of the political priorities of the Union as far as they are related to the general objectives of market surveillance activities, expenses linked to information technology networks focusing on information processing and exchange, together with all other technical and administrative assistance expenses incurred by the Commission for the management of the activities pursuant to this Regulation.

5. The Commission shall evaluate the relevance of the market surveillance activities that receive Union financing in the light of the requirements of Union policies and legislation and inform the European Parliament and the Council of the outcome of that evaluation by [*five years following the date of application*] and every five years thereafter.

Article 30

Protection of the Union's financial interests

1. The Commission shall take appropriate measures ensuring that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive penalties.

2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot checks, over all grant beneficiaries, contractors and subcontractors and other third parties who have received Union funds under this Regulation.

3. The European Anti-fraud Office (OLAF) may carry out on-the-spot checks and inspections on economic operators concerned directly or indirectly by such funding in accordance with the procedures laid down in Council Regulation (Euratom, EC) No 2185/96[41] with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract concerning Union funding.

4. Without prejudice to paragraphs 1 and 2, cooperation agreements with third countries and international organisations and grant agreements and grant decisions and contracts resulting from the implementation of this Regulation shall expressly empower the Commission, the Court of Auditors and OLAF to conduct audits, on-the-spot checks and inspections.

CHAPTER VIII

Final provisions

Article 31

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation that impose obligations on economic operators and to infringements of provisions of any Union harmonisation legislation on products covered by this Regulation that impose obligations on economic operators where that legislation does not

[41] OJ L292, 14.11.1996, p.2.

provide for penalties, 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.

The penalties referred to in the first subparagraph 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 32

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.

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

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 33

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. That report shall assess if this Regulation achieved its objectives, in particular with regard to ensuring more effective and efficient enforcement of product safety rules and Union harmonisation legislation, improving cooperation between market surveillance authorities, strengthening the controls of products entering the Union and better protecting the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests, taking into account its impact on business and in particular on small and medium-sized enterprises.

Article 34

Amendments

1. The following provisions are deleted:

   (a) Article 18 of Directive 2011/65/EU;

   (b) Article 7 of Council Directive 89/686/EEC;

   (c) Paragraphs 2 and 3 of Article 7 and Article 8 of Directive 93/15/EEC;

(d) Article 7 of Directive 94/9/EC;

(e) Article 7, paragraph 4 of Article 10 and Article 11 of Directive 94/25/EC;

(f) Articles 7 and 11 of Directive 95/16/EC;

(g) Articles 8, 16 and 18 of Directive 97/23/EC;

(h) Article 9 of Directive 1999/5/EC;

(i) Articles 14, 15 and 19 of Directive 2000/9/EC;

(j) Article 5 of Directive 2000/14/EC;

(k) Paragraphs 2 and 3 of Article 6 and Articles 8, 9, 10, 11, 12 and 13 of, and Annex II to, Directive 2001/95/EC;

(l) Articles 10 and 11 of Directive 2004/108/EC;

(m) Paragraphs 3 and 4 of Article 4 and Articles 11, 17 and 20 of Directive 2006/42/EC;

(n) Article 9 of Directive 2006/95/EC;

(o) Paragraphs 5 and 6 of Article 14 and Articles 15, 16 and 17 of Directive 2007/23/EC;

(p) Paragraph 5 of Article 13 and Article 14 of Directive 2008/57/EC;

(q) Articles 39, 40, 42 to 45 of Directive 2009/48/EC;

(r) Articles 7, 15 and 17 of Directive 2009/105/EC;

(s) Articles 7, 11 and 12 of Directive 2009/142/EC;

(t) Articles 56 to 59 of Regulation (EU) No 305/2011.

2. Point (a) of Article 3(2) of Regulation (EC) No 764/2008 is replaced by the following:

'(a) Article 10 of Regulation (EU) No […] [on market surveillance of products];'

3. Regulation (EC) No 765/2008 is amended as follows:

(a) Paragraphs 2 and 3 of Article 1, points 14, 15, 17, 18 and 19 of Article 2, Chapter III and Article 32(1)(e) of Regulation (EC) No 765/2008 are deleted;

(b) The title of Regulation (EC) No 765/2008 is replaced by the following:

'Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 laying down the requirements for accreditation of conformity assessment bodies and general principles of CE marking and repealing Regulation (EEC) No 339/93'

References to the provisions of Articles 15 to 29 of Regulation (EC) No 765/2008 shall be construed as references to this Regulation and shall be read in accordance with the correlation table in the Annex.

Article 35

Transitional provisions

Procedures initiated at national or Union level pursuant to any of the provisions referred to in Article 34 of this Regulation or to Articles 6 to 9 of Directive 2001/95/EC shall continue to be governed by those provisions.

Article 36

Entry into force

This Regulation shall enter into force on [*insert date - the same day as Regulation (EU) No […/…] [on Consumer Product Safety*]

It shall apply from 1 January 2015.

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

Regulation EC No. 765/2008	**This Regulation**
Article 15(1), (2) and (5)	Article 2
Article 15(3)	-
Article 15(4)	Article 3(1)
Article 16(1)	Article 4(1)
Article 16(2)	Article 4(2) read in conjunction with Article 3(12); Article 17(1) and Article 26 (5)
Article 16(3)	-
Article 16(4)	-
Article 17(1)	Article 5(4)
Article 17(2)	Article 26(1)
Article 18(1)	Article 5(3)
Article 18(2)	Article 6(6)
Article 18(3)	Article 5(2)
Article 18(4)	Article 6(4)
Article 18(5) and (6)	Article 4(3), Article 6(7)(8) and (9) and Article 26(2)
Article 19(1) first subparagraph	Article 6(1)
Article 19(1) second subparagraph	Article 6(5) and Article 7
Article 19(1) third subparagraph	Article 8(1) second subparagraph
Article 19(2)	Article 6(2)
Article 19(3)	Article 9(5)(a)
Article 19(4)	Article 6(3)
Article 19(5)	Article 26(5) and Article 27
Article 20(1)	Articles 9(4) and 18(1)(b)

Article 20(2)	Article 12
Article 21	Article 6(4) and Article 9
Article 22(1), (2) and (3)	Article 18(1) and (2)
Article 22(4)	Article 17
Article 23(1) and (2)	Article 19
Article 23(3)	Article 27
Article 24(1) and (2)	Article 20
Article 24(3)	Article 19(1)
Article 24(4)	Article 18(2) and Article 19(2)
Article 25	Articles 22 to 24
Article 26	Article 21
Article 27	Article 13
Article 28	Article 14
Article 29	Article 15

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 market surveillance of products

1.2. Policy area(s) concerned in the ABM/ABB structure[42]

Title 2 – Enterprise - Chapter 02 03: Internal market for goods and sectoral policies

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

1.3. Nature of the proposal/initiative

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

1.4. Objectives

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

Internal market for goods and sectoral policies: to improve the functioning of the single market and to achieve a high level of protection of consumers, other users and other public interests;

Security and citizenship – consumer policy.

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

ENTR specific objective: To continually review existing internal market acquis and propose new legislative or non-legislative action whenever appropriate.

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

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

1.4.3. Expected result(s) and impact

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

The expected result of this initiative is to improve the framework of the market surveillance which is still fragmented in the Union. This proposal amalgamates the provisions of the Regulation 765/2008/EC and of the General Product Safety Directive regarding the market surveillance into one single piece of legislation covering products in both the harmonised and non-harmonised acquis, regardless whether they are destined for use, or are likely to be used, by consumers or professionals.

This proposal will have an impact on economic operators and national authorities who will be better informed on their obligations regarding market surveillance actions.

The proposal will also enhance the protection of consumers and other users of products through more effective enforcement of product-related requirements.

1.4.4. Indicators of results and impact

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

- Number of notifications regarding unsafe products in the GRAS-RAPEX information system;

- % of RAPEX notifications entailing at least one reaction (by other Member States

- Ratio number of reactions / number of notifications (serious risks)-

- Volume and quality of data exchanged the general information support system ICSMS,

- Number and results of joint market surveillance actions,

- Work- and resource-sharing.

- Product safety enforcement indicators (budgets, inspections, laboratory tests, measures taken etc.)

1.5. Grounds for the proposal

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

The general objective of this initiative is to improve the functioning of the single market and to achieve a high level of protection of consumers, other users and other public interests through the reduction of number of unsafe or non-compliant products.

1.5.2. Added value of EU involvement

Despite the existence of the single European market, the enforcement of product safety requirements is the Member States' competence. Due to the existing differences in the national organisation of market surveillance in the Member States and to the interdependence of the national market surveillance authorities, problems still appears. The EU has the right to act on the basis of Article 114 TFEU, in order to ensure the proper functioning of the single market for consumer products and to increase the efficiency of cross-border market surveillance. Article 169(1) of TFEU complements this right to act. It stipulates that in order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall, amongst others, contribute to protecting the health, safety and economic interests of consumers. However, in order to comply with the subsidiarity principle, this proposal does not affect the competence of the Member States to carry out procedures and actions against concrete products posing risks.

1.5.3. Lessons learned from similar experiences in the past

Although the EU has achieved the Single Market and the free movement of goods is the most developed and best established of the four freedoms making up the internal market, there are still things to be done. Public health and safety in the workplace, protection of consumers, protection of the environment and other public interests may be undermined due to some traders who do not comply with the law and place on the market dangerous products. Market surveillance is meant to be an answer to all these issues. Nevertheless, market surveillance has not kept pace with developments in the Union regulatory framework. It needs to be highly coordinated and capable of reacting rapidly throughout EU. It is true that progress has been made with the implementation of the General Product Safety Directive and with the Regulation 765/2008/EC, but the fragmentation of market surveillance rules among different pieces of EU legislation (the General Product Safety Directive, the Regulation 765/2008/EC and many sectorial directives) has led to confusion of both economic operators and national authorities and to a reduced effectiveness of market surveillance activity in the Union. Therefore, this proposal for a single, self-standing market surveillance regulation would be essential to tackle these problems.

1.5.4. Coherence and possible synergy with other relevant instruments

This initiative is entirely coherent with the acquis on the free movement of goods, in particular Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE), Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE), Directive 2006/95/EC of the European Parliament and of the Council of 12 December 2006 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits, Directive

2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels.[43]

This proposal is also coherent with the accompanying proposal for a Regulation on Consumer Product Safety which will replace Directive 2001/95/EC on General Product Safety.

The proposal creates synergies with regard to the notification of unsafe products and of safeguard measures under sectoral legislation which in the future will need to be notified only once under the revised RAPEX system.

[43] The whole list of the sectoral legislation can be found in the annex of this regulation.

1.6. Duration and financial impact

Proposal/initiative of unlimited duration

1.7. Management mode(s) envisaged

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[44]
- ☐ 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.

Comment:

This initiative does not require new budgetary resources but will be financed through redeployment of existing resources. Some actions will be managed by the Executive Agency for Health and Consumers (EAHC): In accordance with Council Regulation (EC) No 58/2003 of 19 December 2002 laying down the statute for Executive Agencies to be entrusted with certain tasks in the management of Community programmes[45], the Commission has entrusted[46] 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. The envisaged programme delegation will be the extension of tasks already externalised to the EAHC.

Furthermore, this initiative does not require additional budget resources for the costs related to the management, maintenance and adaptations for both IT systems, i.e.

44 As referred to in Article 185 of the Financial Regulation.
45 OJ L 11, 16.1.2003, p. 1.
46 Commission Decision C(2008)4943 of 9 September 2008.

GRAS-RAPEX and ICSMS, compared to those already included in the operational budgets of DG SANCO and DG ENTR proposed for the MFF 2014-2020.

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

The future market Surveillance Forum (EMSF) will be the platform for discussions regarding the proper implementation of the future regulation.

A final provision also proposes that the Commission makes an evaluation and drafts a report regarding the implementation five years after its entry into force. This should identify possible problems and shortcomings of the Regulation and could be the starting point for further actions, including a possible proposal to amend it, in view of further improvement of market surveillance framework.

2.2. Management and control system

2.2.1. Risk(s) identified

Risks relating to the proper functioning of RAPEX (e.g. increase of number of notifications diverting attention from really dangerous products or reducing its credibility; IT-related probems such as breakdown of the system, confidentiality issues).

The risks related to the functioning of ICSMS relate mainly to IT-related probems such as a possible breakdown of the system and confidentiality issues.

2.2.2. Control method(s) envisaged

The control methods envisaged are laid down in the Financial Regulation and Rules of Application.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

The Commission must ensure that the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and other illegal activities, by effective checks and by the recovery of amounts unduly paid and, if irregularities are detected, by effective, proportionate and dissuasive penalties, in accordance with Regulations (EC, Euratom) No 2988/95, (Euratom, EC) No 2185/96 and (EC) No 1073/1999. In addition to the application of all regulatory control mechanisms, the competent Commission services 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. (47)	from EFTA[48] countries	from candidate countries[49]	from third countries	within the meaning of Article 18(1)(aa) of the Financial Regulation
N° 1: Internal Market for goods and sectoral policies	02.03.01.	Diff	YES	NO	NO	NO
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

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

48 EFTA: European Free Trade Association.

49 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[50]

EUR million in current prices (to 3 decimal places)

Heading of multiannual financial framework:	1	Internal market for goods and sectoral policies

DG: ENTR			2015	2016	2017	2018	2019	2020	**TOTAL**
• Operational appropriations									
Number of budget line 02.03.01	Commitments	(1)	1,300	1,300	1,300	1,300	1,300	1,300	7,800
	Payments	(2)	1,300	1,300	1,300	1,300	1,300	1,300	7,800
Appropriations of an administrative nature financed from the envelope for specific programmes[51]			0	0	0	0	0	0	0
Number of budget line:	Commitments	(1a)	0	0	0	0	0	0	0
	Payments	(2a)	0	0	0	0	0	0	0
TOTAL appropriations for DG ENTR	Commitments	=1+1a	1,300	1,300	1,300	1,300	1,300	1,300	**7,800**
	Payments	=2+2a	1,300	1,300	1,300	1,300	1,300	1,300	**7,800**

• TOTAL operational appropriations	Commitments	(3)	1,300	1,300	1,300	1,300	1,300	1,300	7,800
	Payments	(4)	1,300	1,300	1,300	1,300	1,300	1,300	7,800

50 Amounts subject to the outcome of the Commission proposal for the new Multi-annual Financial Framework 2014-2020.

51 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.

• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(5)	0	0	0	0	0	0	0
TOTAL appropriations under HEADING 02 of the multiannual financial framework	**Commitments**	**=3+ 5**	**1,300**	**1,300**	**1,300**	**1,300**	**1,300**	**1,300**	**7,800**
	Payments	**=4+ 5**	**1,300**	**1,300**	**1,300**	**1,300**	**1,300**	**1,300**	**7,800**

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)	3,000	3,060	3,121	3,184	3,247	3,312	18,924
	Payments	(2)	1,500	3,030	3,091	3,152	3,215	4,936	18,924
Appropriations of an administrative nature financed from the envelope for specific programmes[52]									
Number of budget line: 17.01.04.01	Commitments	(1a)	0,100	0,100	0,100	0,100	0,100	0,100	0,600
	Payments	(2a)	0,100	0,100	0,100	0,100	0,100	0,100	0,600
TOTAL appropriations for DG SANCO	Commitments	=1+1a	3,100	3,160	3,221	3,284	3,347	3,412	**19,524**
	Payments	=2+2a	1,600	3,130	3,191	3,252	3,315	5,036	**19,524**

[52] 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.

• TOTAL operational appropriations	Commitments	(3)	3,000	3,060	3,121	3,184	3,247	3,312	**18,924**
	Payments	(4)	1,500	3,030	3,091	3,152	3,215	4,936	**18,924**
•TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(5)	0,100	0,100	0,100	0,100	0,100	0,100	**0,600**
TOTAL appropriations under HEADING 3 of the multiannual financial framework	Commitments	=3+ 5	**3,100**	**3,160**	**3,221**	**3,284**	**3,347**	**3,412**	**19,524**
	Payments	=4+ 5	**1,600**	**3,130**	**3,191**	**3,252**	**3,315**	**5,036**	**19,524**

If more than one heading is affected by the proposal / initiative:

• TOTAL operational appropriations	Commitments	(6)	4,300	4,360	4,421	4,484	4,547	4,612	26,724
	Payments	(7)	2,800	4,330	4,391	4,452	4,515	6,236	26,724
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(8)	0,100	0,100	0,100	0,100	0,100	0,100	0,600
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)	Commitments	=6+ 8	4,400	4,460	4,521	4,584	4,647	4,712	**27,324**
	Payments	=7+ 8	2,900	4,430	4,491	4,552	4,615	6,336	**27,324**

Heading of multiannual financial framework:	5	" Administrative expenditure "

EUR million in current prices (to 3 decimal places)

		2015	2016	2017	2018	2019	2020	TOTAL
DG: ENTR								
• Human resources		0,786	0,786	0,786	0,786	0,786	0,786	**4,716**
• Other administrative expenditure		0,079	0,079	0,079	0,079	0,079	0,079	**0,474**
DG SANCO								
• Human resources		1,048	1,048	1,048	1,048	1,048	1,048	**6,288**
• Other administrative expenditure (missions, meetings)		0,079	0,079	0,079	0,079	0,079	0,079	**0,474**
TOTAL	Appropriations	1,992	1,992	1,992	1,992	1,992	1,992	**11,952**

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	1,992	1,992	1,992	1,992	1,992	1,992	11,952

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	6,392	6,452	6,513	6,576	6,639	6,704	39,276
	Payments	4,892	6,422	6,483	6,544	6,607	8,328	39,276

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 ⇩	Type of output [53]	Average cost of the output	2015		2016		2017		2018		2019		2020		TOTAL	
			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[54]: To continually review existing internal market acquis and propose new legislative or non-legislative action whenever appropriate																
Guidelines and inter-comparison activities		0.050	1	0.050	1	0.050	1	0.050	1	0.050	1	0.050	1	0,050	6	0.300
Technical expertise and assistance		0.600	1	0.600	1	0.600	1	0.600	1	0.600	1	0.600	1	0,600	6	3.600
Promotion of European market surveillance policies		0.050	1	0.050	1	0.050	1	0.050	1	0.050	1	0.050	1	0.050	6	0.300

[53] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

[54] As described in Section 1.4.2. "Specific objective(s)…"

Cooperation with third countries		0.100	1	0.100	1	0.100	1	0.100	1	0.100	1	0.100	1	0.100	6	0.600
Support to market surveillance authorities (including ICSMS)		0.500	2	0.500	2	0.500	2	0.500	2	0.500	2	0.500	2	0.500	12	3.000
Sub-total for specific objective ENTR			6	1.300	6	1.300	6	1.300	6	1.300	6	1.300	6	1.300	36	7.800
SPECIFIC OBJECTIVE: SANCO																
- Output																
Market surveillance and enforcement actions (joint actions, exchange of officials, funding of the Market Surveillance Forum Secretariat)		2,357	3	2,242	3	2,287	3	2,333	3	2,380	3	2,427	3	2,425	18	14,144
Further development and management of RAPEX (especially IT applications)		0,797	1	0,758	1	0,773	1	0,788	1	0,804	1	0,820	1	0,837	6	4,780

Sub-total for specific objective SANCO			4	3,000	4	3,060	4	3,121	4	3,184	4	3,247	4	3,312	24	18,924
TOTAL COST				**4,300**		**4,360**		**4,421**		**4,484**		**4,547**		**4,612**		**26,724**

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 ENTR	0,786	0,786	0,786	0,786	0,786	0,786	**4.716**
Human resources SANCO (Average cost FTE: 131.000 €)	1,048	1,048	1,048	1,048	1,048	1,048	**6,288**
Other administrative expenditure ENTR	0,079	0,079	0,079	0,079	0,079	0,079	**0,474**
Other administrative expenditure SANCO	0,079	0,079	0,079	0,079	0,079	0,079	**0,474**
Subtotal HEADING 5 of the multiannual financial framework	1,992	1,992	1,992	1,992	1,992	1,992	**11,952**
Outside HEADING 5[55] of the multiannual financial framework							
Human resources	0	0	0	0	0	0	
Other expenditure of an administrative nature SANCO	0,100	0,100	0,100	0,100	0,100	0,100	**0,600**
Subtotal outside HEADING 5 of the multiannual financial framework	0,100	0,100	0,100	0,100	0,100	0,100	**0,600**
TOTAL	2,092	2,092	2,092	2,092	2,092	2,092	**12,552**

[55] 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
02 01 01 01 (Headquarters and Commission's Representation Offices) – **ENTR**		0,786	0,786	0,786	0,786	0,786	0,786
17 01 01 01 (Headquarters and Commission's Representation Offices) – **SANCO** (Average cost FTE: 131.000 €)		1,048	1,048	1,048	1,048	1,048	1,048
XX 01 01 02 (Delegations)		0	0	0	0	0	0
XX 01 05 01 (Indirect research)		0	0	0	0	0	0
10 01 05 01 (Direct research)		0	0	0	0	0	0
XX 01 02 01 (CA, INT, SNE from the "global envelope")		0	0	0	0	0	0
XX 01 02 02 (CA, INT, JED, LA and SNE in the delegations)		0	0	0	0	0	0
XX 01 04 ***yy*** [56]	- at Headquarters[57]	0	0	0	0	0	0
	- in delegations	0	0	0	0	0	0
XX 01 05 02 (CA, INT, SNE - Indirect research)		0	0	0	0	0	0
10 01 05 02 (CA, INT, SNE - Direct research)		0	0	0	0	0	0
Other budget lines (specify)		0	0	0	0	0	0
TOTAL (ENTR, SANCO)		1,834	1,834	1,834	1,834	1,834	1,834

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 into account 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 market surveillance. • Participate in developing tools and carrying out benchmarking of Member States' enforcement of the Market surveillance Regulation. • Participate in the operation of the RAPEX system, including

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

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

	assessment of notifications and reactions; • Management and development of the ICSMS platform and the corresponding guidelines; • Follow policy developments in the area of market surveillance and information exchange between Member States. • Participate and represent the Commission in expert groups linked to market surveillance. • Conceive new activities or extensions of existing activities and perform conceptual reflections. • Develop and ensure Member States' market surveillance coordination and joint actions. • Participate in the development, adoption and then implementation of revised RAPEX guidelines and revised risk-assessment guidelines. Assistants: • Provide administrative assistance in relation to the operation of the RAPEX system as a member of the internal RAPEX team. • Signal possible inconsistencies or overlaps in notifications and contribute to and provide assistance in RAPEX Contact Points meetings. • Contribute to follow up of RAPEX notifications, under the supervision of the responsible Administrator, in case of a formal noncompliance of notification. • Contribute towards the preparation of the weekly report regarding validated notifications. • Co-ordinate and authorize translation requests through Poetry. • Contribute to the implementation and the carrying out of the internal control standards in particular by ensuring business continuity in RAPEX alerting team coordinator and management in cases of issues arising requiring their attention • Coordinate information and document management in relation to validation of notifications and reactions in RAPEX. • Elaborate and manage statistics and reports related to RAPEX. • Elaborate internal procedures relating to GRAS RAPEX management and contribute to corresponding manuals.
External personnel	

3.2.4. Compatibility with the current multiannual financial framework

The proposal is compatible with the new Multi-annual Financial Framework 2014-2020 as proposed by the Commission.

3.2.5. Third-party contributions

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

3.3. Estimated impact on revenue

The Proposal has no financial impact on revenue.