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POSITION OF THE EUROPEAN PARLIAMENT

adopted at first reading on 15 April 2014 with a view to the adoption of Regulation (EU) No .../2014 of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EC) No 764/2008, Regulation (EC) No 765/2008 and Regulation (EU) No 305/2011 of the European Parliament and of the Council
(EP-PE_TC1-COD(2013)0048)

PE 505.544

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(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[1],

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

[1] OJ C 271, 19.9.2013, p. 86.

[2] Position of the European Parliament of 15 April 2014.

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 of persons in general, health and safety in the workplace, consumer protection, protection of the environment and public security. Robust enforcement of those requirements is essential to the proper protection of those 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 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 ***and applicable environmental legislation***. **[Am. 1]**

(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[1] 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.

[1] 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 (OJ L 218, 13.8.2008, p.30).

(6) Directive 2001/95/EC of the European Parliament and of the Council[1] 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[2] the European Parliament stated that having one single regulation is the only way to have one single market surveillance system for all products and therefore urged 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 (EC) No 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.

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

2 OJ C 199 E, 7.7.2012, p. 1.

(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[1], establishes a comprehensive framework for the performance of official controls and 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. Those 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 to those products insofar as the relevant Union legislation does not contain specific rules relating to the organisation of border controls.

[1] 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 (OJ L 165, 30.4.2004, p. 1).

(11) Directive 2010/35/EU of the European Parliament and of the Council[1] 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. That Directive provides for 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 control of products within the Union laid down in this Regulation should not apply to transportable pressure equipment subject to Directive 2010/35/EU.

[1] Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L165, 30.6.2010, p.1).

(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.

(12a) This Regulation should apply to all forms of supply of products, including distance selling. Member States and the Commission should develop a common approach for the market surveillance of products sold online and, where appropriate, produce guidance on the respective roles and responsibilities of operators involved in the e-commerce supply chain in order to strengthen enforcement of the rules for products sold online. **[Am. 2]**

(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[1]. 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 clauses should be made in relation to products subject to Regulation (EC) No 1907/2006 of the European Parliament and of the Council[2], certain fittings subject to Directive 2009/142/EC of the European Parliament and of the Council[3], certain pressure equipment subject to Directive 97/23/EC of the European Parliament and of the Council[4] and certain pressure vessels subject to Directive 2009/105/EC of the European Parliament and of the Council[5].

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

2 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

3 Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels (OJ L 330, 16.12.2009, p. 10).

4 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 (OJ L 181, 9.7.1997, p. 1).

5 Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels (OJ L 264, 8.10.2009, p. 12).

(14) In order to make the entire market surveillance process transparent and easy to follow for both market surveillance authorities and economic operators, this 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.

(14a) In order to facilitate the work of market surveillance authorities, economic operators should make available all the documentation and information necessary to those authorities for the purpose of carrying out their activities. Market surveillance authorities should only require documentation and information that the relevant economic operator can be expected to possess in accordance with their role in the supply chain. **[Am. 3]**

(15) Market surveillance should be based on the assessment of the risk presented by a product taking all relevant data into account. ***The methodology and criteria for assessing risks should be homogeneous in all Member States in order to ensure a level playing field for all economic operators.*** 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. **[Am. 4]**

(15a) Consumers can play an active and important role in contributing to market surveillance, as they are usually in direct contact with products presenting a risk, including products that are not compliant with applicable Union legislation. In that context Member States should raise consumers' awareness with regard to their right to submit complaints on issues relating to product safety and market surveillance activities and ensure that the reporting procedure is easily accessible, relatively simple and efficient. The Commission should, furthermore, explore the opportunities for making the submission of such complaints harmonised throughout the Union, for example through the creation of a central database where the complaints filed by consumers can be stored, as well as examine the possibility of making those complaints public, subject to the right of review and reply by the economic operators involved. **[Am. 5]**

(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 the references of which are published 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 …./…. of the European Parliament and of the Council[1+], sector-specific Union harmonisation legislation and other Union legislation on products that are subject to this Regulation. Risk assessment 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, and the increased vulnerability of certain categories of consumer such as children, the elderly or the disabled, should be taken into account.

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1 Regulation (EU) No…/…. of the European Parliament and of the Council of… on consumer product safety and repealing Council Directive 87/357/EEC and Directive 2001/95/EC (OJ L…).

+ OJ: please insert the number of Regulation (2013/0049(COD)) in the recital and the number, date of adoption and the publication reference of the Regulation in the footnote.

(19) Both new and second-hand products originating from 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~~ ***those authorities and market surveillance authorities should be obliged to cooperate and exchange information*** concerning products presenting a risk ~~should be enhanced~~ ***and products that are non-compliant***. **[Am. 6]**

(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. ***The relevant economic operator should bear all the costs related to those actions, in particular the costs incurred by the market surveillance authority.*** **[Am. 7]**

(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, that system should be used ***and constantly updated*** for all alert notifications required by this Regulation relating to products presenting a risk. ***RAPEX should also include notifications related to food contact materials, moved there from the Rapid Alert System for Food and Feed (RASFF) platform.*** **[Am. 8]**

(24) Coherent and cost-effective market surveillance activity throughout the Union also requires well-structured, comprehensive archiving and sharing among Member States of all relevant 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 suitable for that 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~~ ***this Regulation builds the framework for*** 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***, enforced, verified and duly financed***. **[Am. 9]**

(25a) The consistent application of this Regulation should be closely monitored by the Commission, which should also, where necessary, give recommendations to Member States where it finds that the powers and resources they have given to their market surveillance authorities are insufficient to meet the requirements of this Regulation properly. **[Am. 10]**

(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 third countries.

(26a) Injuries and accidents place a high social and economic burden on societies in general and on individuals. Injury and accident prevention can be enhanced primarily by improving injury surveillance. Based on the experience gained in the framework of the Joint Action on Monitoring Injuries in Europe (JAMIE) project, a genuine Pan-European Injuries Database should urgently be established, in particular given the fact that the JAMIE project expires in 2014. Moreover, political commitment is necessary to ensure that the exchange of injury data among the Member States is an absolute priority. **[Am. 11]**

(27) A European Market Surveillance Forum (EMSF) composed of representatives from market surveillance authorities should be established. The EMSF should ***serve as a platform for structured cooperation between the authorities of the Member States and should*** provide a ***continuous and permanent*** means of involving all stakeholders concerned, including professional organisations***, business organisations*** and consumer organisations, in order to take advantage of available information relevant for market surveillance when establishing, implementing and updating market surveillance programmes. **[Am. 12]**

(28) The Commission should provide support for cooperation between market surveillance authorities and participate in the EMSF. ~~The~~ ***This*** Regulation should set out a list of tasks to be performed by the EMSF. An executive secretariat should organise the EMSF's meetings and provide other operational support for the accomplishment of its tasks. ***To streamline the practices of market surveillance within the Union and to make market surveillance more effective, the Commission should consider proposing, when this Regulation is next reviewed, that the EMSF is given the power to set binding recommendations as to the quality and practices of market surveillance.*** **[Am. 13]**

(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.

(29a) ***In view of the conflict between the increased number of products in circulation within the internal market on the one hand, and the constraints on public resources that limit the possibility to drastically increase public market surveillance on an adequate scale on the other, the Commission should explore complementary, new and innovative, market-based solutions for more effective market surveillance on a larger scale, such as third party auditing of quality control systems and products. The Commission should include the results of those deliberations in the general evaluation report.*** **[Am. 14]**

(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~~[1]. ***Moreover, this Regulation should respect data protection principles, such as confidential handling of personal data, requirement to process data fairly and lawfully and for specific purpose, while ensuring their quality and allowing the individuals concerned to exercise their rights.*** 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~~[2] 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~~[3] apply in the context of this Regulation. **[Am. 15]**

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1 ***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 (***OJ L 145, 31.5.2001, p. 43***)***.

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

3 ***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 (***OJ L 8, 12.1.2001, p. 1***)***.

(31) Information exchanged between competent authorities should be subject to the strictest guarantees of confidentiality and professional secrecy and be handled in such 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 ***and depend on the seriousness, duration and intentional or recurring character of the infringement, as well as the size of the undertakings, in terms of the number of persons employed by and annual turnover of the economic operators concerned, with particular regard to small and medium-sized enterprises (SMEs). Infringements should entail administrative penalties that are harmonised at Union level. Member States should be encouraged to allocate the revenues collected from such penalties to market surveillance activities***.
[Am. 16]

(33a) In order to enhance the deterrent effect of the penalties, the Commission should make them public. In addition, economic operators who are repeatedly found to have intentionally breached this Regulation should be placed on a public, Union-wide blacklist. **[Am. 17]**

(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. ***Member States should ensure that the revenues collected from fees charged in accordance with this Regulation are allocated to market surveillance activities.*** **[Am. 18]**

(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[1], depending on the nature of the activity to be financed, in particular for support to the executive secretariat of the EMSF.

(36a) In order to facilitate the identification and traceability of products bearing a potential serious risk to health and safety and thus to maintain a high level of health and safety of consumers, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in order to establish a Pan-European Injuries Database. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council. **[Am. 19]**

(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.

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[1] 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 and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

(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 on the Commission 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. ***In addition, implementing powers should be conferred on the Commission as regards the adoption of the general risk assessment methodology.*** Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. **[Am. 20]**

[1] ***Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of its implementing powers (***OJ L 55, 28.2.2011, p. ~~11~~ ***13)***.

(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.

(39a) The precautionary principle, as laid down in Article 191(2) TFEU, and outlined inter alia in the Commission Communication of 2 February 2000 entitled "On the precautionary principle", is a fundamental principle for the safety of products and for the safety of consumers and should be taken into due account by market surveillance authorities when assessing the safety of a product. **[Am. 21]**

(40) The market surveillance provisions of Council Directive 89/686/EEC[1], Council Directive 93/15/EEC[2], Directive 94/9/EC of the European Parliament and the Council[3], Directive 94/25/EC of the European Parliament and of the Council[4], Directive 95/16/EC of the European Parliament and of the Council[5], Directive 97/23/EC, Directive 1999/5/EC of the European Parliament and of the Council[6], Directive 2000/9/EC of the European Parliament and of the Council[7], Directive 2000/14/EC of the European Parliament and of the Council[8], Directive 2001/95/EC, Directive 2004/108/EC of the European Parliament and of the Council[9], Directive 2006/42/EC of the European Parliament and of the Council[10], Directive 2006/95/EC of the European Parliament and of the Council[11], Directive 2007/23/EC of the

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1 Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18).

2 Council 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 (OJ L 121, 15.5.1993, p. 20).

3 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 (OJ L 100, 19.4.1994, p. 1).

4 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 (OJ L 164, 30.6.1994, p. 15).

5 Directive 95/16/EC of the European Parliament and of the Council of 29 June 1995 on the approximation of the laws of the Member States relating to lifts (OJ L 213, 7.9.1995, p. 1).

6 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 conformity (OJ L 91, 7.4.1999, p. 10).

7 Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons (OJ L 106, 3.5.2000, p. 21).

8 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 (OJ L 162, 3.7.2000, p. 1).

9 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 and repealing Directive 89/336/EEC (OJ L 390, 31.12.2004, p. 24).

10 Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).

11 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 (OJ L 374, 27.12.2006, p. 10).

European Parliament and of the Council[1], Directive 2008/57/EC of the European Parliament and of the Council[2], Directive 2009/48/EC of the European Parliament and of the Council[3], Directive 2009/105/EC, Directive 2009/142/EC, Directive 2011/65/EU of the European Parliament and of the Council[4], Regulation (EU) No 305/2011 of the European Parliament and of the Council[5], and Regulation (EC) No 765/2008 overlap with the provisions of this Regulation. Therefore, those provisions should be deleted. Regulation (EC) No 764/2008 of the European Parliament and of the Council[6] should be amended accordingly.

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1 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 (OJ L 154, 14.6.2007, p. 1).

2 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 (OJ L 191, 18.7.2008, p. 1).

3 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

4 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 (OJ L 174, 1.7.2011, p. 88).

5 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 productsand repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5).

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

(40a) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 30 May 2013[1],

[1] OJ C 253, 3.9.2013, p. 8.

(41) Since the objective of this Regulation, namely to ensure that products on the market covered by Union legislation fulfil the requirements providing for 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 that objective requires a very high degree of cooperation, interaction and uniformity of operation among all of the competent authorities of all Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(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 the obligation to ensure a high level of human health protection and consumer protection as well as full respect for 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.

The provisions of this Regulation are based on the precautionary principle. **[Am. 22]**

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 …/…[+] 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.

[+] OJ: please insert the number of Regulation (2013/0049(COD)).

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 point (b) of Article 1(2) 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 apply:

(1) ‘product’ means a ~~product obtained~~ ***substance, mixture, preparation or good produced*** through a manufacturing process ***other than food, feed, products of human origin and products of plants and animals relating directly to their future reproduction***; **[Am. 23]**

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

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

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

(5) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks ***with regard to the manufacturer's obligations under the relevant Union legislation***; **[Am. 24]**

(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;

(7a) 'intermediary service provider' means any natural or legal person who enables the placing or making available on the market of a product via electronic means, such as by operating e-commerce platforms or hosting websites; **[Am. 25]**

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

(9) ‘conformity assessment’ means conformity assessment as defined in point 12 of Article 2 of Regulation (EC) No 765/2008;

(10) ‘conformity assessment body’ means conformity assessment body as defined in point 13 of Article 2 of 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~~ ***competent for exercising the regulated powers under this Regulation***; **[Am. 26]**

(-13) 'non-compliant product' means a product which is not in conformity with the requirements laid down in applicable Union legislation; **[Am. 27]**

(13) ‘product presenting a risk’ means a product ~~having~~ ***which has*** the potential to affect adversely the 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; **[Am. 28]**

(13a) 'product presenting an emerging risk' means a product on which there is solid scientific evidence that it presents a newly developing risk or a known risk if the product is used in new or unfamiliar conditions which cannot be reasonably foreseen by the manufacturer; **[Am. 29]**

(14) ‘product presenting a serious risk’ means a product presenting a serious 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 77 of Regulation (EU) No 952/2013 of the European Parliament and the Council[1];

(18) ‘Union harmonisation legislation’ means Union legislation harmonising the conditions for the marketing of products ***by laying down the characteristics required of a product such as levels of quality, performance, safety or dimensions, including the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures***; **[Am. 30]**

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

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

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

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

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 ***and non-compliant products*** are not ***placed or*** made available on the Union market and, where such products have been ***placed or*** made available, effective ***and proportionate*** measures are taken to remove the risk presented by that product ***or to resolve non-compliance***. **[Am. 31]**

3. ~~The implementation of~~ ***Member States shall report on the*** 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 ***and results*** of controls carried out and shall be communicated to all Member States. ~~Member States may~~ ***The Commission shall*** make ~~a summary of the results accessible~~ ***that information available*** to the public ***electronically and, where appropriate, by other means***. **[Am. 32]**

~~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.~~ **[Am. 33]**

Article 5

Market surveillance authorities

1. Each Member State shall establish or designate market surveillance authorities ~~and define their duties, powers and organisation~~. **[Am. 34]**

2. ~~Market surveillance authorities~~ ***Each Member State*** shall ~~be given~~ ***grant market surveillance authorities*** the powers and ~~entrusted~~ ***entrust them*** with the resources and means necessary for the proper performance of their tasks ***and shall report to the Commission thereon***. ***The Commission shall evaluate whether those powers and resources are sufficient for the proper performance of that Member State's market surveillance obligations under this Regulation, and shall make the outcomes of its evaluations available to the public electronically and, where appropriate, by other means***. **[Am. 35]**

3. ~~Each Member State shall establish appropriate mechanisms to ensure that the~~ Market surveillance authorities ~~that it has established or designated~~ ***shall*** 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. **[Am. 36]**

4. Each Member State shall inform the Commission about its market surveillance authorities and its areas of competence, providing the necessary contact details~~, and~~**.** The Commission shall ~~transmit this information~~ ***make the list available*** to the ~~other Member States and publish a list of market surveillance authorities~~ ***public electronically and, where appropriate, by other means***. **[Am. 37]**

5. Member States shall inform the public of the existence, responsibilities***, powers, available resources, cooperation mechanisms*** and identity of national market surveillance authorities and about the contact details of those authorities. **[Am. 38]**

Article 6

General obligations of market surveillance authorities

1. Market surveillance authorities shall ***organise their activities in such a way that maximum effectiveness can be achieved. They 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. ***Market surveillance authorities shall, accordingly, carry out the sample checks on sufficient numbers of products made available on the market, enabling conformity and the real risk posed to be assessed.*** They shall record those checks in the information and communication system for market surveillance referred to in Article 21. ***Where appropriate, along with those traditional market sampling mechanisms, the market surveillance authorities shall endeavour to move to proactive auditing of supply chain processes at entities involved in the manufacturing, importing, trading, branding and retailing of consumer products.*** **[Am. 39]**

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***, criteria for determination of the amount of samples to be checked in relation to that particular product or category of products*** and the characteristics of that known or emerging risk. ~~These~~ ***Those*** 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~~***Those*** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2). **[Am. 40]**

2. ~~Where appropriate,~~ Market surveillance authorities shall alert users in their territories ~~within an adequate timeframe~~ ***without delay of the identity*** of products that those authorities have identified as presenting a risk. ***Where available, that information shall also include data on the manufacturer, retail channel and period of sales.*** **[Am. 41]**

~~They~~ ***Market surveillance authorities*** shall cooperate with economic operators ***and other competent national authorities*** to prevent or reduce risks caused by products made available by those ***economic*** operators. For that 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. **[Am. 42]**

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***, check, examine and obtain copies of any relevant documents*** and take any necessary samples of products. **[Am. 43]**

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~~ ***within a reasonable timeframe***; **[Am. 44]**

(b) verify that corrective action has been taken ***in a timely manner***; **[Am. 45]**

(c) follow and keep up to date with developments in scientific and technical knowledge concerning the safety of products~~.~~ ***and compliance of products with applicable Union legislation;*** **[Am. 46]**

(ca) monitor accidents and damage to health which are suspected to have been caused by products; **[Am. 47]**

(cb) be encouraged to participate in national standardisation activities aimed at the development or revision of European standards requested by the Commission in accordance with Article 10 of Regulation (EU) No 1025/2012. **[Am. 48]**

6. Adequate procedures shall be established and made known to the public to enable market surveillance authorities to fulfil the obligations laid down in paragraph 5.

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 authority from which the confidential document originated 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 …/…[+] 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;

(ba) the levels and methods for calculation of fees applicable to economic operators pursuant to Articles 10 and 16; **[Am. 49]**

[+] OJ: please insert the number of Regulation (2013/0049(COD)).

(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 obligations laid down in Article 6(5).

2. Each Member State shall draw up sector-specific programmes ***with the input of key stakeholders concerned, including professional organisations, business organisations and consumer organisations,*** and shall review ~~these~~ ***those*** programmes, and update them if necessary, every year. ~~These~~ ***Those*** programmes shall cover all sectors in which authorities conduct market surveillance activities. **[Am. 50]**

3. The general and sector-specific programmes and their updates shall be communicated to the other Member States ~~and~~ ***via*** the Commission ~~and,~~**.** Subject to Article 6(6), ***they*** shall be made accessible to the public electronically and, where appropriate, by other means. **[Am. 51]**

The Commission shall evaluate the general and sector-specific programmes and, if appropriate, make recommendations to the Member States based on that evaluation. The Commission shall make the outcomes of its evaluations and, if applicable, its recommendations to Member States available to the public electronically and, where appropriate, by other means. **[Am. 52]**

Article 8

General obligations of economic operators

1. ~~On~~ ***Further to a reasoned*** request, economic operators***, in accordance with their respective role in the supply chain*** and, where applicable, conformity assessment bodies, shall make available to market surveillance authorities ~~any~~ ***all the*** 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.~~ ***Such information shall include information that enables the precise identification of the product and facilitates the tracing of the product, as appropriate. Where an economic operator has previously received the documentation and information concerned from another economic operator, and where it is classified as confidential under Union and Member State trade secrecy rules, market surveillance authorities shall ensure confidentiality when that documentation and information is made available.*** **[Am. 53]**

2. Economic operators shall ~~provide all necessary information to~~ ***cooperate with*** market surveillance authorities ~~including information that enables the precise identification of the product and facilitates the tracing of the product~~ ***at their request, on any action taken to eliminate the risks presented by or non-compliance of products that they have placed or made available on the market***. **[Am. 54]**

2a. All information supplied or made available to market surveillance authorities under this Article shall be clear, understandable and intelligible. **[Am. 55]**

2b. The obligations laid down in this Article shall also apply to intermediary service providers. **[Am. 56]**

CHAPTER III

Control of products within the Union

Article 9

Non-compliant products and products presenting a risk **[Am. 57]**

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 ***be non-compliant or*** 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 ***of this Regulation and in Article 6 of Regulation (EU) No …/….*** [+]. **[Am. 58]**

Market surveillance authorities shall take ~~due~~ into consideration any readily available ***and comprehensible*** 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. **[Am. 59]**

[+] ***OJ: please insert the number of Regulation (2013/0049(COD)).***

2. In relation to a product ~~that is subject to Union harmonisation legislation~~, formal non-compliance with ~~that~~ ***Union*** legislation ~~shall~~ ***may*** give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases: **[Am. 60]**

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

(aa) the product or any presentation of the product bears without authorisation a trade mark that is essentially similar to a registered trade mark for that product, thereby not allowing its authenticity or origin to be guaranteed; **[Am. 61]**

(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~~ ***may, if appropriate, withdraw or recall*** the product ~~is withdrawn or recalled~~ ***in question until the non-compliance is rectified***. **[Am. 62]**

3. Without prejudice to Article 10(4), where market surveillance authorities find that a product presents 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: **[Am. 63]**

(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: **[Am. 64]**

(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~~ ***immediately*** and in an appropriate form, including by publication of special warnings; **[Am. 65]**

(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) ***immediately*** preventing the product from being placed or made available on the market; **[Am. 66]**

(ii) withdrawing or recalling the product and ***immediately*** alerting the public***,*** ***in an appropriate form,*** to the risk presented; **[Am. 67]**

(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).~~ **[Am. 68]**

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 purposes of paragraph 1 of this Article, 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.~~ **[Am. 69]**

All of the expenses incurred by the market surveillance authority in the course of the application of the first subparagraph shall be borne by the relevant economic operator unless the market surveillance authority considers it to be disproportionate, in which case it may decide that the cost shall be borne only partly by that economic operator. **[Am. 70]**

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.~~ **[Am. 71]**

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 corrective 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. ***In the case of products found to present a risk,*** 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. That 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.
[Am. 72]

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~~ ***shall*** charge fees to ***the relevant*** economic operators which ***are caught placing or making available non-compliant products and products presenting a risk on the Union market. Such fees shall*** 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.
[Am. 73]

The fees shall be calculated on the basis of the actual costs incurred for each market surveillance activity, and shall be applied to the economic operators subject to such market surveillance activities. Such fees shall not exceed the actual costs of the market surveillance activity performed and may partly or entirely reflect the time taken by the staff of the market surveillance authorities to perform the market surveillance controls. **[Am. 74]**

Article 11

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

1. Within ~~60~~ ***30*** 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***(1) or (4)*** 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. **[Am. 75]**

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 notifying Member State and*** the relevant economic operator or operators and shall evaluate***, within a maximum of 30 days*** the national measures, taking account of all available scientific or technical evidence. **[Am. 76]**

3a. If an objection is raised pursuant to paragraph 1 by a Member State or the Commission considers that the national measures may be contrary to Union legislation, the Commission shall inform all the Member States through the RAPEX contact points. **[Am. 77]**

4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission ~~may~~ ***shall*** decide by means of implementing acts ***within three months*** whether the national measures are justified and similar measures should be taken by all Member States that have not already done so. In ~~this~~ ***that*** 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. **[Am. 78]**

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 it and the notification made under RAPEX 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 means of 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 of this paragraph 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, ***the Commission may take a decision, pursuant to paragraph 1 of this Article, only if it has justifiable grounds for believing that urgent action is essential to protect human health or the environment.*** 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. ***The Commission shall immediately inform the Member States and the European Chemicals Agency thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based. If the provisional measure adopted by the Commission involves restricting the placing on the market or use of a substance, the Commission shall initiate a Community restrictions procedure by submitting to European Chemicals Agency a dossier, in accordance with Annex XV to Regulation (EC) No 1907/2006, within three months of the date of the Commission decision.*** **[Am. 79]**

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. ***Risk assessment shall be carried out in accordance with the general risk assessment methodology and, where appropriate, Commission guidelines on the application of that methodology to a specific category of products. The Commission shall, by means of implementing acts, adopt the general risk assessment methodology. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).*** **[Am. 80]**

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***, inspection and calibration*** reports or certificates attesting conformity and issued by a conformity assessment body ***accredited in accordance with Regulation (EC) No 765/2008, including assessments drawn up pursuant to Regulation (EC) No 1907/2006, for instance in connection with registration, authorisation, restrictions or reporting***; **[Am. 81]**

(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*.

2a. In the absence of criteria referred to in points (a), (b) and (c) of paragraph 2 of this Article, account shall be taken of Article 6 of Regulation (EU) No …/…[+]. **[Am. 82]**

3. Compliance with ***any of*** 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. ***In that case, the market surveillance authority shall demonstrate that the product presents a risk.*** **[Am. 83]**

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~~ ***sufficient*** reason to consider that a product presents a risk. **[Am. 84]**

[+] ***OJ: please insert the number of Regulation (2013/0049(COD)).***

4a. ***The Commission may, on its own initiative or at the request of a market surveillance authority, have a risk assessment carried out by a Union reference laboratory, in accordance with Article 28. Such assessment shall be binding on all stakeholders.*** **[Am. 85]**

4b. ***In cases where Member State risk assessment practices differ and result in divergent interpretations as to the necessity of measures in respect of similar products, the Commission shall provide guidance on appropriate risk assessment practices. The Commission shall be assisted by the Scientific Committees established under Commission Decision 2004/210/EC[1] and shall take into account all available scientific and technical evidence relating to the risks under consideration.*** **[Am. 86]**

[1] ***Commission Decision 2004/210/EC of 3 March 2004 setting up Scientific Committees in the field of consumer safety, public health and the environment (OJ L 66, 4.3.2004, p. 45).***

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 of this Article, 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 Union harmonisation legislation;

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

(ba) the product or any presentation of the product bears without authorisation a trade mark that is essentially similar to a registered trade mark for that product, thereby not allowing its authenticity or origin to be guaranteed; **[Am. 87]**

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

3a. ***Where products are not intended to be placed on the market in the Member State in which they are released for free circulation, the language in which the information set out in points (a), (b), (ba) and (c) of the second subparagraph of paragraph 3 is presented shall not give the authorities in charge of external border controls sufficient reason to believe that the product may present a risk.*** **[Am. 88]**

3b. ***The corrective measures of the market surveillance authorities shall be proportionate to the seriousness of the non-compliance.*** **[Am. 89]**

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~~ ***facilitate measures 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. **[Am. 90]**

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 ***notification of*** 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. **[Am. 91]**

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 subparagraph of Article 14(3) 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***, inspection and calibration*** reports or certificates attesting conformity and issued by a conformity assessment body ***accredited in accordance with Regulation (EC) No 765/2008***, 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. **[Am. 92]**

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 …/…/EU[+]".

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 referred to in paragraph 1 shall also be included, under the conditions set out in that paragraph, 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.

[+] OJ: please insert the number of this Regulation.

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~~ ***shall*** charge fees ***to the person declaring the product for free circulation*** 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. **[Am. 93]**

The fees shall be calculated on the basis of the actual costs of each market surveillance activity, and applied to the person declaring the product for free circulation subject to such market surveillance activities. Such fees shall not exceed the actual costs of the market surveillance activity performed and may partly or entirely reflect the time taken by the staff of the market surveillance authorities to perform the market surveillance controls. **[Am. 94]**

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 Union harmonisation legislation

1. Within ~~60~~ ***30*** 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. **[Am. 95]**

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 notifying Member State and*** the relevant economic operator or operators and shall***, within 30 days,*** evaluate the ~~refusal~~ ***national measures***, taking account of all available scientific or technical evidence. **[Am. 96]**

3a. If an objection is raised within 30 days pursuant to paragraph 1 by a Member State or the Commission considers that the national measures may be contrary to Union legislation, the Commission shall inform all the Member States through the RAPEX contact points. **[Am. 97]**

4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission may decide by means of implementing acts whether the refusal is justified and similar action should be taken by all Member States that have not already done so. In that 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 System - RAPEX

1. The Commission shall maintain the Union Rapid Information System (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, lay down 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 ***as well as special provisions on personal data protection, as required by Article 25 of Directive 95/46/EC and Article 9 of Regulation (EC) No 45/2001***. **[Am. 98]**

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) of this paragraph;

(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.~~ **[Am. 99]**

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~~ ***data necessary for product identification and traceability***; **[Am. 100]**

(b) the nature ~~of any non-compliance with Union harmonisation legislation~~ ***and level of the risk and a summary of safety and risk assessment findings***; **[Am. 101]**

~~(c) the data necessary to identify the product~~ ***the nature of any infringement of Union legislation***; **[Am. 102]**

(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;

(fa) whether the product is known to be counterfeit; **[Am. 103]**

(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 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~~ ***without delay to the relevant economic operator and*** 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. **[Am. 104]**

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 that information to other Member States.

5a. ***Information on a product contained in a notification in RAPEX shall be updated, where appropriate.*** **[Am. 105]**

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~~,~~***. Member States shall collect and enter into ICSMS*** in particular the following information: **[Am. 106]**

(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;

(da) the identification of risks and their characteristics; **[Am. 107]**

(e) any non-compliance with Union ~~harmonisation~~ legislation other than measures or corrective action notified under RAPEX in accordance with Article 20; **[Am. 108]**

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

The Commission shall provide an interface solution through which ICSMS can be connected to RAPEX for data interchange between those systems, where appropriate. **[Am. 109]**

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~~ ***shall*** also be made available, where necessary or appropriate, for use by the authorities in charge of controls at the external borders. **[Am. 110]**

2. For the purposes of paragraph 1 of this Article, 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***, inspection or calibration*** reports prepared by or for their counterparts in other Member States and entered into ICSMS. **[Am. 111]**

Article 21a

Pan-European Injuries Database

1. The Commission shall adopt delegated acts, in accordance with Article 31a, establishing a Pan-European Injuries Database ("the Database") which would cover all types of injuries, and in particular those related to products used at home and for leisure, transportation and work activities by …[+]. The Database shall be coordinated and operated by the Commission.

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

2. The relevant market surveillance authorities of the Member States shall contribute to the establishment of the Database and deliver comprehensive injury data. In consultation with the Member States, the Commission shall draw up and publish detailed guidance on the relevant data to be included in the Database, as well as the methods for electronic communication of the data.

Not later than two years after the establishment of the Database, the Commission shall report to the European Parliament and to the Council on the functioning of the Database. **[Am. 112]**

Article 22

International exchange of confidential information

The Commission ~~and~~***, together with the*** Member States, may exchange confidential information, including information exchanged through RAPEX, with regulatory authorities of ***applicant countries,*** 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. ***Any such arrangements shall include provisions on confidentiality corresponding to those applicable in the Union as well as special provisions on personal data protection, as required by Article 25 of Directive 95/46/EC and Article 9 of Regulation (EC) No 45/2001.*** **[Am. 113]**

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~~ ***and among the*** Member ~~State~~ ***States*** 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.
[Am. 114]

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 RAPEX 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.

2a. Where, in an exchange of information, personal data are exchanged, Directive 95/46/EC shall apply. **[Am. 115]**

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 ***on a regular and continuous basis***. ***Business organisations, SMEs, consumers, laboratories and conformity assessment bodies at Union level may be consulted on the annual market surveillance programme.*** **[Am. 116]**

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~~ ***SMEs***, consumers, laboratories and conformity assessment bodies at Union level ~~may~~ ***shall*** be invited to participate in such sub-groups as observers ***on a regular and continuous basis***. **[Am. 117]**

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 EMSF 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. In order 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~~ ***facilitate the organisation of*** joint market surveillance and joint testing projects; **[Am. 118]**

(d) to exchange expertise and best practices;

(e) to ~~organise~~ ***facilitate the organisation of*** training programmes and exchanges of national officials; **[Am. 119]**

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

(g) to ~~organise~~ ***facilitate the organisation of*** information campaigns and joint visit programmes***, including controls at borders***; **[Am. 120]**

(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~~ ***SMEs***, ***consumer protection***, and other stakeholders; **[Am. 121]**

(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;

(la) to organise specific and regular market surveillance actions on products that are distributed on-line; **[Am. 122]**

(lb) to ensure adequate involvement of and cooperation with customs authorities; **[Am. 123]**

(lc) to contribute to a streamlining of administrative and enforcement practices with regard to market surveillance in the Member States. **[Am. 124]**

Article 28

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;

(da) be accredited pursuant to the provisions of Regulation (EC) No 765/2008. **[Am. 125]**

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~~ ***settling any disputes arising out of a divergent risk assessment among the market surveillance*** authorities of ***different*** Member States, ***the*** economic operators and ***the*** conformity assessment bodies; **[Am. 126]**

(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 EMSF executive secretariat 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 entrusting budget implementation tasks to the entities listed in point (c) of Article 58(1) of Regulation (EU, Euratom) No 966/2012.

3. The appropriations allocated to activities referred to in paragraph 1 shall be determined each year by the European Parliament and the Council within the limits of the financial framework in force.

4. The appropriations determined by the European Parliament and the Council 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 … [+] and every five years thereafter.

[+] OJ: please insert the date: [five years following the date of application of this Regulation].

Article 30

Protection of the financial interests of the Union

1. The Commission shall take appropriate measures to ensure that, where 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 unduly 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[1] 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, 2 and 3, 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.

[1] Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 14.11.1996, p.2).

CHAPTER VIII

Final provisions

Article 31

Penalties

1. The Member States shall lay down the rules ~~on~~ ***establishing appropriate*** 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 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. **[Am. 127]**

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

The penalties provided for shall be effective, proportionate and dissuasive. 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.~~ ***seriousness, the duration and, where applicable, the intentional character of the infringement***. ***In addition,*** the penalties ~~may be increased if~~ ***shall take into account whether*** the relevant economic operator has previously committed a similar infringement ~~and may include criminal sanctions for serious infringements~~.
[Am. 128]

1a. Administrative penalties applicable to infringements shall at least offset the economic advantage sought through the infringement, but shall not exceed 10 % of the annual turnover or an estimate thereof. The penalties imposed may be higher than 10 % of the annual turnover or an estimate thereof, where it is necessary to offset the economic advantage sought through the infringement. The penalties may include criminal sanctions for serious infringements. **[Am. 129]**

1b. ***The Member States shall inform the Commission of the type and the size of the penalties imposed under this Regulation, identify the actual infringements of this Regulation, and indicate the identity of economic operators upon which penalties have been imposed. The Commission shall make that information available to the public without undue delay electronically and, where appropriate, by other means.*** **[Am. 130]**

The Commission shall, on the basis of the information received under the first subparagraph, publish and update a Union-wide blacklist of economic operators who are repeatedly found to intentionally infringe this Regulation. **[Am. 131]**

Article 31a

Exercise of the delegation

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

2. ***The power to adopt delegated acts referred to in Article 21a shall be conferred on the Commission for an indeterminate period of time from …[+].***

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

3. ***The delegation of power referred to in Article 21a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.***

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

5. ***A delegated act adopted pursuant to Article 21a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by two months at the initiative of the European Parliament or of the Council.*** **[Am. 132]**

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 …[+] the Commission shall assess the application of this Regulation and transmit an evaluation report to the European Parliament and to the Council. That report shall assess whether this Regulation has 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 protection of environment, ***energy efficiency,*** public security and other public interests, taking into account its impact on business and in particular on ~~small and medium-sized enterprises~~ ***SMEs***. ***In addition, that report shall explore new and innovative, market-based solutions that could effectively complement the market surveillance actions carried out by the market surveillance authorities, and shall include, but not be limited to, exploring the potential of compulsory third party auditing schemes.*** **[Am. 133]**

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

Article 34

Amendments

1. The following provisions are deleted:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(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 …/… of the European Parliament and of the Council of … [*].

_____

[*] Regulation (EU) No …/… of the European Parliament and of the Council of … on market surveillance of products and amending Council Directives 89/686/EEC and93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EC) No 764/2008, Regulation (EC) No 765/2008 and Regulation (EU) No 305/2011 of the European Parliament and of the Council (OJ L…)[+]."."

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

(a) The title 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";

(b) Article 1(2) and (3), points 14, 15, 17, 18 and 19 of Article 2, Chapter III and point (e) of Article 32(1) are deleted.

[+] OJ: please insert the number, date of adoption and publication reference of this Regulation.

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 set out in the Annex to this Regulation.

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 …[+]

It shall apply from 1 January 2015.

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

Done at …,

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

[+] OJ: please insert the date of entry into force of Regulation (2013/0049(COD)).

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)
First subparagraph of Article 19(1)	Article 6(1)
Second subparagraph of Article 19(1)	Article 6(5) and Article 7
Third subparagraph of Article 19(1)	Second subparagraph of Article 8(1)
Article 19(2)	Article 6(2)
Article 19(3)	Point (a) of Article 9(5)
Article 19(4)	Article 6(3)
Article 19(5)	Article 26(5) and Article 27
Article 20(1)	Articles 9(4) and point (b) of 18(1)
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