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

- *General approach*

Please find attached the Presidency compromise text for the proposal on Market Surveillance.

Please note that this text is identical to the text set out in document 16902/13 presented to Coreper on 20 May 2015¹. Changes to the Commission Proposal are indicated.

¹ A new document number has been taken to facilitate the translation into all languages.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 33, 114 and 207 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee²,

After consulting the European Data Protection Supervisor,

Acting in accordance with the ordinary legislative procedure,

Whereas:

² OJ C , , p. .

- (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, protection of consumers, ~~protection~~ of the environment and public security. Robust enforcement of these requirements is essential to the proper protection of these interests and to create the conditions in which fair competition in the Union goods market can thrive. Rules are therefore necessary on market surveillance and on controls of products entering the Union from third countries.
- (2) Market surveillance activities covered by this Regulation should not be directed exclusively towards the protection of health and safety but should also be applicable to the enforcement of Union **harmonisation** legislation which seeks to safeguard other public interests, for example, by means of regulating the accuracy of measurement, electromagnetic compatibility and energy efficiency.
- (3) It is necessary to establish an overall framework of rules and principles in relation to market surveillance which should not affect the substantive rules of existing Union legislation designed to protect public interests such as health and safety, consumer protection and the protection of the environment, but should aim at enhancing their operation.
- (4) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products³ 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.

³ OJ L 218, 13.8.2008, p.30.

- (6) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety⁴ 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 surveillance⁵ the European Parliament states~~ed~~ that having one single regulation **is was** the only way to have one single market surveillance system for all products and therefore **urgesd** the Commission to establish a single market surveillance system for all products, based on one act covering both Directive 2001/95/EC and Regulation (EC) No 765/2008.
- (8) This Regulation should therefore integrate the provisions of Regulation 765/2008, Directive 2001/95/EC and several sector-specific acts of Union harmonisation legislation relating to market surveillance into a single regulation which covers products in both the harmonised and non-harmonised areas of the Union legislation, regardless whether they are intended for use, or are likely to be used, by consumers or professionals. **For reasons of transparency, the Commission should provide guidance regarding the relevant Union legislation falling under the scope of this Regulation.**

⁴ OJ L 11, 15.1.2002, p. 4.

⁵ 2010/2085(INI).

- (9) ~~Union legislation applicable to products and processes of the food chain, and in particular Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules⁶ and other Union legislation applicable to products and processes of the agri-food chain,~~ 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,~~ **and plant protection products, and pesticides.** These areas should ~~therefore~~ be excluded from the scope of this Regulation **insofar as they are governed by such legislation.**
- (9a) **This Regulation does not affect the application of the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiations within the meaning of Article 30 of the Treaty establishing the European Atomic Energy Community.**
- (10) Union legislation concerning medicinal products, medical devices, in vitro diagnostic medical devices and substances of human origin contain special provisions to ensure post-market safety based in particular on sector-specific vigilance and market surveillance systems. Those products should therefore also be excluded from the scope of this Regulation, with the exception of its provisions on control of products entering the Union market which should apply insofar as the relevant Union legislation does not contain specific rules relating to the organisation of border controls.

⁶ OJ L 165, 30.4.2004, p. 1.

(11) Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment⁷ applies not only to new transportable pressure equipment for the purpose of making it available on the market but also to certain other transportable pressure equipment for the purposes of its periodic inspections, intermediate inspections, exceptional checks and use. It provides for the specific Pi-marking and for a Union safeguard procedure and particular procedures for dealing with transportable pressure equipment presenting a risk at national level, with compliant transportable pressure equipment which presents a risk to health and safety and with formal non-compliance. Therefore, the procedures for the controls of products within the Union laid down in this Regulation should not apply to transportable pressure equipment subject to Directive 2010/35/EU.

(11a) 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 market surveillance of products sold online, including products from third countries and, where appropriate, produce guidance on the respective roles and responsibilities of operators involved in the e-commerce supply chain to strengthen enforcement of the rules for products sold online.

(11b) At trade fairs, exhibitions, demonstrations and such like, it should be possible to exhibit products which do not satisfy the requirements of applicable Union harmonisation legislation if it provides for such exception. However, interested parties should be properly informed that the product concerned does not conform and cannot be purchased in that condition. Furthermore, during demonstrations of such products, adequate safety measures shall be taken to ensure the protection of health and safety of persons.

⁷ 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, **and** impose an obligation on Member States to organise and carry out market surveillance. **This Regulation should** require Member States to appoint market surveillance authorities ~~and~~ **in line with the organisational structure of administration of Member States**, to specify their **market surveillance authorities'** powers and duties, and make Member States responsible for setting up general and sector-specific market surveillance programmes. **Market surveillance authority should mean be any authority deemed competent by the relevant Member State for the purposes of this Regulation and may include any competent authority which verifies compliance with Union harmonisation legislation or the general safety requirement for the purposes of Regulation (EU) No [.../...] [on consumer product safety].**⁸

(12a) Member States should regularly provide information on the outcome of controls carried out by their market surveillance authorities and authorities in charge of the control of products at the external borders. The availability of factual data should contribute to the assessment of the functioning and effectiveness of market surveillance activities and controls of products entering the Union and to the coordination of enforcement actions across the Union. The data should also be taken into account by the Commission for the preparation of the evaluation report on the application of this Regulation⁹.

⁸ OJ L ...

⁹ For further information, Delegations can refer to Annex 10 of the Impact Assessment accompanying the Product Safety and market Surveillance Package, SWD(2013)33 and to the manual for data collection and related spread sheet to be used by MS as common template for data gathering developed by the project group under Customs 2013 and adopted by the MS in the Expert Working Group in 2012.

(13) Some Union harmonisation legislation contains provisions on market surveillance and safeguard clauses. These may be based on the reference provisions on market surveillance and safeguard clauses contained in Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products¹⁰. This Regulation should contain all of the market surveillance provisions applicable to the products falling within its scope. This Regulation should therefore include the reference provisions on market surveillance and safeguard clauses contained in Decision No 768/2008/EC. Provisions in existing Union harmonisation legislation that relate to market surveillance and safeguard clauses, whether drafted before the adoption of Decision No 768/2008/EC or based on its reference provisions, should be removed from that harmonisation legislation unless there are specific sectoral reasons for retaining them. Exemptions from the safeguard provisions should be made in relation to ~~products subject to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), certain fittings subject to Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009, certain pressure equipment subject to Directive 97/23/EC of the European Parliament and of the Council of 29 May 1997 and certain pressure vessels subject to Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009. **Any provisional measures against products complying with the requirements of 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) or Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures or authorised pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products should be taken in accordance with the safeguard procedures laid down in those Regulations. To avoid interference with those procedures, the provisions on Union assessment should not apply to such products.**~~

¹⁰ OJ L 218, 13.8.2008, p.82.

(14) In order to make the entire market surveillance process transparent and easy to follow for both market surveillance authorities and economic operators, the Regulation should clearly set out the chronological steps of that process, from the moment when market surveillance authorities identify a product which they believe may **be non-compliant and/or may** present a risk, to the **further evaluation of the product concerned, including, where necessary,** assessment of the risk presented, the corrective action to be taken by the relevant economic operator within a specified period and the **effective and proportionate** measures to be taken by market surveillance authorities themselves if economic operators ~~do not comply~~ **have not taken necessary corrective actions** or in cases of urgency. **For this purpose a clear distinction should be made between non-compliant products, that do not present a risk (such as formal non-compliance as referred to in Union harmonisation legislation), products, that are non-compliant and present a risk, and products, that are in compliance with applicable requirements, but nevertheless present a risk, in order for market surveillance authorities to choose the right approach and proportionate corrective actions or measures.**

(14a) In order to ensure effective market surveillance, market surveillance authorities should be able to request economic operators to provide documentation necessary to demonstrate compliance of a product where there are doubts in respect of such compliance. Requests of the market surveillance authorities of the Member States to economic operators in connection to the fulfilment of their obligations under this Regulation should be reasoned, as appropriate, in accordance with national rules of the Member States of these market surveillance authorities.

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

- (16) Products subject to Union harmonisation legislation that does not lay down essential requirements but which is designed to ensure the protection of certain public interests should be presumed not to present a risk to those public interests provided that they comply with that legislation.
- (17) Similarly, a product that is not subject to Union harmonisation legislation but which complies with national rules on the health and safety of persons or with European standards referenced in the *Official Journal of the European Union* should be presumed not to present a risk to health and safety.
- (18) For the purposes of this Regulation **evaluation, including, where necessary**, risk assessment should be carried out to identify products which have the potential to affect adversely the public interests protected by Regulation (EU) No xxxx on consumer product safety, **by** sector-specific Union harmonisation legislation ~~and~~ **or by** other Union legislation on products that are subject to this Regulation. It should include, where available, data on risks that have materialised previously with respect to the product in question. Account should also be taken of any measures that may have been taken by the economic operators concerned to alleviate the risks. The particular potential vulnerability of consumers, as opposed to professional users, should be taken into account as should the increased vulnerability of certain categories of consumer such as children, the elderly or the disabled.
- (18a) Based on the risk assessment guidelines laid down in Commission Decision 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX'¹¹, the Commission should further develop a methodology for the assessment of risks for products covered by this Regulation.**

¹¹ OJ L 22, 26.1.2010, p. 1.

- (19) Both new and second hand products originating outside the Union may be placed on the market only after they have been released for free circulation. Effective controls are required at the external borders of the Union to suspend the release of products that may **be non-compliant and/or 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~~ **in charge of** the control of products ~~entering at the external borders~~ of the Union ~~market~~ to carry out checks on an adequate scale therefore contributes to a safer Union market for products. **It is for Member States to designate the specific authorities that should be responsible for the appropriate documentary and, where necessary, physical or laboratory checks of products before those products are released for free circulation.** In order to increase the effectiveness of such checks, **good and close administrative** cooperation, ~~and~~ exchange of information **and effective communication** between those authorities and market surveillance authorities concerning **non-compliant products and/or products** presenting a risk **is necessary** ~~should be enhanced~~. **In general, cooperation between Customs (or other authorities in charge of the control of products at the external borders) and market surveillance authorities should be based on agreements that cover all necessary aspects with the objective of carrying out the checks in an appropriate manner and taking into consideration the Guidelines on import controls issued by the Commission.**
- (21) Market surveillance authorities should be given the power to destroy products, render **them** inoperable or order their destruction by the relevant economic operator, if they deem it necessary and proportionate to ensure that such goods cannot pose any further threats.
- (22) The release for free circulation of products that are imported in the physical possession of persons entering the Union for their personal, ~~non-commercial~~ use should not be suspended or refused under this Regulation by the authorities responsible for the control of products entering the Union market. **If those authorities have reason to believe that the product is imported for commercial purposes, then it may be suspended or refused under this Regulation.**

- (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 **exchange** system (RAPEX) has proved its effectiveness and efficiency. RAPEX enables measures to be taken across the Union in relation to products that present a **serious** risk beyond the territory of a single Member State. To avoid unnecessary duplication, this system should be used for all alert notifications required by this Regulation relating to products presenting a **serious** risk.
- (24) Coherent and cost-effective market surveillance activity throughout the Union also requires well-structured, comprehensive archiving and sharing among Member States of all pertinent information on national activities in this context, including a reference to notifications required by this Regulation, **in order** to form a complete database of market surveillance information. The Commission has established a database called 'Information and Communication System for Market Surveillance' (ICSMS) which is suited for this purpose and should therefore be used.
- (24a) In order to avoid unnecessary duplication of work for Member States' authorities when notifying or entering relevant information, the Commission together with Member States should explore the possibility to develop an interface solution to ensure data transfer from national market surveillance systems into ICSMS. For the same purpose, as mentioned in the Commission's multi-annual action plan for the surveillance of products in the EU¹², an interface should be developed to permit data transfer from ICSMS into the RAPEX operating system and, ~~when~~ where appropriate, vice versa.**
- (25) Given the size of the Union market for goods and as there are no internal borders, it is imperative that the market surveillance authorities of the Member States ~~are~~ **be** willing and able to cooperate with each other effectively and to coordinate joint support and action. Accordingly, mechanisms for mutual assistance should be established.

¹² COM(2013)76.

- (26) In order to facilitate market surveillance of products entering the Union market from third countries, this Regulation should provide a basis for cooperation between market surveillance authorities of Member States and the authorities of those countries.
- (27) A European Market Surveillance Forum (**EMSF**) composed of representatives from market surveillance authorities should be established. The Forum should provide a means of involving all stakeholders concerned, including professional organisations and consumer organisations, in order to take advantage of available information relevant for market surveillance when establishing, implementing and updating market surveillance programmes.
- (28) The Commission should provide support for cooperation between market surveillance authorities and participate in the Forum. ~~The~~is Regulation should set out a list of tasks to be performed by the Forum. An executive secretariat should organise the Forum's meetings and provide other operational support for the accomplishment of its tasks.
- ~~(29) Where appropriate, reference laboratories should be established with a view to providing expert, impartial technical advice and conducting tests on products required in relation to market surveillance activities.~~

- (30) This Regulation should strike a balance between transparency through the release of the maximum possible amount of information to the public and maintaining confidentiality, for example for reasons of personal data protection, commercial secrecy or the protection of investigations, in accordance with rules on confidentiality pursuant to applicable national law or, as regards the Commission, Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents¹³. 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 data¹⁴ 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 data¹⁵ **should** apply in the context of this Regulation.
- (31) Information exchanged between competent authorities should be subject to the strictest guarantees of confidentiality and professional secrecy and be handled in a way that investigations are not compromised and that the reputations of economic operators are not prejudiced.
- (32) Member States should provide means of redress in the competent courts and tribunals in respect of restrictive measures taken by their authorities.
- (33) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties ~~must~~ **should** be effective, proportionate and dissuasive.

¹³ OJ L 145, 31.5.2001, p. 43.

¹⁴ OJ L 281, 23.11.1995, p. 31.

¹⁵ OJ L 8, 12.1.2001, p. 1.

- (34) **The activities of market surveillance authorities in relation to products that were found non-compliant and/or presenting a risk** ~~should~~ **could** be financed at least in part by fees charged to **relevant** economic operators ~~where they are required by market surveillance authorities to take corrective action or where those authorities are obliged to take action themselves.~~
- (35) In order to achieve the objectives of this Regulation, the Union should contribute to the financing of activities required to implement policies in the field of market surveillance such as the drawing-up and updating of guidelines, preliminary or ancillary activities in connection with the implementation of Union legislation and programmes of technical assistance and cooperation with third countries as well as the enhancement of policies at Union and international level.
- (36) Union financing should be made available in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union¹⁶, depending on the nature of the activity to be financed, in particular for support to the executive secretariat of the EMSF.
- (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.~~

¹⁶ 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 as regards the modalities and procedures for the exchange of information through RAPEX and as regards the adoption of temporary or permanent marketing restrictions on products presenting a serious risk, where appropriate, specifying the necessary control measures to be taken by the Member States for their effective implementation~~ where other Union legislation does not provide a specific procedure to address the risks in question. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of its implementing powers¹⁷.
- (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.

¹⁷ OJ L 55, 28.2.2011, p. 11.

(40) The market surveillance provisions of **Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers**¹⁸, Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment¹⁹, 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 uses²⁰, 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 atmospheres²¹, 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 craft²², European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts²³, 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 equipment²⁴, 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 conformity²⁵, Directive 2000/9/EC of the European Parliament and of the Council of 20 March 2000 relating to cableway installations designed to carry persons²⁶, 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 outdoors²⁷, Directive 2001/95/EC, Directive 2004/108/EC of the European Parliament and of the Council of 15 December 2004 on the approximation of the laws of the Member States relating to electromagnetic compatibility²⁸,

¹⁸ *OJ L 147, 9.6.1975, p. 40*

¹⁹ OJ L 399, 30.12.1989, p. 18.

²⁰ OJ L 121, 15.5.1993, p. 20.

²¹ OJ L 100, 19.4.1994, p. 1.

²² OJ L 164, 30.6.1994, p. 15.

²³ OJ L 213, 7.9.1995, p. 1.

²⁴ OJ L 181, 9.7.1997, p. 1.

²⁵ OJ L 91, 7.4.1999, p. 10.

²⁶ OJ L 106, 3.5.2000, p. 21.

²⁷ OJ L 162, 3.7.2000, p. 1.

²⁸ OJ L 390, 31.12.2004, p. 24.

Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery²⁹, 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 limits³⁰, Directive 2007/23/EC of the European Parliament and of the Council of 23 May 2007 on the placing on the market of pyrotechnic articles³¹, 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 Community³², Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys³³, Directive 2009/105/EC of the European Parliament and of the Council of 16 September 2009 relating to simple pressure vessels³⁴, Directive 2009/142/EC of the European Parliament and of the Council of 30 November 2009 relating to appliances burning gaseous fuels³⁵, 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 equipment³⁶, 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 products³⁷, and Regulation (EC) No 765/2008 overlap with the provisions of this Regulation. Therefore, these provisions should be deleted. Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC should be amended accordingly³⁸.

²⁹ OJ L 157, 9.6.2006, p. 24.

³⁰ OJ L 374, 27.12.2006, p. 10.

³¹ OJ L 154, 14.6.2007, p. 1.

³² OJ L 191, 18.7.2008, p. 1.

³³ OJ L 170, 30.6.2009, p. 1.

³⁴ OJ L 264, 8.10.2009, p. 12.

³⁵ OJ L 330, 16.12.2009, p. 10.

³⁶ OJ L 174, 1.7.2011, p. 88.

³⁷ OJ L 88, 4.4.2011, p. 5.

³⁸ OJ L 218, 13.8.2008, p. 21.

- (41) Since the objective of this Regulation, namely to ensure that products on the market covered by Union legislation fulfil the requirements providing a high level of protection of health and safety and other public interests while guaranteeing the functioning of the internal market by providing a framework for coherent market surveillance in the Union, cannot be sufficiently achieved by the Member States as the attainment of this objective requires a very high degree of cooperation, interaction and uniformity of operation among all of the competent authorities of all Member States, and can therefore, by reason of its scale and effects, be better achieved at Union level, 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. **The aim of this Regulation is** ~~in particular this Regulation seeks~~ to ensure full respect for obligation to ensure a high level of human health protection and consumer protection as well as full respect of the freedom to conduct a business and the right to property,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

General provisions

Article 1

Subject matter

1. This Regulation lays down a framework for **the market surveillance of products to** verifying that products **comply with Union harmonisation legislation or Regulation (EU) No ... [CPSR] and therefore** meet requirements which safeguard, at a high level, the health and safety of persons in general, health and safety in the workplace, **protection of** consumers ~~protection~~, the environment, public security and other public interests **protected by that legislation.**
- 2. The objective of this Regulation is to improve the functioning of the internal market.**

Article 2

Scope

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

2. Chapters I and IV and Article 23 shall apply to all products covered by Union legislation to the extent that other Union legislation does not contain specific provisions relating to the organisation of ~~external border~~ controls **of products at the external border** or to cooperation between authorities in charge of **controls of products at the 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 **as defined by Directive 2001/83/EC or Directive 2001/82/EC;**
 - (b) medical devices and in vitro diagnostic medical devices **as regards the aspects covered by Directives 90/385/EEC, 93/42/EEC and 98/79/EC;**
 - (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.

~~**4a. Articles 10, 11 and 18 of this Regulation shall not apply to products satisfying the requirements of Regulation (EC) No 1907/2006, to which Article 129 of that Regulation applies.**~~

5. Articles 11 and 18 of this Regulation shall not apply to the following products:
 - (a) products subject to **satisfying the requirements of Regulation (EC) No 1907/2006, to which Article 129 of that Regulation applies, or of Regulation (EC) No 1272/2008, to which Article 52 of that Regulation applies;**
 - (aa) **biocidal products covered by an authorisation granted in accordance with Regulation (EU) No 528/2012, to which Article 88 of that Regulation applies;**

- ~~(b) fittings as defined in Article 1(2)(b) of Directive 2009/142/EC;~~
 - (c) pressure equipment subject to the provisions of Article 3(3) of Directive 97/23/EC;
 - (d) simple pressure vessels subject to the provisions of Article 3(2) of Directive 2009/105/EC.
6. This Regulation shall not apply in the areas governed by ~~Union legislation on official controls and other official activities carried out for the verification of compliance with the following rules:~~ **Regulation (EC) No 882/2004 and in those areas governed by other Union legislation on official controls and other official activities performed to ensure the application of rules on plant health and plant reproductive material.**
- ~~(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; *wording to be proposed by the COM*~~
 - ~~(b) rules governing the manufacture and use of materials and articles intended to come into contact with food;~~
 - ~~(c) rules governing the deliberate release into the environment of genetically modified organisms;~~
 - ~~(d) rules governing feed and feed safety, at all stages of production, processing and distribution of feed and the use of feed, including rules aimed at guaranteeing fair practices in trade and protecting consumer interests and information;~~
 - ~~(e) rules laying down animal health requirements;~~
 - ~~(f) rules aiming at preventing and minimising risks to human and animal health arising from animal by products and derived products;~~

- ~~(g) — rules laying down welfare requirements for animals;~~
- ~~(h) — rules on protective measures against pests of plants;~~
- ~~(i) — rules on the production, with a view to placing on the market, and placing on the market of plant reproductive material;~~
- ~~(j) — rules laying down the requirements for placing on the market and the use of plant protection products and the sustainable use of pesticides;~~
- ~~(k) — rules governing organic production and labelling of organic products;~~
- ~~(l) — rules on the use and labelling of protected designations of origin, protected geographical indications and traditional specialities guaranteed.~~

Article 3

Definitions

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

- (1) ‘product’ means ~~a product obtained~~ **a substance, mixture or good produced** through a manufacturing process;
- (2) ‘making available on the market’ means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (3) ‘placing on the market’ means the first making available of a product on the Union market;

- (4) ‘manufacturer’ means any natural or legal person who manufactures a product or has a product designed or manufactured and markets that product under his name or trademark;
- (5) ‘authorised representative’ means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks **with regard to the latter's obligations under the relevant Union legislation;**
- (6) ‘importer’ means any natural or legal person established within the Union who places a product from a third country on the Union market;
- (7) ‘distributor’ means any natural or legal person in the supply chain, other than a manufacturer or importer, who makes a product available on the market;
- (8) ‘economic operators’ means the manufacturer, the authorised representative, the importer, ~~and~~ the distributor, **and any other person subject to obligations in relation to the making products available of products on the market or putting them into service in accordance with the relevant Union harmonisation legislation;**
- (9) ‘conformity assessment’ means conformity assessment as defined in Regulation (EC) No 765/2008;
- (10) ‘conformity assessment body’ means conformity assessment body as defined in Regulation (EC) No 765/2008;
- (11) ‘market surveillance’ means the activities carried out and measures taken by public authorities to ensure that products ~~do not endanger~~ **comply with the requirements set out in Union harmonisation legislation or Regulation (EU) No ... [CPSR] and thus therefore meet the requirements which safeguard the health, and safety of persons in general, health and safety in the workplace, protection of consumers, the environment, public security and other public interests protected by that legislation** ~~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;
- (12a) ‘non-compliant product’ means a product which fails to meet the requirements of applicable Union harmonisation legislation or Regulation (EU) No ... [CPSR];**
- (12b) ‘risk’ means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm;**
- (13) ‘product presenting a risk’ means a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, **protection of consumers** ~~protection~~, the environment, ~~and public security as well as~~ **and** other public interests, **protected by the applicable Union harmonisation legislation or Regulation (EU) No ... [CPSR]**, to a degree which goes beyond that considered reasonable and acceptable **in relation to its intended purpose or** under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;
- (14) ‘product presenting a serious risk’ means a product presenting a risk **for which the combination of the probability of occurrence of a hazard causing harm and the degree of severity of the harm is considered serious based on a risk assessment and thus** requiring rapid intervention and follow-up, including cases where the effects may not be immediate;
- (15) ‘recall’ means any measure aimed at achieving the return of a product that has already been made available to the end user;
- (16) ‘withdrawal’ means any measure aimed at preventing a product in the supply chain from being made available on the market;
- (17) ‘release for free circulation’ means the procedure laid down in Article 79 of Council Regulation (EEC) No 2913/92³⁹;

³⁹ OJ L 302, 19.10.1992, p. 1

- (18) ‘Union harmonisation legislation’ means Union legislation harmonising the conditions for the marketing of products;
- (19) ‘European standard’ means a European standard as defined in Article 2(1)(b) of Regulation (EU) No 1025/2012 of the European Parliament and the Council⁴⁰;
- (20) ‘harmonised standard’ means a harmonised standard as defined in Article 2(1)(c) of Regulation (EU) No 1025/2012-;
- (20a) ‘technical specification’ means technical specification as defined in Article 2(4) of Regulation (EC) No 1025/2012.**

CHAPTER II

Union market surveillance framework

Article 4

Market surveillance obligation

1. Member States shall **organise and** 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~~ **achieving the objective** that **non-compliant products and/or** products presenting a risk 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~~ **bring the product into non-compliance** and/or ~~remove~~ **ensure that the product no longer presents** the risk ~~presented by the product.~~

⁴⁰ OJ L 316, 14.11.2012, p. 12.

3. The implementation of market surveillance activities and ~~external border~~ controls **of products entering the Union** shall be monitored by the Member States which shall report **to the Commission** on these activities, ~~and controls to the Commission~~ **and the results of those controls at least every two years**. The **Commission shall communicate this** information reported ~~shall include statistics regarding the number of controls carried out and shall be communicated~~ to all Member States. ~~Member States~~ **and** may make a summary of the results accessible to the public.
4. ~~The results of the monitoring and assessment of market surveillance activities carried out pursuant to paragraph 3 shall be made available to the public, electronically and, where appropriate, by other means.~~

Article 5

Market surveillance authorities

1. Each Member State shall establish or designate market surveillance authorities and define their duties, powers and organisation.
2. **Each Member State shall give m**Market surveillance authorities ~~shall be given~~ the powers and entrusted **them** with the resources and means necessary for the proper performance of their tasks.
3. Each Member State shall establish appropriate mechanisms to ensure that the market surveillance authorities that it has established or designated exchange information, cooperate and coordinate their activities both among themselves and with the authorities in charge of controls of products at the external borders of the Union.
4. Each Member State shall inform the Commission about its market surveillance authorities and their areas of competence, providing the necessary contact details, and the Commission shall ~~transmit this information to the other Member States and~~ publish a **consolidated** list of market surveillance authorities.

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

Article 6

General obligations of market surveillance authorities

1. Market surveillance authorities shall perform appropriate checks on ~~the characteristics of~~ products on an adequate scale and with adequate frequency, by means of ~~a documentary, check and, where necessary, a physical and or laboratory checks,~~ **as appropriate**, on the basis of ~~an~~ adequate samples. **When doing so, they shall take account of established principles of risk assessment, complaints and other information.** ~~They shall record these checks in the information and communication system for market surveillance referred to in Article 21.~~

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

2. Where appropriate, market surveillance authorities shall **without delay** alert users in their territories ~~within an adequate timeframe~~ of products that those authorities have identified as presenting a risk.

Information available to market surveillance authorities or the Commission relating to products presenting a risk shall in general be available to the public, in accordance with the requirements of transparency and without prejudice to the restrictions required for monitoring and investigation activities. In particular the public shall have access to information on product identification, the nature of the risk and the measures taken to prevent it or ~~remove~~ **ensure** that **the product concerned no longer presents a risk to the fullest extent necessary to protect the interests of users of products in the Union.** This information shall not be published where it is imperative to observe confidentiality in order to protect commercial secrets, preserve personal data or avoid undermining monitoring and investigation activities pursuant to national and Union legislation.

[Partly moved from Article 10(6)]

- 2a. ~~They~~ **Market surveillance authorities** shall cooperate with economic operators to prevent ~~or reduce~~ ~~remove~~ risks caused by products made available by those operators **or ensure that those products no longer present a risk.** For this purpose, they shall ~~encourage and~~ promote voluntary action by economic operators ~~including, where applicable, through the development of and adherence to codes of good practice.~~
3. Market surveillance authorities shall carry out their duties independently, impartially and without bias ~~and shall fulfil their obligations under this Regulation;~~ they shall exercise their powers in relation to economic operators in accordance with the principle of proportionality.
4. Where it is necessary and justified for carrying out their duties, **market surveillance authorities may** enter the premises of economic operators and take any necessary **documentation and** samples of products. **These powers shall be exercised in accordance with national law.**

5. Market surveillance authorities shall:
- (a) ~~provide~~ **allow** consumers and other interested parties ~~with the opportunity~~ to submit complaints on issues relating to **compliance of products safety**, market surveillance activities and risks arising in connection with products and follow up those complaints as appropriate. **For this purpose, they shall establish procedures and make these known to the public;**
 - (b) verify that corrective action has been taken;
 - (c) ~~follow and~~ keep up to date with developments in scientific and technical knowledge concerning ~~the safety of products~~ **in the area of their competence, covered by this Regulation.**
- ~~6. Adequate procedures shall be established and made known to the public to enable market surveillance authorities to fulfil these obligations.~~
7. Without prejudice to national legislation in the area of confidentiality, the safeguarding of confidentiality with regard to information received and collated by market surveillance authorities shall be ensured. ~~Information exchanged between national market surveillance authorities and between them and the Commission on condition of confidentiality shall remain confidential unless the originating authority has agreed to its disclosure.~~
8. The protection of confidentiality shall not prevent the dissemination to market surveillance authorities of information necessary to ensure effective market surveillance.

Article 7

Market surveillance programmes

1. Each Member State shall draw up a general market surveillance programme and shall review that programme, and update it if necessary, at least every four years. The programme shall cover market surveillance organisation and related activities ~~and take into account the specific needs of business generally, and SMEs in particular, when implementing Union harmonisation legislation and Regulation (EU) No [.../...] [on consumer product safety], and provide for guidance and assistance.~~ It shall include the following:
 - (a) the **organisation of market surveillance authorities designated under Article 5(1) and their** sectoral and geographical competence ~~of the authorities designated under Article 5(1);~~
 - ~~(b) the financial resources, staff, technical and other means attributed to the authorities;~~
 - (c) an indication of the priority areas of work of the different authorities;
 - (d) the mechanisms of ~~coordination~~ **cooperation** among the different **market surveillance** authorities and with ~~customs~~ **authorities in charge of the controls of products at the external border;**
 - (e) the participation of the authorities in the exchange of information under Chapter V;
 - ~~(f) the participation of the authorities in sectoral or project-oriented cooperation at Union level;~~
 - (g) the means to fulfil the requirements of Article 6(5).

2. Each Member State shall draw up sector-specific programmes ~~and shall review these programmes,~~ **describing the activities planned for at least the following year** and update them **regularly** ~~if necessary, every year~~. These programmes shall cover all sectors in which authorities conduct market surveillance activities **under this Regulation**.
3. The general and sector-specific programmes and their updates shall be communicated to ~~the other Member States and the Commission~~ **through the information and communication system for market surveillance referred to in Article 21**, ~~and, subject to Article 6(6), shall be made~~ **The Commission and the Member States shall make the general programmes** accessible to the public ~~electronically and, where appropriate, by other means~~.

Article 8

General obligations of economic operators and conformity assessment bodies

1. On **reasoned** request, economic operators and, where applicable, conformity assessment bodies, shall, **according to their respective role and responsibility**, ~~make available~~ **provide** to market surveillance authorities any documentation and information, **including information that enables the precise identification and tracing of the product**, that those authorities require for the purpose of carrying out their activities, in a language which can be easily understood by them **and as determined by the Member State of the market surveillance authority concerned**.

2. Economic operators shall ~~provide all necessary information to cooperate with~~ market surveillance authorities **on actions taken to prevent or remove bring the products into non-compliance and/or ensure that risks of products that have been placed or made available by those operators no longer present a risk** including information that enables the precise identification of the product and facilitates the tracing of the product. **For this purpose ~~and without prejudice to Article 13 of Regulation (EU) No ... [CPSR]~~, economic operators, who consider or have reason to believe that a product which they have placed or made available on the market presents a risk, shall, ~~immediately~~ inform market surveillance authorities to that effect, giving details, in particular, of products presenting a the risk, presented by the product, and of any corrective actions taken, in accordance with the applicable Union harmonisation legislation or Regulation (EU) No ... [CPSR].**

CHAPTER III

Control of products within the Union

Article 9

General provisions for evaluation of products

Products presenting a risk

1. Where, in the course of carrying out the checks referred to in Article 6(1) or as a result of information received, market surveillance authorities have sufficient reason to believe that a product that is placed or made available on the market ~~or is used in the course of the provision of a service~~ **may be non-compliant and/or** may present a risk, they shall **carry out an evaluation in relation to the product concerned covering the relevant requirements laid down in the applicable Union harmonisation legislation or Regulation (EU) No ... [CPSR] and, where necessary, carry out a risk assessment in relation to that product taking account of the considerations and criteria set out in Article 13.**

For this purpose, market surveillance authorities may temporarily prevent the product that is may be non-compliant and/or may present a risk from being placed or made available on the market pending evaluation, including, where necessary, the risk assessment. *[Moved from Article 9(4)(c)]*

~~Market surveillance authorities shall take due consideration of any readily available test result and risk assessment that has already been carried out or issued in relation to the product by an economic operator or any other person or authority including the authorities of other Member States.~~ *[Moved to Article 9(2b)]*

2. ~~In relation to a product that is subject to Union harmonisation legislation, formal non-compliance with that legislation shall give market surveillance authorities sufficient reason to believe that the product may present a risk in any of the following cases:~~
- ~~(a) the CE marking or other markings required by Union harmonisation legislation have not been affixed or have been affixed incorrectly;~~
 - ~~(b) the EU declaration of conformity, where required, has not been drawn up or has been drawn up incorrectly;~~
 - ~~(c) the technical documentation is incomplete or unavailable;~~
 - ~~(d) the required labelling or instructions for use are incomplete or missing.~~

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

In the context of the evaluation of the product, including, where necessary, risk assessment, market surveillance authorities shall take into account the extent to which the product complies with the following: *[Moved from Article 13(2)]*

- (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; *[Moved from Article 13(2)(a)]*
- (aa) ~~in the absence of requirements laid down in point (a)~~, any relevant European standards or other technical specifications the references of which have been published in the *Official Journal of the European Union*; *[Moved from Article 13(2)(c)]*
- (b) in the absence of requirements laid down in point (a), 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; *[Moved from Article 13(2)(b)]*

2aa. In the absence of requirements laid down in points (a), (aa) or (b) of paragraph 2, market surveillance authorities shall take into account aspects for assessing the compliance with the general safety requirement as set out in Article 6 of Regulation (EU) No ... [CPSR].

2a. Compliance with the requirements referred to in points (a), (aa) or (b) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those requirements relate. However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is evidence that, despite such compliance, the product presents a risk. *[Moved from Article 13(3)]*

2b. Evaluation, including, where necessary, risk assessment of the product concerned shall be based on available evidence and technical data. *[Moved from Article 13(1)]*

Market surveillance authorities shall take into consideration ~~of~~ any readily available relevant 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. Such tests or risk assessment results shall not prevent market surveillance authorities from performing any additional checks or risk assessment. *[Moved from Article 9(1)]*

- 2c. **The feasibility of obtaining higher levels of protection of the public interest concerned or the availability of other products providing higher level of protection shall not be a reason, in itself, to consider that a product presents a risk.** [*Moved from Article 13(4)*]

Article 9a

Corrective actions taken by economic operators

- 1.3.—Without prejudice to Article 10(4), where market surveillance authorities find that a product ~~does~~ **is non-compliant and/or** presents a risk, they shall without delay ~~specify the request~~ **the relevant economic operator to take** necessary corrective action to address ~~to be taken,~~ **as applicable, the non-compliance and/or the risk** within a ~~specified period~~ **they specify.**
- 1a. **For the purpose of paragraph 1,** market surveillance authorities may recommend or agree with the relevant economic operator ~~on appropriate and proportionate~~ **on appropriate and proportionate** the corrective action to be taken, **which may include inter alia:-**
- (a) **bringing the product into compliance and/or ensuring that the product no longer presents a risk;**
- ~~(aa) in case when action referred to in point (a) is impossible, or when a product~~
presents a serious risk;
- ~~(i)~~**(b) preventing the product from being placed on the market;**

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

(iii)(d) destroying the product or otherwise rendering it inoperable;

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

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

(ii)(f) setting prior conditions for making the product concerned available on the market;

(iii)(g) alerting the persons at risk immediately and in an appropriate form, including by publication of special warnings in the language or languages determined by the Member State in which the product is made available on the market.² *[Moved from Article 9b(2)]*

Corrective actions referred to in points (e), (f) and (g) may only be taken in cases where a product 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.

1aa. Economic operators shall ensure that all necessary corrective action is taken in respect of all the products concerned made available on the Union market. They shall inform the market surveillance authorities about the corrective action undertaken and the results thereof. *[Moved from Article 9b(1)]*

~~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.~~
[Moved to Article 9b(1)]

~~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.~~

1ab. For the purpose of paragraph 1 and where the relevant economic operator is a distributor, ~~Where possible,~~ market surveillance authorities shall, **where possible,** also identify the manufacturer, **authorised representative,** or importer of the product and, **where appropriate,** take action in relation to ~~that~~ **those** economic operators in addition to the distributor.

2. The costs related to corrective actions referred to in paragraph 1 taken by an economic operator shall be borne by that economic operator.

Member States may authorise their market surveillance authorities to charge fees on relevant economic operators which wholly or partly cover the costs of their activities in relation to products that were found non-compliant and/or presenting a risk, such as testing carried out for the evaluation of products, including, where necessary, the risk assessment, and corrective measures taken in accordance with paragraphs 2 or 4 of Article 10. *[Partly moved from Article 9b(3) and Article 10(8)]*

~~Article 9b~~

~~Corrective actions taken by economic operators~~

- ~~1. The economic operator shall ensure that all necessary corrective action **to remove any non-compliance and/or risk** is taken in respect of all the products concerned that it has made available on the market throughout the Union. **They shall inform the market surveillance authorities about the corrective action undertaken and the results thereof.** *[Moved from Article 9(3)]*~~
- ~~42. Corrective action to be taken by economic operators in relation to **a non-compliant product and/or** a product presenting a risk may include *inter alia*:~~
- ~~(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 bringing the product into compliance with those requirements **and/or ensuring that the product no longer presents a risk;**~~
 - ~~(aa) in case when action referred to in point (a) is impossible, or when a product presents a serious risk: *[Moved from Article 9(4)(d)]*~~
 - ~~(i) preventing the product from being placed on the market; *[Moved from Article 9(4)(c)(i)]*~~
 - ~~(ii) withdrawing or recalling immediately the product and alerting the public to the risk presented; *[Moved from Article 9(4)(c)(ii)]*~~
 - ~~(iii) destroying the product or otherwise rendering it inoperable; *[Moved from Article 9(4)(c)(iii)]*~~

- (b) ~~in the case of a product that is liable to present a risk only in certain conditions or only to certain persons and where such risk is not addressed by requirements of Union harmonisation legislation:~~
- (i) ~~affixing to the product suitable, clearly worded, easily comprehensible warnings of the risks it may present, in the official language or languages of **determined by the Member State** in which the product is made available on the market;~~
 - (ii) ~~**set prior conditions for making the product concerned available on the market** make 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 **in the language or languages determined by the Member State in which the product is made available on the market**;~~
- (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: *[Moved to Article 9b(2)(aa)]*~~
- (i) ~~preventing the product from being placed or made available on the market;~~
[Moved to Article 9b(2)(aa)(i)]
 - (ii) ~~withdrawing or recalling the product and alerting the public to the risk presented;~~
[Moved to Article 9b(2)(aa)(ii)]
 - (iii) ~~destroying the product or otherwise rendering it inoperable. *[Moved to Article 9b(2)(aa)(iii)]*~~

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

Article 10

Measures taken by market surveillance authorities

- ~~1. Where the identity of the relevant economic operator cannot be ascertained by the market surveillance authorities or where an economic operator has not taken the necessary corrective action pursuant to Article 9(3) within the period specified, market surveillance authorities shall take all necessary measures to deal with the risk presented by the product. [Partly moved to Article 10 (2a)]~~
2. ~~For the purpose of paragraph 1,~~ **If an economic operator has not taken the necessary corrective action pursuant to Article 9a(1) within the specified period,** market surveillance authorities ~~may~~ **shall** oblige ~~the relevant economic operators~~ **him** to take, inter alia, ~~any of the corrective action referred to in Article 9(4) 9b(2) 9a(1a),~~ **as specified by market surveillance authorities,** or take such measures themselves, as appropriate.

The measures shall be addressed, as appropriate, to:

- (a) **the manufacturer established within the Union, the authorised representative or the importer;**
- (b) **within the limits of their respective activities, distributors who made the products available on the market of the Member State concerned;-**
- (c) **within the limits of their respective activities, any other economic operator subject to obligations in relation to the making products available of products on the market or putting them into service under the applicable Union harmonisation legislation**

Where necessary and appropriate, market surveillance authorities may address measures also ask to any other person with a view to obtain their cooperation in the corrective action.

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

~~The first subparagraph shall not prevent Member States from enabling market surveillance authorities to from obliging the economic operators to take other, supplementary measures, or to taking such measures themselves.~~

- 2a. Where the identity of the relevant economic operator cannot be ascertained, market surveillance authorities shall take all necessary measures pursuant to Article 9a(1a) in relation to a non-compliant product and/or a product presenting a risk. [Partly moved from Article 10(1)]**
3. ~~Prior to taking any measure taken pursuant to under paragraph 1 2 in relation to an economic operator who has failed to take the necessary corrective action, market surveillance authorities shall allow him~~ **economic operators shall be allowed** at least 10 days, within which to be heard. **For this purpose the period specified by market surveillance authority's request to take necessary corrective action pursuant to Article 9a(1) may be taken into consideration.**
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~~ **requesting** the economic operator to take corrective action pursuant to Article ~~9(3)~~ **9a(1)** 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 2 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) **be proportionate and** state the exact grounds on which it is based;
 - (c) **where applicable**, be lifted without delay where the economic operator has demonstrated that he has taken the required action.

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

~~6. Market surveillance authorities shall publish information about product identification, the nature of a risk and the measures taken to prevent, reduce or eliminate that risk on a dedicated website to the fullest extent necessary to protect the interests of users of products in the Union. This information shall not be published where it is imperative to observe confidentiality in order to protect commercial secrets, preserve personal data pursuant to national and Union legislation or avoid undermining monitoring and investigation activities.~~
[Partly moved to Article 6(3)]

7. Any measure taken in accordance with paragraphs 1 2 or 4 shall be subject to legal remedies, ~~including~~ **such as** recourse to the competent national courts.

~~8. Market surveillance authorities may charge fees on economic operators which wholly or partly cover the costs of their activities, including testing carried out for the risk assessment, where they take measures in accordance with paragraphs 1 or 4.~~ *[Partly moved to Article 9a(2)]*

Article 11

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

0. Where the market surveillance authorities consider that **non-compliance and/or** the risk, presented by a product subject to Union harmonisation legislation, is not restricted to their national territory, they shall inform the Commission, **which shall inform the other and the** Member States of the results of the evaluation and of the measures taken pursuant to paragraphs 2, 2a or 4 of Article 10.

A separate notification shall not be necessary if a measure referred to in the first subparagraph is a type of measure which is required to be notified through the Union Rapid Information Exchange System (RAPEX) pursuant to Article 20.

1. Within ~~60~~ 45 days of communication of the information referred to in paragraph 0 by the Commission to the Member States, pursuant to Article 20(4), of measures taken pursuant to paragraphs 1 or 4 of Article 10 by the original notifying Member State, a Member State may raise an objection to the ~~those~~ measures taken by the original notifying Member State where they relate to a product subject to Union harmonisation legislation. The Member State shall state its reasons for objecting, indicate any difference in its assessment of the risk presented by the product and mention any special circumstances and any additional information relating to the product in question.
2. If no objection is raised by a Member State pursuant to paragraph 1 and the Commission does not consider that the national measures are contrary to Union **harmonisation** 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 **harmonisation** legislation, the Commission shall without delay enter into consultation **with Member States and** with the relevant economic operator(s) and shall evaluate the national measures, taking account of all available ~~scientific evidence or~~ **and technical evidence data**.
4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission ~~may~~ **shall** decide by implementing acts whether the national measures are justified and ~~whether similar~~ **same** measures ~~should~~ **shall** be taken by all Member States that have not already done so. In this case, it shall address the decision to the Member States concerned and immediately communicate it to all Member States and the relevant economic operator or operators. **These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).**
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~~ **the same** measure shall withdraw the measure and the notification **if that notification was** made under the rapid information exchange system pursuant to Article 20.
6. Where a national measure is considered justified and the product is found not to be in compliance with Union harmonisation legislation because of shortcomings in the relevant harmonised standards, ~~the Commission shall inform the relevant European standardisation organisation and may make an appropriate request pursuant to Article 11 of Regulation (EU) No 1025/2012~~ **shall apply**.

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 other technical specifications conferring a presumption of conformity, appropriate measures should be taken in accordance with the procedures, specified in the relevant Union harmonisation legislation.

Where a national measure is considered justified and the product is found not to be in compliance with Regulation (EU) No 305/2011 because of shortcomings in the European Assessment Document or in the Specific Technical Documentation as referred to in Article 19, 37 and 38 of that Regulation, the Commission shall bring the matter before the Standing Committee on Construction referred to in Article 64 of that Regulation and subsequently adopt the appropriate measures.

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 such as prohibiting, suspending, restricting or,~~ **in case of a serious risk for the health and safety of consumers, laying down special conditions for the placing or making available on the market of such products or laying down special conditions for their marketing,** in order to ensure a high level of protection of the public interest, provided that the risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned or by any other procedure under Union legislation. ~~By those implementing acts, the Commission may lay down the appropriate control measures to be taken by Member States to ensure their effective implementation.~~

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article 32(2) **and shall establish the duration of the measures concerned.**

On duly justified imperative grounds of urgency relating to the health and safety of persons in general, health and safety in the workplace, **protection of consumers protection**, the environment and public security and other public interests, **protected by Union harmonisation legislation or Regulation (EU) No ... [CPSR]**, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 32(3).

2. For products and risks subject to Regulation (EC) No 1907/2006, a ~~decision~~ **measure** 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~~ **measure** shall be without prejudice to procedures provided in that Regulation.
3. The exportation from the Union of a product that has been prohibited to be placed or made available on the Union market pursuant to a measure adopted in accordance with paragraph 1 shall be prohibited, unless the measure expressly so permits.
4. Any Member State may submit a substantiated request to the Commission to examine the need for the adoption of a measure referred to in paragraph 1.

Article 13

Risk assessment

[Moved to Article 9]

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

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

- ~~2.—In the context of the risk assessment, market surveillance authorities shall take into account the extent to which the product complies with the following:~~
- ~~(a)—any requirements laid down in or pursuant to Union harmonisation legislation that apply to the product and relate to the potential risk under consideration, taking full account of test reports or certificates attesting conformity and issued by a conformity assessment body;~~
 - ~~(b)—in the absence of requirements laid down in or pursuant to Union harmonisation legislation, specific rules laying down health and safety requirements for such products in the national law of the Member State where it is made available on the market, provided that such rules are in accordance with Union law;.~~
 - ~~(c)—any European standards the references of which have been published in the *Official Journal of the European Union*.~~
- ~~3.—Compliance with the criteria referred to in points (a), (b) and (c) of paragraph 2 shall raise a presumption that the product adequately safeguards the public interests to which those criteria relate. However, this shall not prevent market surveillance authorities from taking action under this Regulation where there is new evidence that, despite such conformity or compliance, the product presents a risk.~~
- ~~4.—The feasibility of obtaining higher levels of protection of the public interest concerned and the availability of other products presenting a lesser risk shall not be a reason to consider that a product presents a risk. [Moved to Article 9]~~

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 **respective** tasks. They shall ~~carry out~~ **ensure that** appropriate documentary and, where necessary, physical and/or laboratory checks on products **be carried out** before those products are released for free circulation.
2. Where more than one authority is responsible for market surveillance or **control of products at the external border controls** in a Member State, those authorities shall cooperate with each other, by sharing information relevant to their functions.
3. ~~Subject~~ **Without prejudice** to Article 17, the authorities in charge of **the control of products at the external border controls** shall suspend release of a product for free circulation on the Union market when, in the course of the checks referred to in paragraph 1, they have reason to believe that the product **may be non-compliant and/or 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 sufficient reason to believe that the product may present a risk in any of the following cases:~~

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

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

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

4. The authorities in charge of **the control of products at the external border controls** shall immediately notify the market surveillance authorities of any suspension under paragraph 3 **and shall transmit to them all relevant available information that is useful for the identification of the product and of the relevant economic operator(s) as well as for the determination whether the product is non-compliant and/or presents a risk.**
5. In the case of perishable products **or products requiring special handling or storage procedures**, the authorities in charge of **control of products at the external border controls** shall, as far as possible, ~~seek~~ **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~~ **do not endanger** the preservation of those products.
6. Where, in relation to products that are not declared for free circulation, the authorities in charge of **the control of products at the external border controls** have reason to believe that those products **may be non-compliant and/or may** present a risk, they shall ~~transmit~~ **ensure the transmission of** all relevant information to the authorities in charge of **the control of products at the external border controls** in the Member States of final destination **or may decide to place the products under official detention.**

Article 15

Release

1. ~~A product the release of which has been suspended by~~ **Where** the authorities in charge of **the control of products at the external border controls have suspended the release of a product** pursuant to Article 14, ~~they shall be released if~~ **they shall be released if**, within three working days of the suspension of release, ~~those authorities have not been requested by the market surveillance authorities~~ **the market surveillance authorities do not request** to continue the suspension ~~or do not inform the authorities in charge of the control of products at the external border that the product is non-compliant and/or presents a risk, or they have been informed by the market surveillance authorities that the product does not present a risk,~~ and provided that all the other requirements and formalities pertaining to such release have been fulfilled.
2. ~~If the market surveillance authorities conclude that a product the release of which was suspended due to formal non-compliance in accordance with the second sub-paragraph of paragraph 3 of Article 14 does not in fact present a risk, the economic operator shall nevertheless rectify the formal non-compliance before the product is released.~~
3. Compliance with the requirements of any Union harmonisation legislation **or Regulation (EU) No ... [CPSR]** that apply to the product upon its release ~~which relate to the potential risk under consideration,~~ taking full account of **into consideration in-house or third party** tests reports or certificates attesting conformity ~~and~~ issued by a conformity assessment body, shall raise a presumption on the part of market surveillance authorities that the product does not present a risk. However, this shall not prevent those authorities from instructing the authorities in charge of **the control of products at the external border controls** not to release the product where there is evidence that, despite such compliance, the product does in fact present a risk.

Article 16
Refusal to release

1. Where the market surveillance authorities conclude that a product ~~does~~ **is non-compliant and/or** presents a risk, they shall instruct the authorities in charge of **the control of products at the 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 **or, where the data processing is carried out electronically, in the data-processing system itself:**

“**Non-compliant product or p**Product presents a risk — release for free circulation not authorised — Regulation (EU) No XXX/XXXX”.
2. Where that product is subsequently declared for a customs procedure other than release for free circulation and provided that the market surveillance authorities do not object, the endorsement set out in paragraph 1 shall also be included, under the conditions set out in paragraph 1, on the documents used in connection with that procedure.
3. Market surveillance authorities or the authorities in charge of **the control of products at the 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~~ **lodging the customs declaration in his own name, or by the person in whose name that customs declaration is made. In cases of indirect representation as referred to in Article 5 of Council Regulation (EEC) No 2913/92, the representative and the person on whose behalf the declaration is made shall be considered jointly and severally liable regarding the obligation to bear costs.**

4. Market surveillance authorities ~~shall provide~~ **and** the authorities in charge of **the control of products at the external border** ~~controls with~~ **shall exchange** information on product categories in which **non-compliance and/or** 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 such as~~ recourse to the competent national courts.
6. **Member States may authorise their** ~~Market surveillance authorities~~ **or the authorities in charge of the control of products at the external border** ~~may~~ to charge fees **on the relevant person referred to in paragraph 3** which wholly or partly cover the costs of their activities, ~~including such as~~ testing carried out **for evaluation, including where necessary,** the risk assessment, ~~where they take~~ **and** measures **taken** in accordance with paragraph 1.

Article 17

Personal imports

1. Where a product enters the Union accompanied by, and in the physical possession of, a natural person and reasonably appears to be destined for the personal use of that person, **the provisions of this Chapter shall not apply** ~~its release shall not be suspended pursuant to Article 14(3), except~~ **However, in cases where** the use of the product can endanger the health and life of persons, animals or plants, **the authorities in charge of the control of products at the external border may suspend and/or refuse the release of the product concerned.**
2. A product shall be deemed to be destined for the personal use of a natural person bringing it into the Union if it is of an occasional nature and exclusively intended for use by that person or his family and does not by its nature or quantity indicate any commercial intent.

Article 18

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

0. **Where the market surveillance authorities or the authorities in charge of the control of products at the external border consider that non-compliance and/or the risk, presented by a product subject to Union harmonisation legislation, is not restricted to their national territory, they shall inform the Commission, which shall inform the other and the Member States of the results of the evaluation and of the measures taken pursuant to paragraph 1 of Article 16.**

A separate notification shall not be necessary if a measure referred to in the first subparagraph is a type of measure which is required to be notified through the RAPEX pursuant to Article 20.

1. Within ~~60~~ **45** days of communication of the information referred to in paragraph 0 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 **raise an objection to the that refusal to release a product for free circulation** where it relates to a product subject to Union harmonisation legislation. The Member State shall state its reasons for objecting, indicate any difference in its assessment of the risk presented by the product and mention any special circumstances and any additional information relating to the product in question.
2. If no objection is raised by a Member State under paragraph 1 and the Commission does not consider that the national measures are contrary to Union **harmonisation** 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 **harmonisation** legislation, the Commission shall without delay enter into consultation with the **Member States and the** relevant economic operator(s) and shall evaluate the refusal, taking account of all available ~~scientific~~ **evidence and** ~~or technical evidence~~ **data**.
4. On the basis of the results of the evaluation conducted pursuant to paragraph 3, the Commission ~~may~~ **shall** decide by implementing acts whether the refusal is justified and ~~similar~~ **whether same** action should be taken by all Member States that have not already done so. In this case, it shall address the decision to the Member States concerned and immediately communicate it to all Member States and the relevant economic operator or operators.

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

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~~ **the same** measure shall withdraw it and the notification, **if that notification was** 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~~ **shall apply.**

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 other technical specifications conferring a presumption of conformity, appropriate measures should be taken in accordance with the procedures, specified in the relevant Union harmonisation legislation.

Where a national measure is considered justified and the product is found not to be in compliance with Regulation (EU) No 305/2011 because of shortcomings in the European Assessment Document or in the Specific Technical Documentation as referred to in Article 19, 37 and 38 of ~~the~~ that Regulation, the Commission shall bring the matter before the Standing Committee on Construction referred to in Article 64 of that Regulation and subsequently adopt the appropriate measures.

CHAPTER V

Exchange of information

Article 19

Union Rapid Information Exchange System - RAPEX

1. The Commission shall maintain the system for rapid exchange of information (RAPEX). Member States shall use RAPEX for exchanging information about products presenting a **serious** risk in accordance with this Regulation.
2. Each Member State shall designate a single contact point for **receiving RAPEX notifications and that single contact point or more contact points for sending RAPEX notifications.**
3. The Commission may, by means of implementing acts, prescribe the modalities and procedures for the exchange of information through RAPEX. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 32(2).
4. ~~Participation in RAPEX shall be open to applicant countries, third countries or international organisations within the framework of and in accordance with agreements between the Union and those countries or organisations. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Union. [Moved to Article 24]~~

Article 20

*Notification through RAPEX of products presenting a **serious 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)~~ **9a(1) with regard to products presenting a serious risk**;
 - (b) any measure taken by market surveillance authorities pursuant to Article ~~10(1)~~ **10(2), (2a)** or (4) **with regard to product presenting a serious risk**, unless it concerns a product subject to a notification pursuant to point (a);
 - (c) any refusal to release a product **presenting a serious risk** for free circulation pursuant to Article 16.

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

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

2. The information provided in accordance with paragraph 1 shall include all available details relating to the **serious** risk and at least the following information:
- (a) the nature ~~and level~~ of the **serious** risk, presented by the product ~~including a summary of the results of the risk assessment~~;
 - ~~(b) the nature of any non-compliance with Union harmonisation legislation;~~
 - (ba) a concise summary of the results of the evaluation of the product, including, where carried out, risk assessment;**
 - (bb) if applicable, shortcomings in the European standards, European Assessment Document, Specific Technical Documentation or other technical specifications which confer a presumption of conformity with the requirements of the applicable Union harmonisation legislation;**
 - (c) the data necessary to identify the product;
 - (d) the origin and the supply chain of the product;
 - (e) the date on which the measure or corrective action was taken and its duration **or the date of the refusal to release the product for free circulation**;
 - (f) the nature of the measure or corrective action taken and whether voluntary, approved, required;
 - (g) whether the economic operator has been given the opportunity to be heard.

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

3. ~~Where a notification relates to a product found not to comply with Union harmonisation legislation, the information provided shall also indicate whether the non-compliance is due to any of the following:~~
- ~~(a) the failure of the product to satisfy the requirements of the applicable legislation;~~
 - ~~(b) shortcomings in the harmonised standards referred to in that legislation which confer a presumption of conformity with those requirements. [Moved to paragraph 2(bb)]~~

Where ~~a measure or~~ corrective action, **measure or refusal to release** 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 or **of the refusal to release a product for free circulation.**

4. On receiving a notification, the Commission shall communicate it to the other Member States. If the notification does not satisfy the requirements set out in paragraphs 1, 2 and 3, the Commission may suspend it **and ask Member States to rectify the deficiencies in the notification.**
5. The Member States shall ~~immediately~~ **without delay** inform the Commission of the action or measures taken following receipt of a notification and shall provide any supplementary information, including the results of any tests or analyses carried out or possible differences in views. The Commission shall immediately transmit this information to other Member States.

Article 21

Information and communication system for market surveillance

1. The Commission shall maintain an information and communication system for market surveillance (ICSMS) for the collection, **exchange** and structured storage of information on issues relating to market surveillance, ~~in particular the following information:~~
 - 1a. **Member States shall collect and enter in ICSMS in particular the following information:**
 - (a) market surveillance authorities and their areas of competence;
 - (b) market surveillance programmes;
 - (c) **reporting of** the monitoring, review and assessment of market surveillance activities **referred to in Article 4(3);**
 - ~~(d) complaints or reports about issues relating to risks arising from products;~~
 - (e) ~~any non-compliance with Union harmonisation legislation other than measures or corrective actions~~ **taken by economic operators pursuant to Article 9a(1), when those actions are based on documented in-depth inspections performed by the market surveillance authority, or are otherwise expected to be of relevance to other market surveillance authorities laboratory tests results, except for the corrective actions notified under RAPEX in accordance with Article 20;**
 - ~~(f) any objection raised by a Member State in accordance with Articles 11(1) or 18(1) and the follow-up. [Moved to paragraph 1aa(c)]~~

1aa. Member States shall without delay enter in ICSMS information on any of the following:

- (0) any results of the evaluation and measures referred to in paragraph 0 of Article 11 and paragraph 0 of Article 18, ~~except for the information notified under RAPEX in accordance with Article 20;~~
- (aa) any objection raised in accordance with Articles 11(1) or 18(1) and, where appropriate, the follow-up of decisions taken by the Commission;
- (a) without prejudice to point (0), any measures taken by market surveillance authorities pursuant to paragraphs 2, 2a or 4 of Article 10, when those measures are based on documented in-depth inspections or otherwise expected to be of relevance to other market surveillance authorities except for the measures notified under RAPEX in accordance with Article 20;
- (b) without prejudice to point (0), any refusal to release a product for free circulation pursuant to Article 16, when those refusals are based on documented in-depth inspections or otherwise expected to be of relevance to other market surveillance authorities except for refusal to release a product notified under RAPEX in accordance with Article 20.

~~ICSMS shall contain a record of references to the notifications of measures or corrective action made under RAPEX in accordance with Article 20. [Moved to paragraph 2b]~~

~~ICSMS may also be made available, where necessary or appropriate, for use by the authorities in charge of controls at the external borders. [Moved to paragraph 3a]~~

2. For the purposes of paragraphs 1a and 1aa, Member States shall enter into ICSMS any information at their disposal ~~and not already notified under~~ **referred to in Article 20(2).** **Moreover, they shall enter information** about products presenting a risk regarding, in particular,:

~~(a) the identification of risks,~~

~~(b) results of testing carried out,~~

~~(c) restrictive measures taken,~~

(d) ~~contacts with~~ **information provided** by the economic operators concerned, ~~and justification for action or inaction and~~

(e) **reasons for inaction if no corrective action or measure have been taken.**

Where market surveillance authorities consider it useful, they may enter any additional information on the checks they performed according to Article 6(1).

2b. **ICSMS shall contain a record of references to the notifications of measures, corrective actions or refusals to release made under RAPEX in accordance with Article 20.**

The Commission shall provide an interface solution through which ICSMS can be connected to RAPEX for data interchange between these systems.

3. Market surveillance authorities, **where possible and appropriate**, shall ~~recognise the validity and make use~~ **take account** of test reports prepared by or for their counterparts in other Member States and entered into ICSMS.

3a. **ICSMS may also be made available, where necessary or appropriate, for use by the authorities in charge of controls at the external borders.**

Article 22

International exchange of confidential information

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

CHAPTER VI

Cooperation

Article 23

Mutual assistance

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

2. **On receipt of a duly motivated request, market surveillance authorities of one Member State shall, on receipt of a duly motivated request from a give the market surveillance authority in an of another Member State, provide any relevant assistance on an adequate scale by supplying information or documentation and carry out checks, inspections or, by carrying out appropriate investigations and report on them and on any follow-up action taken to the requesting authority or any other appropriate measure, and by participating in investigations initiated in the other Member States.**

When in conflict with national law, a request pursuant to the first subparagraph may not be used to demand the disclosure of information or documents.

The information, or 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

International Cooperation with the competent authorities of third countries

0. **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 and protection of personal data corresponding to those applicable in the Union as required by Article 25 of Directive 95/46/EC and Article 9 of Regulation (EC) No 45/2001.**

[Moved from Article 19(4)]

1. **Without prejudice to paragraph 0, the Commission and m**Market surveillance authorities may cooperate with the competent authorities of third countries **or international organisations** with a view to exchanging information, **best practices** and technical support, ~~promoting and facilitating access to Union information exchange systems including the RAPEX system in accordance with Article 19(4), and~~ promoting activities relating to conformity assessment and market surveillance surveillance **or other types of activities referred to in Article 27.**
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~~ **encourage** their competent authorities **to** participate in those activities.

Article 25

European Market Surveillance Forum

1. A European Market Surveillance Forum (EMSF) is established.
2. Each Member State shall be represented in meetings of the EMSF by **one or more** ~~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 **duly motivated** request of the Commission or a Member State.
4. The EMSF shall use its best endeavours to reach consensus. If consensus cannot be reached, the EMSF shall adopt its position by a simple majority of its members. Members may request that their positions and the grounds on which they are based are officially recorded.

5. The EMSF may invite experts and other third parties to attend meetings or provide written contributions.
6. The EMSF may establish standing or temporary sub-groups which shall include the administrative cooperation groups for market surveillance set up for the implementation of Union harmonisation legislation. Organisations representing the interests of industry, small and medium-sized enterprises, consumers, laboratories and conformity assessment bodies at Union level may be invited to participate in such sub-groups as observers.
7. The EMSF, **together with the Commission**, shall establish its rules of procedure ~~which shall enter into force after receiving a favourable opinion from the Commission~~.
8. The EMSF shall cooperate with the Forum for Exchange of Information on Enforcement established by Regulation (EC) No 1907/2006.

Article 26

Commission support and executive secretariat

1. The Commission shall support cooperation between market surveillance authorities. It shall participate in the meetings of the EMSF and its sub-groups.
2. To perform the tasks set out in Article 27, the EMSF shall be assisted by an executive secretariat that provides technical and logistic support to the EMSF and its sub-groups.

Article 27
Tasks of the EMSF

The EMSF shall have the following tasks:

- (a) to facilitate the exchange of information on **non-compliant products and/or** products presenting a risk, **evaluations of products including** risk assessment, test methods and results, recent scientific developments and other aspects relevant to control activities;
- (b) to **promote** ~~coordinate~~**ion of** 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;
- (d) to exchange expertise and best practices, **in particular regarding the implementation of market surveillance programmes;**
- (e) to ~~organise~~ **facilitate the organisation of** training programmes and exchanges of national officials;
- (f) to assist in monitoring activities as described in Article 4(3);
- (g) to ~~organise~~ **facilitate the organisation of** information campaigns and joint visit programmes;

- (h) to ~~improve~~ **promote** cooperation at Union level with regard to the tracing, withdrawal and recall of **non-compliant products and/or** products presenting a risk;
- (i) to ~~ensure~~ **promote** the easy access, retrieval and sharing of product safety information collected by market surveillance authorities, including information on complaints, accidents, injury reports and investigation and test results;
- (j) to contribute to the development of guidance to ensure the effective and uniform implementation of this Regulation, ~~taking due account of the interests of business, in particular small and medium-sized enterprises, and other stakeholders;~~
- (k) to provide advice and assist the Commission, at its request, ~~in its assessment of any issue relating with~~ **issues related** to the implementation of this Regulation;
- (ka) to propose the financing of activities foreseen in Article 29;**
- (l) to contribute to uniform administrative practices with regard to market surveillance in the Member States;-
- (m) to provide advice and assist the Commission with issues related to the further development of RAPEX and ICSMS;**
- (n) to promote the cooperation and exchange of expertise and best practices between market surveillance authorities and authorities in charge of controls at the external borders.**

European Union reference laboratories

1. ~~For specific products or a category or group of products or for specific risks related to a category or group of products, the Commission may by means of implementing acts designate Union reference laboratories that satisfy the criteria set out in paragraph 2.~~
2. ~~Each Union reference laboratory shall satisfy the following criteria:~~
 - (a) ~~have suitably qualified staff with adequate training in the analytical techniques used in their area of competence and an adequate knowledge of standards and practices;~~
 - (b) ~~possess the equipment and reference material needed to carry out the tasks assigned to them;~~
 - (c) ~~act in the public interest in an impartial and independent manner;~~
 - (d) ~~ensure that the staff respect the confidential nature of certain subjects, results or communications.~~
3. ~~Within the area of their designation, Union reference laboratories shall where appropriate have the following tasks:~~
 - (a) ~~carrying out product testing in relation to market surveillance activities and investigations;~~
 - (b) ~~contributing to the resolution of disputes between the authorities of Member States, economic operators and conformity assessment bodies;~~
 - (c) ~~providing independent technical or scientific advice to the Commission and the Member States;~~
 - (d) ~~developing new techniques and methods of analysis;~~
 - (e) ~~disseminating information and providing training.~~

CHAPTER VII

Financing

Article 29

Financing activities

1. The Union may finance the following activities in relation to the application of this Regulation:
 - (a) the drawing up and updating of contributions to guidelines on market surveillance;
 - (b) the making available to the Commission of technical or scientific expertise for the purpose of assisting the Commission in its implementation of market surveillance administrative cooperation and the Union assessment procedures referred to in Articles 11 and 18;
 - (c) the performance of preliminary or ancillary work in connection with the implementation of market surveillance activities linked to the application of Union legislation such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits, research work, the development and maintenance of databases, training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work, and European market surveillance campaigns and similar activities;
 - (d) activities carried out under programmes of technical assistance, cooperation with third countries and the promotion and enhancement of European market surveillance policies and systems among interested parties at European and international levels;
 - (e) the functioning of cooperation among market surveillance authorities and the technical and logistic support by the Executive Secretariat to the EMSF and its sub-groups.

2. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012, either directly, or indirectly by delegating budget implementation tasks to the entities listed in **point (c) of** Article 58(1)~~(e)~~ of Regulation (EU, Euratom) No 966/2012.
3. The appropriations allocated to activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the financial framework in force.
4. The appropriations determined by the budgetary authority for the financing of market surveillance activities may also cover expenses pertaining to preparatory, monitoring, control, audit and evaluation activities which are required for the management of the activities pursuant to this Regulation and the achievement of their objectives; in particular, studies, meetings of experts, information and communication actions, including corporate communication of the political priorities of the Union as far as they are related to the general objectives of market surveillance activities, expenses linked to information technology networks focusing on information processing and exchange, together with all other technical and administrative assistance expenses incurred by the Commission for the management of the activities pursuant to this Regulation.
5. The Commission shall evaluate the relevance of the market surveillance activities that receive Union financing in the light of the requirements of Union policies and legislation and inform the European Parliament and the Council of the outcome of that evaluation by [*five years following the date of application*] and every five years thereafter.

Article 30

Protection of the Union's financial interests

1. The Commission shall take appropriate measures ensuring that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by the recovery of amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive penalties.
2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and on-the-spot checks, over all grant beneficiaries, contractors and subcontractors and other third parties who have received Union funds under this Regulation.
3. The European Anti-fraud Office (OLAF) may carry out on-the-spot checks and inspections on economic operators concerned directly or indirectly by such funding in accordance with the procedures laid down in Council Regulation (Euratom, EC) No 2185/96⁴¹ with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract concerning Union funding.
4. Without prejudice to paragraphs 1 and 2, cooperation agreements with third countries and international organisations and grant agreements and grant decisions and contracts resulting from the implementation of this Regulation shall expressly empower the Commission, the Court of Auditors and OLAF to conduct audits, on-the-spot checks and inspections.

⁴¹ OJ L292, 14.11.1996, p.2.

CHAPTER VIII

Final provisions

Article 31

Penalties

The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation that impose obligations on economic operators ~~and to infringements of provisions of any Union harmonisation legislation on products covered by this Regulation that impose obligations on economic operators where that legislation does not provide for penalties,~~ and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by ~~{insert date - 3 months prior to the date of application of this Regulation}~~ and shall notify it without delay of any subsequent amendment affecting them.

~~The penalties referred to in the first subparagraph shall have regard to the size of the undertakings and in particular to the situation of small and medium-sized enterprises. The penalties may be increased if the relevant economic operator has previously committed a similar infringement and may include criminal sanctions for serious infringements.~~

Article 32
Committee procedure

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

However, for the purposes of Article 12 of this Regulation, the Commission shall be assisted:

- (a) **by the Committee established by the corresponding Union harmonisation legislation regulating the product concerned, when such a committee exists;**
 - (aa) **in the absence of a committee referred to in point (a), by the Committee referred to in first subparagraph;**
 - (b) **by the Committee referred to in first subparagraph of Article 19(1), first subparagraph, of the Regulation (EU) No ... [CPSR] as regards non-harmonised consumer products.**
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) 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

1. **No later than [two] years after the date of application, the Commission shall assess the application of provisions of Chapter V of this Regulation and provide for a solution in order to ensure that all information, communication and publication obligations of market surveillance authorities under this Regulation are met through ICSMS as one single information and communication system.**
2. No later than [five] years after the date of application, the Commission shall assess the application of this Regulation and transmit an evaluation report to the European Parliament and the Council. That report shall assess if this Regulation achieved its objectives, in particular with regard to ensuring more effective and efficient enforcement of product safety rules and Union harmonisation legislation, improving cooperation between market surveillance authorities, strengthening the controls of products entering the Union and better protecting the health and safety of persons in general, health and safety in the workplace, consumer protection, the environment, public security and other public interests, taking into account its impact on business and in particular on small and medium-sized enterprises.

Article 34⁴²

Amendments

1. The following provisions are deleted:
 - (a) Article 18 of Directive 2011/65/EU;
 - (b) Article 7 of Council Directive 89/686/EEC;
 - (c) Paragraphs 2 and 3 of Article 7 and Article 8 of Directive 93/15/EEC;
 - (d) Article 7 of Directive 94/9/EC;

⁴² **The entire Article 34 will require a throughout revision during the technical meetings**

- (e) Article 7, paragraph 4 of Article 10 and Article 11 of Directive 94/25/EC;
- (f) Articles 7 and 11 of Directive 95/16/EC;
- (g) Articles 8, 16 and 18 of Directive 97/23/EC;
- (h) Article 9 of Directive 1999/5/EC;
- (i) Articles 14, ~~15~~ and 19 of Directive 2000/9/EC;
- (j) Article 5 of Directive 2000/14/EC;
- (k) Paragraphs 2 and 3 of Article 6 and Articles 8, 9, 10, 11, 12 and 13 of, and Annex II to, Directive 2001/95/EC;
- (l) Articles 10 and 11 of Directive 2004/108/EC;
- (m) Paragraphs 3 and 4 of Article 4 and Articles 11, 17 and 20 of Directive 2006/42/EC;
- (n) Article 9 of Directive 2006/95/EC;
- (o) Paragraphs 5 and 6 of Article 14 and Articles 15, 16 and 17 of Directive 2007/23/EC;
- (p) Paragraph 5 of Article 13 and Article 14 of Directive 2008/57/EC;
- (q) Articles 39, 40, 42 to 45 of Directive 2009/48/EC;
- (r) Articles 7, 15 and 17 of Directive 2009/105/EC;
- (s) Articles 7, 11 and 12 of Directive 2009/142/EC;
- (t) Articles 56 to 59 of Regulation (EU) No 305/2011;
- (u) **Article 10 of Directive 75/324/EEC.**

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

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

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

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

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

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

References to the provisions of Articles 15 to 29 of Regulation (EC) No 765/2008 shall be construed as references to this Regulation and shall be read in accordance with the correlation table ⁴³ in the Annex.

⁴³ The correlation table should be updated in respect of provisions of the GPSD that are moved into the MSR.

Article 35

Transitional provisions

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

Article 36

Entry into force

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

It shall apply from ~~1 January 2015~~ [**insert date – the same day as date of application of NLF package**].

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

Done at Brussels,

For the European Parliament

The President

For the Council

The President