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WORKING PAPER

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WORKING DOCUMENT

From:	Presidency
To:	Working Party on Technical Harmonisation (Goods package)
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council - Presidency discussion paper

Legend:

All changes made in the Presidency discussion paper (WK 5486/2018 INIT) in comparison to the Commission proposal are given in the following way: all additions are in **bold** and all deletions are in ~~strikethrough~~.

All new changes in comparison to WK 5486/2018 INIT are given in the following way: all new additions are in **bold** and all new deletions are in ~~strikethrough~~.

The title of Article 10 is highlighted in yellow for easy tracking of changes.

2017/0353 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[1],

Acting in accordance with the ordinary legislative procedure,

Whereas:

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

(2) Strengthening the Single Market for goods through further enhancing efforts to keep non-compliant products from being placed on the Union market was identified as a priority in the Communication from the Commission 'Upgrading the Single Market: more opportunities for people and businesses'[2]. This should be achieved by strengthening market surveillance, providing the right incentives to economic

[1] OJ C , , p. .

[2] COM(2015) 550 final of 28 October 2015.

operators, intensifying compliance controls and promoting closer cross-border cooperation among enforcement authorities, including through cooperation with customs authorities.

(3) The framework for market surveillance should be strengthened, with a view to further improving compliance with and enforcement of Union harmonisation legislation on products.

(4) Directive 2001/95/EC of the European Parliament and of the Council[3] lays down the general safety requirements for all consumer products and provides for specific obligations and powers of the Member States in relation to dangerous products as well as for the exchange of information to that effect through the Union Rapid Alert System for dangerous non-food products (RAPEX). Market surveillance authorities should have the possibility of taking the more specific measures available to them under that Directive. In order to achieve a higher level of safety for consumer products, the mechanisms for exchanges of information and rapid intervention situations provided for in Directive 2001/95/EC and reinforced by Regulation (EC) No 765/2008 of the European Parliament and of the Council[4] should be complemented to make them more effective.

(5) This Regulation should cover products that are subject to the Union harmonisation legislation listed in the Annex. The legislation listed in the Annex should cover all Union harmonisation legislation concerning manufactured products other than food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. This will ensure a uniform framework for market surveillance of those products at Union level. Several instruments of Union harmonisation legislation on products need to be amended in consequence, in particular to remove references to certain provisions of Regulation (EC) No 765/2008. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to provide whether this Regulation is also to apply to that legislation.

(6) In order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of Better Regulation, the rules applicable to controls on products entering the Union market should be revisited and integrated into a single legislative framework for controls on products at the external borders.

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

4 Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

(7) Safety of consumers largely depends on the active enforcement of Union harmonisation legislation on products providing for safety requirements. It is therefore necessary to strengthen enforcement measures. These measures should be continuously improved and increasingly effective with a view to meeting the current challenges of a global market and an increasingly complex supply chain.

(8) The framework established by this Regulation should complement and strengthen existing provisions in Union harmonisation legislation relating to the provision of compliance information about products and the framework for cooperation with economic operators, the market surveillance of products and controls on those products entering the Union. However, in accordance with the principle of lex specialis, this Regulation should apply only in so far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of Union harmonisation legislation. The corresponding provisions of this Regulation should not therefore apply in the areas covered by such specific provisions, for instance those set out in Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors[5], Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products[6], Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices[7] and Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices[8].

(9) Responsibility for enforcing Union harmonisation legislation should lie with the Member States, whose market surveillance authorities should be required to ensure that the legislation is fully complied with. The Member States should, therefore, establish systematic approaches to ensure effectiveness of market surveillance and other enforcement activities.

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5 Regulation (EU) No 1258/2013 of the European Parliament and of the Council of 20 November 2013 amending Regulation (EC) No 273/2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).

6 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

7 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

8 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

(10) Certain definitions currently set out in Regulation (EC) No 765/2008 should be aligned with definitions set out in other Union acts and, where appropriate, reflect the architecture of modern supply chains.

(11) Economic operators throughout the entire supply chain should be expected to act responsibly and in full accordance with the legal requirements applicable when placing or making products available on the market, so as to ensure compliance with the Union harmonisation legislation on products. This Regulation should be without prejudice to the obligations which correspond to the role of each economic operator in the supply and distribution process pursuant to specific provisions in Union harmonisation legislation, with the manufacturer retaining ultimate responsibility for compliance of the product with requirements in the Union harmonisation legislation.

(12) Modern supply chains encompass a wide variety of economic operators who should all be subject to enforcement of Union harmonisation legislation, while taking due consideration of their respective role in the supply chain, and the extent to which they contribute to the making available of products on the Union market. Therefore, it is necessary to apply this Regulation to economic operators that are directly concerned by Regulation (EC) No 273/2004 of the European Parliament and of the Council[9], Regulation (EC) No 1907/2006 of the European Parliament and of the Council[10], Regulation (EC) No 1272/2008 of the European Parliament and of the Council[11], Regulation (EC) No 1222/2009 of the European Parliament and of the Council[12], Regulation (EC) No 1223/2009, Regulation (EU) 2016/424 of the European Parliament and of the Council[13], Regulation (EU) 2016/425 of the European Parliament and of the Council[14], Regulation (EU) 2016/426 of the European Parliament and of the Council[15] and Regulation (EU) 2017/1369 of the European Parliament and of the Council[16], Regulation (EU) 2017/745 and Regulation (EU) 2017/746, and in Directive 2006/42/EC of the European Parliament and of the Council[17], Directive 2006/66/EC of the European Parliament and of the Council[18], Directive 2009/48/EC of the European Parliament and of the Council[19], Directive 2010/35/EU of the European Parliament and of the Council[20], Directive 2013/29/EU of the European Parliament and of the Council[21], Directive 2013/53/EU of the

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9 Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).

10 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

11 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

12 Regulation (EC) No 1222/2009 of the European Parliament and of the Council of 25 November 2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters (OJ L 342, 22.12.2009, p. 46).

13 Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1).

14 Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).

15 Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99).

16 Regulation (EU) 2017/1369 of the European Parliament and of the Council of 4 July 2017 setting a framework for energy labelling and repealing Directive 2010/30/EU (OJ L 198, 28.7.2017, p. 1).

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

18 Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (OJ L 266, 26.9.2006, p. 1).

19 Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1–37).

20 Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36 (OJ L 165, 30.6.2010, p. 1–18).

21 Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (recast) (OJ L 178, 28.6.2013, p. 27).

European Parliament and of the Council[22], Directive 2014/28/EU of the European Parliament and of the Council[23], Directive 2014/29/EU of the European Parliament and of the Council[24], Directive 2014/30/EU of the European Parliament and of the Council[25], Directive 2014/31/EU of the European Parliament and of the Council[26], Directive 2014/32/EU of the European Parliament and of the Council[27], Directive 2014/33/EU of the European Parliament and of the Council[28], Directive 2014/34/EU of the European Parliament and of the Council[29], Directive 2014/35/EU of the European Parliament and of the Council[30], Directive 2014/68/EU of the European Parliament and of the Council[31], and Directive 2014/90/EU of the European Parliament and of the Council[32].

22 Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90).

23 Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (recast) (OJ L 96, 29.3.2014, p. 1).

24 Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45).

25 Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (recast) (OJ L 96, 29.3.2014, p. 79).

26 Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107).

27 Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (recast) (OJ L 96, 29.3.2014, p. 149).

28 Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251).

29 Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (recast) (OJ L 96, 29.3.2014, p. 309).

30 Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357).

31 Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164).

32 Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146).

(13) The development of e-commerce is also due to a great extent to the proliferation of information society service providers, normally through platforms and for remuneration, which offer intermediary services by storing third party content, but without exercising any control over such content, thus not acting on behalf of an economic operator. Removal of content regarding non-compliant products or where it is not feasible blocking access to non-compliant products offered through their services should be without prejudice to the rules laid down in Directive 2000/31/EC of the European Parliament and of the Council[33]. In particular, no general obligation should be imposed on service providers to monitor the information which they transmit or store, nor should a general obligation be imposed upon them to actively seek facts or circumstances indicating illegal activity. Furthermore, hosting service providers should not be held liable as long as they do not have actual knowledge of illegal activity or information and are not aware of the facts or circumstances from which the illegal activity or information is apparent.

(14) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this purpose, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers and the market surveillance authorities is a key element allowing immediate intervention and corrective action in relation to the product. It is important that there should be a contact person established in the Union so that market surveillance authorities have someone to whom questions can be addressed regarding a product's compliance with Union harmonisation legislation. The person responsible for providing such compliance information should be the manufacturer, or the importer, or another person designated by the manufacturer for this purpose, for example another economic operator. The role of a person responsible for compliance information established in the Union is essential for providing market surveillance authorities with an interlocutor established in the Union, and for performing specific tasks in a timely manner to ensure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, workers and businesses within the Union. The provisions in this Regulation requiring there to be a person established in the Union responsible for compliance information should not apply where specific requirements set out in certain legal instruments on products achieve the same result in effect, namely Article 4 of Regulation (EC) No 1223/2009, Article 15 of Regulation (EU) 2017/745 and Article 15 of Regulation 2017/746.

[33] Directive 2000/31/EC of the European Parliament and of the Council on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce) (OJ L 178, 17.07.2000, p. 1).

(15) Member States should provide assistance to economic operators either through information on the applicable Union harmonisation legislation by the Product Contact Points established under Regulation (EU) [Reference to new Regulation on mutual recognition to be inserted][34], or through guidance on the applicable Union harmonisation legislation by the market surveillance authority within the framework of compliance partnership arrangements. Market surveillance authorities should able to build on the existing cooperation with stakeholders and be permitted to conclude memoranda of understanding with stakeholders, with a view to promoting compliance or identifying non-compliance with regard to categories of product within a given geographical area.

(16) Member States should designate their own market surveillance authorities. In order to facilitate administrative assistance and cooperation, Member States should also designate a single liaison office. Liaison offices should ensure the coordination of enforcement and market surveillance activities, as well as communication with the market surveillance of other Member States and with the Commission.

(17) It is necessary to establish a Union Product Compliance Network, hosted by the Commission, aimed at coordinating and facilitating the implementation of joint enforcement activities by Member States, such as joint investigations. This administrative support structure should allow the pooling of resources and maintain a communication and information system between Member States and the Commission, thereby helping to strengthen enforcement of Union harmonisation legislation on products and deter infringements.

(18) Market surveillance activities should be thorough and effective, to ensure that Union harmonisation legislation on products is applied correctly. Given that controls may represent a burden for economic operators, market surveillance authorities should organise and conduct inspection activities, taking their interests into account and limiting the said burden to what is necessary for the performance of efficient and effective controls. Furthermore, market surveillance activities should be performed with the same level of care by the competent authorities of the Member State irrespective of whether non-compliance of the given product is relevant on the territory of that Member State or is likely to have an impact on the market of another Member State.

[34] Regulation (EU) […] of the European Parliament and of the Council of … (OJ L, , p.)

(19) In order to ensure that the Union harmonisation legislation on products is correctly enforced, market surveillance authorities should have a common set of investigative and enforcement powers, allowing for enhanced cooperation between market surveillance authorities and more effective deterrence for economic operators that willingly infringe Union harmonisation legislation. Those powers should be sufficiently robust to tackle the enforcement challenges of Union harmonisation legislation, along with the challenges of e-commerce and the digital environment and to prevent economic operators from exploiting gaps in the enforcement system by relocating to Member States whose market surveillance authorities are not equipped to tackle unlawful practices. In particular, the powers should ensure that information and evidence can be exchanged between competent authorities so that enforcement can be undertaken equally in all Member States.

(20) This Regulation should be without prejudice to the freedom of Member States to choose the enforcement system that they deem appropriate. Member States should be free to choose whether their market surveillance authorities can exercise investigation and enforcement directly under their own authority or by application to the competent courts.

(21) Market surveillance authorities should be in a position to open investigations on their own initiative if they become aware of non-compliant products placed on the market.

(22) Market surveillance authorities should have access to all necessary evidence, data and information relating to the subject matter of an investigation in order to determine whether applicable Union harmonisation legislation has been infringed, and in particular to identify the economic operator responsible, irrespective of who possesses the evidence, information or data in question and regardless of where it is located and of the format in which it is held. Market surveillance authorities should be able to request third parties in the digital value chain to provide all the evidence, data and information necessary.

(23) Market surveillance authorities should be able to carry out the necessary on-site inspections, and should have the power to enter any premises, land or means of transport, that the economic operator uses for purposes relating to his trade, business, craft or profession.

(24) Market surveillance authorities should be able to require any representative or member of staff of the economic operator concerned to give explanations or provide facts, information or documents relating to the subject matter of the on-site inspection, and to record the answers given by that representative or staff member.

(25) Market surveillance authorities should be able to check the compliance of products to be made available on the market with Union harmonisation legislation and to obtain evidence of non-compliance. They should, therefore, have the power to make test purchases and, where the evidence cannot be obtained by other means, to purchase products under a cover identity.

(26) In the digital environment in particular, market surveillance authorities should be able to bring non-compliance to an end quickly and effectively, notably where the economic operator selling the product conceals his identity or relocates within the Union or to a third country in order to avoid enforcement. In cases where there is a risk of serious and irreparable harm to end-users due to non-compliance, market surveillance authorities should be able to take temporary measures, where there are no other means available to prevent or mitigate such harm, including, where necessary, the suspension of a website, service or account, or putting a fully qualified domain name on hold for a specific period of time, in accordance with the principles laid down in Directive 2000/31/EC. Furthermore, market surveillance authorities should have the power to close down or require a third party service provider to close down a website, service or account or a part of it, or to delete a fully qualified domain name.

(27) Market surveillance authorities act in the interest of economic operators, end-users, and of the general public, to ensure that public interests established by Union harmonisation legislation on products are consistently preserved and protected through appropriate enforcement action, and that compliance with such legislation is ensured across the supply chain through appropriate controls. Consequently, market surveillance authorities should account to economic operators, end-users and the general public for the efficiency and effectiveness of the activities they perform. They should provide access to information concerning the organisation and performance of their activities, including controls, and regularly publish information on activities performed and the results of such activities. They should also, subject to certain conditions, be entitled to publish or to make available information about the compliance record of individual economic operators based on the outcome of market surveillance controls.

(28) Economic operators should fully cooperate with market surveillance authorities and other competent authorities to ensure the smooth performance of market surveillance activities and to enable the authorities to perform their tasks.

(29) This Regulation should be without prejudice to the functioning of RAPEX in accordance with Directive 2001/95/EC and Regulation (EC) No 765/2008.

(30) This Regulation should be without prejudice to the safeguard clause procedure provided for by sectoral Union harmonisation legislation, pursuant to Article 114(10) of the Treaty. With a view to ensuring an equivalent level of protection throughout the Union, Member States should be authorised to take restrictive measures in relation to products presenting a risk to health and safety, or other aspects of public interest protection. They should also be required to notify those measures to other Member States and the Commission, allowing the Commission to take a position on the national measures that restrict the free movement of products with a view to ensuring the functioning of the internal market.

(31) Information exchanged between market surveillance authorities, and the use of evidence and investigation findings should be subject to the strictest guarantees of confidentiality and of professional and commercial secrecy. Information should be handled according to applicable national law, in order to ensure that investigations are not compromised and that the reputation of the economic operator is not prejudiced.

(32) Where for the purposes of this Regulation it is necessary to process personal data, this should be carried out in accordance with Union law on the protection of personal data. Any processing of personal data under this Regulation is subject to Regulation (EU) 2016/679 of the European Parliament and of the Council[35] and Regulation (EC) No 45/2001 of the European Parliament and of the Council[36], as the case may be.

(33) To ensure the reliability and consistency of testing across the Union in the market surveillance framework, the Commission should designate Union testing facilities. Furthermore, a more comprehensive information system should be developed for sharing test results within the Union in order to avoid unnecessary duplication and to ensure greater consistency at Union level.

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35 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

36 Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(34) Laboratories designated by the Commission as Union testing facilities should possess the expertise, equipment, infrastructure and staff to carry out tasks to the highest standards. To ensure sound and reliable results, Union testing facilities should be accredited according to the relevant Union harmonised standards. The accreditation should be delivered by a national accreditation body operating in accordance with Regulation (EC) No 765/2008.

(35) Member States should be required to ensure that adequate financial resources are always available in order to staff and equip the market surveillance authorities appropriately. An efficient market surveillance activity is demanding in terms of resources, and stable resources should be provided, at a level appropriate to the enforcement needs at any given moment. Public financing should therefore be supplemented by the collection of fees to cover the costs incurred when performing market surveillance activities in relation to products that were found to be non-compliant, and taking due account of the economic operator's compliance record.

(36) The financing of market surveillance activities through fees collected from economic operators should take place in full transparency, so as to enable citizens and businesses to understand the method and data used to establish fees and to be informed on the use of revenue from fees.

(37) It is appropriate that Member States designate the authorities responsible for applying the customs legislation and any other authorities in charge under national law of control on products entering the Union market;

(38) An effective way to ensure that unsafe or non-compliant products are not placed on the Union market would be to detect such products before they are released for free circulation. Customs authorities, as authorities in charge of the control on products entering the customs territory of the Union, enjoy a complete overview of trade flows across the external borders, and should therefore be required to carry out adequate controls on a risk assessment basis, to contribute to a safer market place. A uniform enforcement of Union harmonisation legislation on products can only be achieved through systematic cooperation and exchange of information between market surveillance and customs authorities. These authorities should receive well in advance from the market surveillance authorities all the necessary information concerning non-compliant products or information on economic operators where a higher risk of non-compliance has been identified. In turn, customs authorities should inform the market surveillance authorities in a timely manner of the release of products for free circulation, and the results of controls, where such information is relevant for the enforcement of Union harmonisation legislation on products. Furthermore, where the Commission becomes aware of a serious risk posed by an imported product, it should inform the Member States about those risks in order to ensure coordinated and more effective compliance and enforcement controls at the first points of entry to the Union.

(39) In order to support customs and market surveillance authorities in carrying out tasks related to controls on products entering the customs territory of the Union, a more favourable treatment should be granted for products declared for free circulation by an authorised economic operator, as defined in Article 38(2) of Regulation (EU) No 952/2013, pending the establishment of the procedure for the exchange of information on the status of the authorised economic operators and their record of compliance related to product safety. Such an approach should allow a more targeted control, on a risk basis, of products released for free circulation.

(40) The Commission should be able to exchange market surveillance related information with regulatory authorities of third countries or international organisations, with a view to ensuring compliance prior to their export of products to the Union market.

(41) In that context, it is necessary to maintain and further develop the existing Information and Communication System for Market Surveillance (ICSMS). For the purpose of collecting information relating to the enforcement of Union harmonisation legislation on products, ICSMS should be upgraded and be accessible to the Commission, single liaison offices, and market surveillance authorities, as well as to the general public through a public interface. Furthermore, an electronic interface should be developed to allow effective exchange of information between national customs systems and market surveillance authorities.

(42) The Commission should carry out an evaluation of this Regulation against the objectives it pursues. Pursuant to point 22 of the Interinstitutional Agreement of 13 April 2016 on Better Law Making[37], the evaluation, based on efficiency, effectiveness, relevance, coherence and value added, should provide the basis for impact assessments of options for further action.

(43) The financial interests of the Union should be protected through proportionate measures throughout the expenditure cycle, including the prevention, detection and investigation of irregularities, the recovery of funds lost, wrongly paid or incorrectly used and, where appropriate, administrative and financial penalties.

(44) The diversity of sanctions across the Union is one of the main reasons for inadequate deterrence and uneven protection. Rules on establishing sanctions, including monetary penalties, are a matter of national jurisdiction and should, therefore, be determined by national law. However, common criteria and guidance principles in determining the level of penalties should be established in order to achieve uniform and effective deterrence across the Union. Defining a set of criteria for determining effective, proportionate and dissuasive levels of penalty across the Union, in particular as regards the past behaviour of the economic operators, their cooperation during investigation by market surveillance authorities, and the level of harm, is essential to avoid weak spots that could encourage forum-shopping.

[37] OJ L 123, 12.5.2016, p. 1.

(45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission in relation to the procedures for designating Union testing facilities, to the procedure for requests for information and requests for enforcement measures, to statistical data covering controls performed by customs authorities with respect to products subject to Union harmonisation legislation, to the data to be exchanged and the procedure to be followed for the exchange of information between customs authorities and market surveillance authorities on the status of authorised economic operators, to details of implementation arrangements for the information and communication system and data relating to the placing of products under the customs procedure 'release for free circulation' transmitted by customs authorities, and to the implementation of the system of product-related pre-export controls, including a model for the certificates of compliance or verification to be used. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[38].

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

(47) This Regulation respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union. Accordingly this Regulation must be interpreted and applied respecting those rights and principles. In particular, this Regulation seeks to ensure full respect for consumer protection, the freedom to conduct a business, the freedom of expression and information, the right to property and the protection of personal data,

HAVE ADOPTED THIS REGULATION:

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

Chapter I

General provisions

Article 1

Subject matter

1. This Regulation **aims to improve the functioning of the internal market by** ~~lays down rules and procedures for the provision of~~**ensuring** compliance ~~information about certain products that are the subject of~~ **with and enforcement of** Union ~~acts~~ **legislation** harmonising the conditions for the marketing of ~~those~~ products**, including those sold online, in order to provide a high level of protection of public interests such as health and safety in general, health and safety in the workplace, the protection of consumers, protection of the environment, public security and any other public interest protected by that legislation and to ensure fair**~~. It establishes a framework for cooperation with~~ **competition between** economic operators ~~in relation to such products~~.

2. To that end, this Regulation ~~It also~~ provides a framework for ~~the~~ market surveillance ~~of such products to ensure that those products fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, the protection of consumers, protection of the environment and security~~.

~~This Regulation also provides a framework~~ and for controls on ~~such~~ **those** products entering the Union market **and lays down rules for the provision of compliance information**.

Article 2

Scope

1. This Regulation applies to all products that are subject to the Union harmonisation legislation set out in the Annex to this Regulation ('Union harmonisation legislation').

2. Each of the provisions of this Regulation shall apply in so far as there are no specific provisions with the same objective in the Union harmonisation legislation, which regulate in a more specific manner particular aspects of market surveillance and enforcement.

3. The application of this Regulation shall not prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC.

4. This Regulation is without prejudice to Articles 12, 13, 14 and 15 of Directive 2000/31/EC.

Article 3

Definitions

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

(1) '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;

(2) 'placing on the market' means the first making available of a product on the Union market;

(3) 'market surveillance' means the activities carried out and measures taken by ~~market surveillance~~ **~~public~~ market surveillance** authorities to ensure that products comply with the requirements ~~under~~ **set out in** Union harmonisation legislation and **therefore** do not endanger health~~,~~ **and** safety **of persons in general, health and safety in the workplace, protection of consumers, the environment, public security** or any other ~~aspect of~~ public interest **protected by that legislation** ~~protection~~;

(4) 'market surveillance authority' means ~~an a public~~**an** authority designated by a Member State under Article 1~~1~~**0** as a market surveillance authority in the territory of that Member State;

(5) 'applicant authority' means the market surveillance authority that makes a request for mutual assistance;

(6) 'requested authority' means the market surveillance authority that receives a request for mutual assistance;

(7) 'non-compliance' means any failure to comply with any of the requirements under the Union harmonisation legislation ~~applicable to the product in question or to the relevant economic operator~~ **or the requirements of this Regulation**;

(8) 'manufacturer' means**:**

(a) 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 **or, where provided for in the applicable Union harmonisation legislation, uses it for his own purposes, or**~~;~~

(b) any natural or legal person who modifies a product already placed on the market in such a way that compliance with the applicable Union harmonisation legislation may be affected, or

(c) any other natural or legal person who places a product on the market under his name or trade mark;

(9) 'importer' means any natural or legal person established within the Union who places a product from a third country on the Union market;

(10) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

(11) '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~~s~~ to the manufacturer's obligations under the relevant Union harmonisation legislation;

(12) 'economic operator' means~~ the manufacturer, the authorised representative, the importer or the distributor, and including:~~

~~(a) any of the economic operators as referred to in Directives 2006/66/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU, 2014/90/EU, Regulations (EU) No 305/2011, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2017/745 and (EU) 2017/746;~~

(aa) the manufacturer, the authorised representative, the importer or the distributor;

~~(b) the operators as defined in Regulation (EC) No 273/2004;~~

~~(c) the producer of an article and the downstream user as defined in each case in Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008;~~

~~(d) the private importer as defined in Directive 2013/53/EU;~~

~~(e) the installer as defined in~~ ~~Directives 2006/42/EC and~~ ~~2014/33/EU;~~

~~(f) the supplier and the distributor as defined in Regulation (EC) No 1222/2009;~~

~~(g) the dealer as defined in Regulation (EU) 2017/1369;~~

(ab) any other natural or legal person subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant Union harmonisation legislation;

(h) any other natural or legal person established in the Union ~~and other than a distributor,~~ who warehouses, packages and ~~ships~~ **~~delivers~~ ships** products to or within the Union market;

(13) 'corrective action' means any action taken by an economic operator to bring any non-compliance to an end~~, including action to restrict the making available of products on the market or to destroy a product on the market~~**where requested by market surveillance authorities or on his own initiative**;

(14) 'temporary measure' means any ~~temporary~~ measure taken by a market surveillance authority aimed at suspending or **temporary** restricting the making available of products on the market pending a final assessment on non-compliance, without prejudging any subsequent decisions;

(14a) 'risk' means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm;

(14b) '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, the environment, public security and other public interests, protected by the applicable Union harmonisation legislation, 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;

(15) '**product presenting a** serious risk' means ~~any serious risk, including a serious risk~~ **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, including cases** where the effects are not immediate, **and thus** requiring rapid intervention by the market surveillance authorities;

(16) 'end-user' means any natural or legal person, residing or established in the Union, to whom a product was made available either as a consumer, outside any trade, business, craft or profession, or as a professional end-user in the course of his industrial or professional activities**, or any natural or legal person whose ~~personal or legal interests~~ may be affected by the product in question**;

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

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

(19) 'customs authorities' means customs authorities as defined in Article 5(1) of Regulation (EU) No 952/2013;

(20) 'release for free circulation' means the procedure laid down in Article 201 of Regulation (EU) No 952/2013;

(21) 'products entering the Union market' means products from third countries intended to be placed on the Union market or intended for private use or consumption within the customs territory of the Union and placed under the customs procedure 'release for free circulation';

(22) 'authorised economic operator' means an economic operator enjoying the status granted pursuant to Article 38(1) of Regulation (EU) No 952/2013.

Chapter II

Compliance information

Article 4

Person responsible for compliance information

1. A product may be made available on the market only if the following conditions are met:

   (a) the manufacturer is established in the Union or there is at least one of the following in place with respect to the product:

      (i) an importer;

      (ii) a natural or legal person established in the Union who has a written mandate from the manufacturer designating him as a person responsible for performing the tasks listed in paragraph 3 and requiring him to perform those tasks on the manufacturer's behalf;

   (b) the identity and contact details of the manufacturer, importer or other person meeting the requirements of point (a) are publicly available in accordance with paragraph 4 and are indicated or identifiable in accordance with paragraph 5.

2. For the purposes of this Article, 'the person responsible for compliance information' means the person, whether the manufacturer, importer or other person, meeting the requirements of paragraph 1(a) with respect to the product or, if there is more than one such person, any of them.

3. The person responsible for compliance information shall perform the following tasks:

   (a) if the Union harmonisation legislation applicable to the product provides for an EU declaration of conformity and technical documentation, keeping the declaration and technical documentation at the disposal of market surveillance authorities for the period required by that legislation;

   (b) further to a reasoned request from a market surveillance authority, providing that authority with all the information and documentation necessary to demonstrate the conformity of the product in an official Union language determined by the Member State concerned;

   (c) cooperating with the market surveillance authorities, at their request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by the product.

4. Manufacturers shall make the identity and contacts details of the person responsible for compliance information with respect to the product publicly available either on their website or, in the absence of a website, by any other means that allows the information to be readily accessed by the general public in the Union free of charge.

5. The identity and contact details of the person responsible for compliance information with respect to the product shall be indicated on or identifiable from information indicated on the product, its packaging, the parcel or an accompanying document.

6. For the purposes of paragraph 1:

   (a) manufacturers may designate a person under paragraph 1(a)(ii) whether or not they have a right or obligation to appoint an authorised representative under the Union harmonisation legislation applicable to the product;

   (b) where the manufacturer has such a right or obligation under the Union harmonisation legislation, the appointment of an authorised representative under that legislation may count as a designation for the purposes of paragraph 1(a)(ii) provided the appointment meets the requirements of that paragraph.

7. This Article shall not apply in relation to a product that is subject to Regulation (EC) No 1223/2009, Regulation (EU) 2017/745, Regulation 2017/746 or Regulation 2017/1369.

Article 5

Declaration of conformity

Where Union harmonisation legislation provides for the drawing up of an EU declaration of conformity, manufacturers ~~shall~~ **may** make the declaration publicly available on their website or, in the absence of a website, by any other means that allows the declaration to be readily accessed by the general public in the Union free of charge.

Chapter III

Assistance to and cooperation with economic operators

Article 6

Information to economic operators

The Product Contact Points referred to in [Regulation (EC) No 764/2008 of the European Parliament and the Council / Regulation (EU)…. of the European Parliament and the Council] shall provide economic operators, at their request**, within 15 working days** and free of charge, with information with respect to the Union harmonisation legislation applicable to a product.

The Commission shall make available relevant information on Union harmonisation legislation to assist the Product Contact Points in carrying out their tasks under the first subparagraph.

Article 7

Compliance partnership arrangements

1. A market surveillance authority may enter into a partnership arrangement with an economic operator established in its territory under which the authority agrees to provide the economic operator with advice and guidance in relation to the Union harmonisation legislation applicable to the products for which the economic operator is responsible.

   The arrangement shall not cover the provision of conformity assessment activities that are entrusted to notified bodies under the Union harmonisation legislation.

   The arrangement shall contain provisions to safeguard the confidentiality, objectivity and impartiality of the market surveillance activities of the authority concerned.

2. If a market surveillance authority enters into a partnership arrangement under paragraph 1, it shall enter that fact in the system referred to in Article 34, along with ~~details of~~ the scope of the arrangement and the ~~names and addresses~~ **identity and contact details** of ~~itself~~ **the authority** and of the economic operator.

3. If a market surveillance authority enters into a partnership arrangement under paragraph 1, other market surveillance authorities shall inform that authority of any temporary measure taken by them against the economic operator, and any corrective action taken by the economic operator, in relation to compliance with the applicable Union harmonisation legislation.

~~4. A market surveillance authority that enters into a partnership arrangement under paragraph 1 may charge the economic operator fees representing the costs reasonably incurred by the authority in the exercise of its functions under paragraphs 1 and 2.~~

Article 8

Memoranda of understanding with stakeholders

1. Market surveillance authorities may enter into memoranda of understanding with **groups of** businesses or organisations representing businesses or end-users for ~~the~~ carrying out~~, or financing, of~~ joint activities aimed at identifying non-compliance~~ or~~ promoting compliance **or exchanging information** in specific geographical areas or with respect to specific categories of product**s**.

   The memorandum shall contain provisions to safeguard the confidentiality, objectivity and impartiality of the market surveillance activities of the authority concerned.

   The market surveillance authority in question shall make the memorandum available to the general public and shall enter it in the system referred to in Article 34.

2. A market surveillance authority may**, as part of its investigations into non-compliance,** use any information resulting from activities carried out ~~or financed~~ by **the** other parties to a memorandum of understanding ~~entered into by it~~ under paragraph 1~~ as part of any investigation undertaken by it into non-compliance~~, ~~but only if~~**provided** the activity in question was carried out independently, impartially and without bias.

3. Any exchange of information between market surveillance authorities and **groups of** businesses or organisations referred to in paragraph 1 for the purposes of preparing or implementing a memorandum of understanding entered into by them under that paragraph shall be deemed not to infringe the requirements of professional secrecy.

Article 9

Publication of voluntary measures

1. The Commission shall develop and maintain an on-line portal on which economic operators may publish information about measures voluntarily taken by them in relation to a product as defined in Directive 2001/95/EC or a product made available by them on the market, where the risks posed by the product go beyond the territory of one Member State.

   The on-line portal shall be one to which end-users and market surveillance authorities are able to have access.

2. If an economic operator chooses to publish information on the portal referred to in paragraph 1, it shall ensure that the product can be precisely identified from the information published and that the risks are explained such that end-users can assess what action it might be appropriate for them to take in response to the risks. The information published shall be provided in all of the official languages of the Member States where the products are made available on the market and the economic operator shall be responsible for the provision and accuracy of the information.

3. Publication referred to in paragraph 1 is without prejudice to any obligations of economic operators under the applicable Union harmonisation legislation or under Directive 2001/95/EC.

Chapter IV

Organisation and general principles of market surveillance

Article 0

General obligation

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

Article 10

Obligations ~~of market surveillance authorities~~ as regards organisation of market surveillance ~~authorities~~

0.1. [***moved from Article 11***] **Each Member State shall designate one or more market surveillance authorities in its territory. It shall inform the Commission**~~, through the Network established under Article 31,~~ **and the other Member States of the market surveillance authorities designated by it and the areas of competence of each of those authorities, using the information and communication system referred to in Article 34.**

0.2. **Each Member State shall designate one of its market surveillance authorities or any other competent authority as a single liaison office.**

0.3. **The single liaison office of a Member State shall be responsible for** ~~coordinating the enforcement and market surveillance activities of~~ **coordination between the market surveillance authorities designated by that Member State and between those authorities and the authorities designated under Article 26(1)**.

0.4. **Member States shall ensure that their market surveillance authorities and single liaison office have the necessary resources, including sufficient budgetary and other resources, expertise, procedures and other arrangements for the proper performance of their duties.**

0.5. **Where there is more than one market surveillance authority in their territory, Member States shall ensure that the respective duties of those authorities are clearly defined and that those authorities collaborate closely so that they can discharge their duties effectively.**

1. ~~Market surveillance authorities~~ **Member States** shall establish appropriate communication and coordination mechanisms ~~with other~~ **between their** market surveillance authorities.

~~2.~~ **[*moved to Article 11*]** ~~Market surveillance authorities shall establish the following procedures in connection with products subject to the Union harmonisation legislation set out in the Annex:~~

~~(a) procedures for following up of complaints or reports on issues relating to risks;~~

~~(b) procedures for monitoring any accidents or any harm to the health or safety of end-users which are suspected of having been caused by such products;~~

~~(c) procedures for verifying that corrective action to be taken by economic operators has been taken;~~

~~(d) procedures for collecting and exploring **follow**~~**ing up** ~~scientific and technical knowledge concerning safety issues.~~

Article 11

Obligations of Mmarket surveillance authorities and single liaison offices

1. **[*moved to Article 10*]** Each Member State shall designate one or more market surveillance authorities in its territory. It shall inform the Commission, through the Network established under Article 31, and the other Member States of the market surveillance authorities designated by it and the areas of competence of each of those authorities, using the information and communication system referred to in Article 34.

2. Each Member State shall designate one of its market surveillance authorities or any other competent authority as a single liaison office.

3. The single liaison office of a Member State shall be responsible for coordinating the enforcement and market surveillance activities of **coordination between** the market surveillance authorities designated by that Member State **and between those authorities and the authorities designated under Article 26(1)**.

4. Member States shall ensure that their market surveillance authorities and single liaison office have the necessary resources, including sufficient budgetary and other resources, expertise, procedures and other arrangements for the proper performance of their duties.

5. Where there is more than one market surveillance authority in their territory, Member States shall ensure that the respective duties of those authorities are clearly defined and that those authorities collaborate closely so that they can discharge their duties effectively.

5a. [*moved from Article 10*] **Market surveillance authorities shall establish the following procedures in connection with products subject to the Union harmonisation legislation** set out in the Annex:

(a) procedures for following up of complaints or reports on issues relating to risks;

(b) procedures for monitoring any accidents or any harm to the health or safety of end-users which are suspected of having been caused by such products;

(c) procedures for verifying that corrective action to be taken by economic operators has been taken;

(d) procedures for collecting and exploring following up scientific and technical knowledge concerning safety issues.

Article 12

Activities of market surveillance authorities

1. Market surveillance authorities shall conduct their activities in order to ensure the following:

   (a) the effective surveillance of the market within their territory with respect to ~~any~~ products that are subject to ~~the~~ Union harmonisation legislation ~~set out in the Annex~~;

   (b) the taking by them of appropriate and proportionate ~~temporary~~ measures and the taking by economic operators of appropriate and proportionate corrective action in relation to compliance with that legislation and this Regulation.

2. [***moved from Article 15(1), first subparagraph***] **Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory controls on the basis of an adequate sample.**

   Market surveillance authorities shall perform controls as part of their activities set out in paragraph 1, on a risk-based approach, taking into account, as a minimum, the following factors:

   (a) the identified risks associated with:

      (i) the product, such as the number of products on the market and any hazards associated with that product;

      (ii) the activities and operations under the control of the economic operator;

   (b) the economic operator's past record of non-compliance~~, including the risk profiling and the status of an authorised economic operator~~;

   (c) **[*partly moved from Article 15(1), second subparagraph*]** any further information**, including complaints,** that might indicate non-compliance in relation to a particular product.

2a. [*moved from Article 15(1), third subparagraph*] Where economic operators present test reports or certificates attesting conformity of their products with Union harmonisation legislation issued by an accredited conformity assessment body, market surveillance authorities shall take due account of such reports or certificates.

2b. [*moved from Article 34(5)*] Market surveillance authorities shall recognise the validity of and shall make use of test reports prepared by or for their counterparts in other Member States and shall enter such information in the information and communication system referred to in Article 34.

3. Market surveillance authorities shall **take appropriate measures** ~~ensure that a product is withdrawn or recalled from the market or that the making available of the product on the market is prohibited or restricted~~ if~~,~~**:**

~~when it is being used either in accordance with its intended purpose or under conditions that can be reasonably foreseen and it is properly installed and maintained, either of the following conditions would be met:~~

(a) ~~the~~**a** product is liable to compromise the health or safety of end-users **when it is used either in accordance with its intended purpose or under conditions that can be reasonably foreseen and it is properly installed and maintained, or**~~;~~

(b) ~~the~~ **a** product does not conform to applicable requirements under Union harmonisation legislation.

Where the products are withdrawn, recalled, prohibited or restricted, the market surveillance authority shall ensure that the Commission ~~through the Network established under Article 31,~~ **and** the other Member States ~~and end-users~~ are informed **through the information and communication system referred to in Article 34, and that the end-users are informed** accordingly.

4. Market surveillance authorities shall perform their activities with a high level of transparency and shall make available to the general public any information that they deem relevant for the general public. **[Moved to Article 34(3)]**~~They shall also ensure that the following information is entered in the system referred to in Article 34:~~

~~(a) the type, number and outcome of the checks performed by them;~~

~~(b) the type and the number of non-compliances detected by them;~~

~~(c) the nature of the temporary measures taken by them against economic operators and of the corrective action taken by economic operators;~~

~~(d) details of the cases of non-compliance where penalties were imposed by them.~~

5. Market surveillance authorities shall exercise their powers and carry out their duties independently, impartially and without bias.

Article 13

National market surveillance strategies

1. Each Member State shall draw up a national market surveillance strategy, as a minimum, every ~~3~~ **4** years. The strategy shall promote a consistent, comprehensive and integrated approach to market surveillance and enforcement of Union harmonisation legislation within the territory of the Member State**. When drawing up the strategy** ~~and shall include~~ all sectors and stages of the product supply chain, including imports and digital supply chains **shall be considered**.

2. The national market surveillance strategy shall include, as a minimum, the following elements:

   (a) an assessment of the occurrence of non-compliant products, in particular taking into account the risk-based controls referred to in Articles 12(2) and 26(3), and**, where applicable,** market trends that may affect non-compliance rates in the categories of product;

   (b) the areas identified as a priority for the enforcement of Union harmonisation legislation;

   (c) the enforcement actions planned in order to reduce the occurrence of non-compliance in those areas identified as a priority, including, where relevant, the minimum control levels envisaged for categories of product which have significant levels of non-compliance;

   (d) an assessment of the effective performance and coordination of market surveillance activities pursuant to this Regulation, and, where applicable, the identification of capacity building needs and measures;

   (e) an assessment of the cooperation with market surveillance authorities in other Member States and of joint actions, where applicable;

   ~~(f) a monitoring programme for the purposes of measuring progress in the implementation of the strategy and verifying compliance with this Regulation.~~

3. Member States shall communicate their national market surveillance strategy through the system referred to under Article 34.

Chapter V

Market surveillance powers and measures

Article 14

Powers and duties of market surveillance authorities

1. Member States shall confer on their market surveillance authorities the powers of market surveillance, investigation and enforcement necessary for the application of this Regulation and for the application of ~~the~~ Union harmonisation legislation ~~set out in the Annex to this Regulation~~.

2. When conferring powers under paragraph 1~~, including a power required by paragraph 3,~~ Member States may provide for the power to be exercisable in one of the following ways as appropriate:

   (a) directly by the market surveillance authorities under their own authority;

   (b) by recourse to other public authorities;

   (c) by application to courts competent to grant the necessary decision to approve the exercise of that power.

3. The powers conferred on market surveillance authorities under paragraph 1 shall include the following powers as a minimum:

   (a) the power to require economic operators to provide information necessary to determine the frequency of checks under Article 15, including information about the number of products on the market and the activities of those operators;

   ~~(b) the power to perform system audits of economic operators' organisations, including audits of any procedures that they have in place to ensure compliance with this Regulation and with applicable Union harmonisation legislation;~~

   (c) the power to have access to any relevant document, data or information related to an instance of non-compliance, in any form or format and irrespective of its storage medium or the place where it is stored;

(d) the power to require any public authority, body or agency within the market surveillance authority's Member State, or any natural or legal person, to provide any **relevant** information, data or document, in any form or format and irrespective of its storage medium or the place where it is stored, for the purposes of enabling the market surveillance authority to investigate whether any non-compliance has occurred or is occurring and to establish the details of that non-compliance, including ~~in particular~~ information, data or documents required for the purposes of ~~identifying and tracing financial and data flows,~~ ascertaining the ~~identity and contact details of persons involved in financial and data flows and ascertaining bank account information and the~~ ownership of websites;

(e) the power to do any of the following, or to request another public authority to do any of the following, for the purposes of an investigation by the market surveillance authority or at the request of an applicant authority:

(1) to carry out on-site inspections, including power to enter any premises, land or means of transport that the economic operator in question uses for purposes related to his trade, business, craft or profession, in order to examine, ~~seize, ~~take or obtain copies of information, data or documents, irrespective of their storage medium;

(2) to seal any premises or seize any **products,** information, data or documents of an economic operator during the inspection for a necessary period and to the extent necessary for the purposes of the investigation;

(3) to request ~~any~~ **relevant** representative**s** or members of staff of the economic operator to give explanations of facts, information or documents relating to the subject-matter of the inspection and to record their answers;

(f) the power to take samples of products free of charge**, where necessary and to the extent that it is proportionate in view of the value of the product,** in order to detect non-compliance and obtain evidence;

(g) the power to purchase products as test purchases, including under a cover identity, in order to detect non-compliance and obtain evidence;

(h) the power to take ~~temporary~~ measures, where there are no other effective means available to prevent a serious risk, including ~~in particular temporary measures~~ requiring hosting service providers to remove, disable or restrict access to content or to suspend or restrict access to a website, service or account or requiring domain registries or registrars to put a fully qualified domain name on hold for a specific period of time;

(i) the power to start investigations or proceedings on their own initiative in order to **ascertain and** bring an instance of non-compliance within the territory of the Member State concerned to an end ~~and, where appropriate, to publish information about the investigation through the system referred to in Article 34~~;

(j) the power to ~~seek to obtain a commitment from~~ **require** an economic operator to bring an instance of non-compliance to an end;

(k) the power to prohibit **or restrict** the making available of products on the market or to withdraw, recall or destroy products, where economic operators fail to **take corrective action requested by the market surveillance authority or fail to** provide the information requested by the market surveillance authority to verify the compliance of those products and while the failure persists;

(l) the power to impose penalties on an economic operator, including fines or periodic penalty payments, for non-compliance or for failure to comply with any decision, order, ~~temporary measure~~ or ~~other~~ measure taken by the market surveillance authority;

(la) [*moved from Article 21(2)*] the power to charge economic operators fees in relation to instances of non-compliance by that economic operator in order to enable the authorities to recover the costs of their activities with respect to these instances of non-compliance; those costs may include the costs of carrying out testing for the purposes of a risk assessment, the costs of taking measures in accordance with Article 30(1) and (2) and the costs of their activities relating to products that are found to be non-compliant and subject to corrective action prior to their release for free circulation;

~~(m) the power to order the restitution of profits obtained as a result of an instance of non-compliance;~~

(n) the power to publish any final decisions, final measures, commitments given by the economic operator or decisions taken or made pursuant to this Regulation, including the publication of the identity of the economic operator who was responsible for the non-compliance.

~~4. [*partly covered by (n) and taking into account Article 16*] Market surveillance authorities shall publish any commitments given to them by economic operators, details of any corrective action taken by economic operators in their territory, and details of any temporary measures taken by the relevant market surveillance authority pursuant to this Regulation.~~

5. Market surveillance authorities shall exercise their powers in accordance with the principle of proportionality.

Article 15

Market surveillance measures

~~1. *[moved to Article 12(2)]* Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory controls on the basis of a representative sample.~~

~~*[partly incorporated in 12(2)(c), the rest covered by Article 12(2)]* In deciding what checks to perform and on what scale, market surveillance authorities shall take into account, in particular, established principles of risk assessment and complaints.~~

~~*[moved to Article 12(3)]* Where economic operators present test reports or certificates attesting conformity of their products with Union harmonisation legislation issued by an accredited conformity assessment body, market surveillance authorities shall take due account of such reports or certificates.~~

1a. [*moved from Article 12(3)*] Market surveillance authorities shall take appropriate measures if:

(a) a product is liable to compromise the health or safety of end-users when it is used either in accordance with its intended purpose or under conditions that can be reasonably foreseen and it is properly installed and maintained, or

(b) a product does not conform to applicable requirements under Union harmonisation legislation.

2. Market surveillance authorities shall take appropriate measures, without delay, to alert end-users within their territories to hazards that they have identified relating to any product so as to reduce the risk of injury or other damage.

The ~~authorities~~ **economic operators** shall cooperate with ~~economic operators~~ **market surveillance authorities** regarding actions which could prevent or reduce risks that are caused by products made available by those operators.

~~3. **[***covered by Article 17(3)***]** Where the market surveillance authorities of one Member State decide to withdraw a product manufactured in another Member State, they shall inform the economic operator concerned without delay.~~

Article 16

Use of information, professional and commercial secrecy

Market surveillance authorities shall observe the principle of confidentiality where necessary in order to protect professional and commercial secrets or to preserve personal data pursuant to national legislation, subject to the requirement that information be made public to the fullest extent possible in order to protect the interests of end-users in the Union.

Article 17

Restrictive measures

1. Any measure, decision or order taken or made by market surveillance authorities pursuant to Union harmonisation legislation or this Regulation to prohibit or restrict the making available of products on the market or to withdraw, recall or destroy products on the market shall be proportionate and shall state the exact grounds on which it is based.

2. Any such measures, decisions or order shall be communicated without delay to the relevant economic operator, who shall at the same time be informed of the remedies available to him under the law of the Member State concerned and of the time limits to which those remedies are subject.

3. Before a measure, decision or order referred to in paragraph 1 is taken or made, the economic operator concerned shall be given the opportunity to be heard within an appropriate period of not less than 10 days, unless it is not possible to give him that opportunity because of the urgency of the measure, decision or order, based on health or safety requirements or other grounds relating to the public interests covered by the relevant Union harmonisation legislation.

   If the measure, decision or order is taken or made without the economic operator being given the opportunity to be heard, he shall be given that opportunity as soon as possible thereafter and the measure, decision or order shall be reviewed promptly by the authority.

4. The market surveillance authority shall promptly withdraw or amend any measure, decision or order referred to in paragraph 1 where the economic operator can demonstrate that he has taken effective corrective action.

Article 18

Products presenting a serious risk

1. Market surveillance authorities shall take measures to **ensure that products which present a serious risk are** recall**ed** or withdraw**n,** ~~products which present a serious risk or to prohibit~~ **that t**he**ir being** ma~~king~~**de** available ~~of them~~ on the market **is prohibited**. They shall inform the Commission of such measures without delay, in accordance with Article 19.

2. The decision whether or not a product presents a serious risk shall be based on an appropriate risk assessment which takes account of the nature of the hazard and the likelihood of its occurrence. The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering that a product presents a serious risk.

Article 19

~~Exchange of information —~~ Union Rapid Alert System (RAPEX)

1. Where a market surveillance authority takes or intends to take a measure in accordance with Article 18 and considers that the reasons which prompted the measure or the effects of the measure go beyond the territory of its Member State, it shall immediately notify the Commission of that measure, in accordance with paragraph 4 of this Article. It shall also inform the Commission without delay of the modification or withdrawal of any such measure.

2. If a product presenting a serious risk has been made available on the market, market surveillance authorities shall notify the Commission of any voluntary measures taken and communicated by an economic operator.

3. The information provided in accordance with paragraphs 1 and 2 shall include all available details, in particular the data necessary for the identification of the product, the origin and the supply chain of the product, the related risk, the nature and the duration of the national measure taken and any voluntary measures taken by economic operators.

4. For the purposes of paragraphs 1, 2 and 3, the market surveillance and information exchange system provided for in Article 12 of Directive 2001/95/EC shall be used. Paragraphs 2, 3 and 4 of Article 12 of that Directive shall apply mutatis mutandis.

Article 20

Union testing facilities

1. The Commission may designate Union testing facilities for specific products or a specific category or group of products or for specific risks related to a category or group of products which are made available on the market.

2. The Union testing facilities referred to in paragraph 1 shall satisfy the following criteria:

~~(a) they must 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) they must be equipped to carry out the tasks assigned to them under paragraph 4;~~

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

~~(d) they must ensure, where appropriate, the confidential nature of topics, results or communications;~~

(e) they must be accredited in accordance with Chapter II of Regulation (EC) No 765/2008.

3. A notified body or any other conformity assessment body designated pursuant to Union harmonisation legislation may not be designated as a Union testing facility.

4. Union testing facilities shall, within the area of their competence, perform the following tasks as a minimum:

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

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

(c) provide independent technical or scientific advice to the Commission including, the Network established under Article 31, and to the Member States;

(d) develop new techniques and methods of analysis;

(e) disseminate information to testing facilities in the Member States and provide training for such testing facilities.

5. The Commission shall adopt implementing acts specifying the procedures for designating Union testing facilities. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.

Article 21

Financing and recovery of costs by market surveillance authorities

1. **[*covered by Article 11(4)*]** Member States shall ensure that market surveillance authorities within their territory are provided with the necessary financial resources for the proper performance of their tasks.

2. **[*moved to Article 14(3)(la)*]** Market surveillance authorities may charge economic operators administrative fees in relation to instances of non-compliance by that economic operator in order to enable the authorities to recover the costs of their activities with respect to these instances of non-compliance. Those costs may include the costs of carrying out testing for the purposes of a risk assessment, the costs of taking measures in accordance with Article 30(1) and (2) and the costs of their activities relating to products that are found to be non-compliant and subject to corrective action prior to their release for free circulation.

Chapter VI

Cooperation and procedure for cross-border mutual assistance

Article 22

Requests for information

1. At the **duly motivated** request of an applicant authority, the requested authority shall **without delay, and in any event within 30 days unless otherwise agreed,** supply any information that the requested authority deems relevant to establish whether a product is non-compliant and to ensure that the non-compliance can be brought to an end.

   The motivated request by the applicant authority shall be submitted after the applicant authority has first undertaken all appropriate efforts to obtain such information itself.

2. The requested authority shall undertake appropriate investigations or take any other **appropriate and necessary** measures ~~that are appropriate~~ in order to gather the required information. Where necessary, those investigations shall be carried out with the assistance of other market surveillance authorities.

3. At the request of the applicant authority, the requested authority may allow officials of the applicant authority to accompany their counterparts in the requested authority during the course of their investigations.

3a. A requested authority may refuse to comply with a request for information under paragraph 1, if one or more of the following applies:

a) following a consultation with the applicant authority, it appears that the requested information is not needed by the applicant authority to determine whether there is a non-compliance;

b) the applicant authority does not agree that the information is subject to the rules on confidentiality and on professional and commercial secrecy as laid down in Article 16;

c) criminal investigations or judicial proceedings have already been initiated against the same economic operator in respect of the same non-compliance before the judicial authorities in the Member State of the requested authority or of the applicant authority.

~~4. The requested authority shall reply to the request under paragraph 1 using the procedure and within the time limits specified by the Commission under paragraph 5.~~

~~5. The Commission shall adopt implementing acts specifying the time limits, standard forms and further details of the procedure to be used for making and responding to requests for information under paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.~~

Article 23

Requests for enforcement measures

1. At the **duly motivated** request of an applicant authority, the requested authority shall without delay **and in any event within three months unless otherwise agreed,** take ~~all necessary~~ enforcement measures using the powers conferred on it under this Regulation in order to bring an instance of non-compliance to an end.

   The motivated request by the applicant authority shall show why measures by the applicant authority are not sufficient to bring the instance of non-compliance to an end.

2. The requested authority shall determine the appropriate enforcement measures required to bring an instance of non-compliance to an end. Where necessary, enforcement measures shall be determined and implemented with the assistance of other public authorities.

3. The requested authority shall regularly and without undue delay inform ~~and consult~~ the applicant authority about the measures referred to in paragraph 2 that have been taken or **agree with it on the measures** which are intended to be taken.

   The requested authority shall without delay notify the applicant authority, the market surveillance authorities of other Member States, and the Commission of the measures taken by it and of their effect on the non-compliance in question. The notification shall be made using the system referred to in Article 34**. [*covered by Article 34*]** ~~and shall include the following information as a minimum:~~

   ~~(a) whether temporary measures have been imposed;~~

   ~~(b) whether the non-compliance has ceased;~~

   ~~(c) whether penalties have been imposed and, if so, what;~~

   ~~(d) whether other measures taken by the requested authority or the economic operator have been implemented.~~

3a. A requested authority may refuse to comply with a mutual assistance request under paragraph 1, if one or more of the following applies:
a) criminal investigations or judicial proceedings have already been initiated, or there is a judgment, a court settlement or a judicial order in respect of the same non-compliance and against the same economic operator before the judicial authorities in the Member State of the requested authority;
b) the exercise of the necessary enforcement powers has already been initiated, or an administrative decision has already been adopted in respect of the same non-compliance and against the same economic operator in the Member State of the requested authority;
c) following an appropriate investigation, the requested authority concludes that there is no non-compliance;
d) the requested authority concludes that the applicant authority has not provided the information that is necessary.

~~4. The requested authority shall reply to the request under paragraph 1 using the procedure and within the time limits specified by the Commission under paragraph 5.~~

~~5. The Commission shall adopt implementing acts specifying the time limits, standard forms and further details of the procedures to be used for making and responding to~~

requests for enforcement measures under paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.

Article 24

Procedure for mutual assistance requests

1. The applicant authority shall provide sufficient information, in the case of requests for mutual assistance under Article 22 or 23, to enable the requested authority to fulfill the request~~, including any necessary evidence obtainable only in the Member State of the applicant authority~~.

2. Requests for mutual assistance under Article 22 or 23 shall be sent by the applicant authority to the single liaison office of the Member State of the requested authority and also to the single liaison office of the Member State of the applicant authority for information purposes. The single liaison office of the Member State of the requested authority shall pass the requests on to the appropriate competent authority, without undue delay.

3. Requests for mutual assistance under Article 22 or 23 and all communication linked to them shall be made using electronic standard forms by means of the system referred to in Article 34.

4. The languages to be used for requests for mutual assistance under Article 22 or 23 and for all communication linked to them shall be agreed upon by the competent authorities concerned.

5. Where no agreement about the languages to be can be reached between the competent authorities concerned, the requests for mutual assistance under Article 22 or 23 shall be sent in the official language of the Member State of the applicant authority and the replies to such requests in the official language of the Member State of the requested authority. In that instance, the applicant authority and the requested authority shall arrange for the translation of the requests, replies or other documents that it receives from the other.

6. The requested authority shall reply directly to the applicant authority and also to the single liaison offices of the Member States of both the applicant authority and the requested authority.

Article 25

Use of evidence and investigation findings

1. Market surveillance authorities may use any information, document ~~or a certified true copy of a document,~~ finding, statement, or any intelligence as evidence for the purpose of their investigations, irrespective of the format in which and medium on which they are stored.

2. The evidence referred to in paragraph 1 that is used by a market surveillance authority in one Member State may be used as part of investigations to verify product compliance carried out by market surveillance authorities in another Member State without any further formal requirements.

3. Products deemed to be non-compliant on the basis of a decision of a market surveillance authority in one Member State, shall be presumed to be non-compliant by market surveillance authorities in another Member State, unless ~~economic operators can provide~~ evidence to the contrary **is provided or a Member State has raised objections in accordance with the applicable Union safeguard procedure**.

~~4.~~ **[*covered by Article 34*]** ~~The decisions of a market surveillance authority referred to in paragraph 3 shall be published in the information and communication system referred to in Article 34.~~

Chapter VII

Products entering the Union market

Article 26

Controls on products entering the Union market

1. Member States shall designate customs authorities, one or more market surveillance authorities or any other authority in their territory as the authorities in charge of the control on products entering the Union market.

   Each Member State shall inform the Commission and the other Member States of the authorities designated under the first subparagraph and of their areas of competence through the system referred to in Article 34.

2. The authorities designated under paragraph 1 shall have the necessary powers and resources for the proper performance of their tasks as referred to in that paragraph.

3. Products subject to Union harmonisation legislation that are to be placed under the customs procedure 'release for free circulation' shall be subject to controls performed by the authorities designated under paragraph 1. They shall perform those controls on the basis of risk analysis in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013.

4. Products entering the Union market that require further processing in order to be in compliance with the Union harmonisation legislation applicable to them shall be placed under the appropriate customs procedure allowing such processing.

5. Risk-related information shall be exchanged between:

   (a) the authorities designated under paragraph 1 in accordance with Article 47(2) of Regulation (EU) No 952/2013;

   (b) customs authorities in accordance with Article 46(5) of Regulation (EU) No 952/2013.

   Where, in relation to products subject to Union harmonisation legislation that are either in temporary storage or placed under a customs procedure other than release for free circulation, customs authorities at the first point of entry have reason to believe that those products present a risk, they shall transmit all relevant information to the competent customs office of destination.

6. Market surveillance authorities shall provide authorities designated under paragraph 1 with information on categories of product or the identity of economic operators where a higher risk of non-compliance has been identified.

7. By 31 March each year, Member States shall submit to the Commission statistical data covering controls performed by the authorities designated under paragraph 1 with respect to products subject to Union harmonisation legislation during the previous calendar year, including data covering:

   (a) the number of interventions in the field of controls on such products, including product safety and compliance;

   (b) the number of cases communicated to the market surveillance authorities;

   (c) the results of controls on such products;

   (d) the characteristics of any product found to be non-compliant.

   The Commission shall draw up a report each year by 30 June, containing the information submitted by the Member States for the previous calendar year. The report shall be published in the system referred to in Article 34.

8. Where the Commission becomes aware of a serious risk posed in a Member State by products subject to Union harmonisation legislation that are imported from a third country, it shall recommend to the Member State concerned that it takes appropriate market surveillance measures.

9. The Commission shall specify further by means of implementing acts the details of the data to be submitted by Member States under paragraph 7. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.

Article 27

Suspension of release for free circulation

1. Authorities designated under Article 26(1) shall suspend the release of a product for free circulation if, in the course of controls referred to in Article 26, it is established that:

   (a) the product is not accompanied by the documentation required by the Union harmonisation legislation applicable to it;

   (b) the product is not marked or labelled in accordance with that Union harmonisation legislation;

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

   (d) the identity and contact details of a person responsible for compliance information with respect to the product is not indicated or identifiable in accordance with Article 4(5);

   (e) for any other reason, there is cause to believe that the product will not comply with the requirements set out in the Union harmonisation legislation applicable to it when it is placed on the market or that it will pose a serious risk.

2. Authorities designated under Article 26(1) shall immediately notify the market surveillance authorities of any suspension of release referred to in paragraph 1.

3. Where the market surveillance authorities have reason to believe that a product will not comply with the Union harmonisation legislation applicable to it or will pose a serious risk, they shall require the authorities designated under Article 26(1) to suspend the process for its release for free circulation.

4. During any suspension of the process for release of a product for free circulation, Articles 197, 198 and 199 of Regulation (EU) No 952/2013 shall apply accordingly.

Article 28

Release of products

Where the release of a product for free circulation of a product has been suspended in accordance with Article 27, that product shall be released for free circulation where all the other requirements and formalities relating to such a release have been fulfilled and if any of the following conditions is satisfied:

(a) within five working days of the suspension, the authorities designated under Article 26(1) have not been requested by the market surveillance authorities to maintain the suspension;

(b) the authorities designated under Article 26(1) have been informed by the market surveillance authorities that there is cause to believe that the product, when it is placed on the market, will comply with the Union harmonisation legislation applicable to it.

A product released for free circulation in accordance with point (a) shall not be deemed to be in compliance with Union harmonisation legislation merely by reason of having been released for free circulation.

Article 29

Cooperation with authorised economic operators

1. Market surveillance authorities shall treat as a matter of priority products declared free for circulation by an authorised economic operator as set out in Article 38(2) of Regulation (EU) No 952/2013, the release of which is suspended in accordance with Article 28(1) of this Regulation.

2. Market surveillance authorities may notify the customs authorities to release such products for free circulation at the request of the authorised economic operator, provided that all the other requirements and formalities pertaining to their release have been fulfilled.

   Without prejudice to Article 47 of Regulation (EU) No 952/2013, on the basis of a request by an authorised economic operator market surveillance authorities may carry out controls on such products at a place other than the place where products have been presented to customs.

3. Market surveillance authorities and the customs authorities shall exchange information on the status of the authorised economic operators and their record of compliance related to product safety.

4. Where any non-compliance is identified in the course of controls described in the second subparagraph of paragraph 2, the market surveillance authorities shall suspend the favourable treatment provided for in paragraph 1 and the first subparagraph of paragraph 2 and shall enter details of the non-compliance in the system referred to in Article 34.

5. The Commission shall specify by means of implementing acts the data to be exchanged and the procedure to be followed for the exchange of information between customs authorities and market surveillance authorities on the status of authorised economic operators and their compliance related to product safety. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.

Article 30

Refusal to release

1. Where the market surveillance authorities conclude that a product presents a serious risk, they shall take measures to prohibit the placing of the product on the market and shall require the authorities designated under Article 26(1) not to release it for free circulation. They shall also require these authorities to include the following notice on the commercial invoice accompanying the product and on any other relevant accompanying document, including in the customs data-processing system:

   'Dangerous product – release for free circulation not authorised – Regulation [Reference to this Regulation to be added]';

   Market surveillance authorities shall immediately enter that information into the system referred to in Article 34.

2. Where market surveillance authorities conclude that a product may not be placed on the market as it does not comply with the Union harmonisation legislation applicable to it, they shall take measures to prohibit the placing of the product on the market and shall require the authorities designated under Article 26(1) not to release it for free circulation. They shall also require these authorities to include the following notice on the commercial invoice accompanying the product and on any other relevant accompanying document, including in the customs data-processing system:

   'Product not in conformity – release for free circulation not authorised – Regulation [Reference to this Regulation to be added].'

   Market surveillance authorities shall immediately enter that information into the system referred to in Article 34.

3. Where the product referred to in paragraph 1 or 2 is subsequently declared for a customs procedure other than release for free circulation and provided that the market surveillance authorities do not object, the notices required by paragraph 1 or 2 shall also be included, under the same conditions as required by that paragraph, on the documents used in connection with that procedure.

4. Authorities designated under Article 26(1) may destroy or otherwise render inoperable a product which presents a risk to the health and safety of end-users where it is deemed, by the authority in question, necessary and proportionate to do so. The cost of such action shall be borne by the person declaring the product for free circulation.

   Articles 197, 198 and 199 of Regulation (EU) No 952/2013 shall apply accordingly.

Chapter VIII

Coordinated enforcement and international cooperation

Article 31

Union Product Compliance Network

An Union Product Compliance Network ('the Network') is hereby established.

Article 32

Composition of the Union Product Compliance Network

1. The Network shall be composed of a Union Product Compliance Board ('EUPC Board'), administrative coordination groups and a secretariat.
2. The EUPC Board shall consist of one representative from each of the single liaison offices referred to in Article 11, and two representatives from the Commission, and their respective alternates.
3. The Commission shall establish separate or joint administrative coordination groups for all the instruments of Union harmonisation legislation listed in the Annex to this Regulation. Each administrative coordination group shall be composed of representatives of the competent national market surveillance authorities and, if appropriate, representatives of the single liaison offices, and representatives of the relevant business associations and of consumer associations.
4. The secretariat shall be composed of Commission staff.
5. The Commission may attend the meetings of the administrative coordination groups.

Article 33

Coordinated enforcement tasks

1. The Commission shall have the following tasks:

(a) to adopt and monitor the implementation of the work programme of the Network on the basis of a proposal from the Secretariat;

(b) to support the functioning of the Product Contact Points referred to in Article 6;

(c) to coordinate the activities of the single liaison offices referred to in Article 11;

(d) to support the establishment and functioning of Union testing facilities referred to in Article 20;

(e) to apply the instruments of international cooperation referred to in Article 35;

(f) to organise cooperation and the effective exchange of information and best practices between market surveillance authorities;

(g) to develop and maintain the system referred to in Article 34, including the interface with the EU Single Window referred to in paragraph 4 of that Article, and provide information to the general public by means of that system;

(h) to organise the meetings of the EUPC Board and administrative coordination groups referred to in Articles 32;

(i) to assist the Network to perform preliminary or ancillary work in connection with the implementation of market surveillance activities linked to the application of Union harmonisation 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 to prepare and assist in the implementation of Union market surveillance campaigns and similar activities;

(j) to organise peer reviews, common training programmes and facilitate exchanges of personnel between market surveillance authorities and, where appropriate, with the market surveillance authorities of third countries or with international organisations;

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

(l) to facilitate technical or scientific expertise for the purpose of implementing market surveillance administrative cooperation;

(m) to examine, on its own initiative or at the request of the EUPC Board, any question covering the application of this Regulation and issue guidelines, recommendations and best practices in order to encourage consistent application of this Regulation, including by setting standards for minimum penalties.

2. The EUPC Board shall have the following tasks:

(a) to define the priorities for common market surveillance actions;

(b) to ensure the coordination and monitoring of the administrative coordination groups and their activities;

(c) to assist in the drawing up and implementation of the memoranda of understanding referred to in Article 8;

(d) to adopt rules of procedure for itself and for the functioning of the administrative coordination groups.

3. The administrative coordination groups shall have the following tasks:

(a) to coordinate the enforcement of Union harmonisation legislation within their area of competence;

(b) to ensure that the enforcement action taken by national market surveillance authorities is followed up across the Union;

(c) to increase the efficiency of market surveillance throughout the single market bearing in mind the existence of different systems of market surveillance in the Member States;

(d) to establish appropriate communication channels between national market surveillance authorities and the Network;

(e) to establish and coordinate common actions such as cross-border market surveillance activities;

(f) to develop common practices and methodologies for effective market surveillance;

(g) to inform each other of national market surveillance methods and activities and to develop and promote best practices;

(h) to identify issues of shared interest relating to market surveillance and suggest common approaches to be adopted.

Article 34

Information and communication system

1. The Commission shall **further** develop and maintain an information and communication system for the collection and storage of information, in a structured form, on issues relating to the enforcement of Union harmonisation legislation. The Commission, **market surveillance authorities,** single liaison offices, and authorities designated in accordance with Article 26(1) shall have access to that system.

2. Single liaison offices shall enter the following information in the system:

   (a) the identity of the market surveillance authorities in their Member State and areas of competence of those authorities pursuant to Article 11(1);

   (b) the identity of the authorities designated by their Member States as authorities in charge of controls on products at the external borders of the Union.

   (ba) [*moved from paragraph 3*] the national market surveillance strategy drawn up by their Member State under Article 13;

3. Market surveillance authorities shall enter the following information into the system:

   ~~(a) details of the national market surveillance strategies strategy drawn up by their Member State under Article 13;~~

   (b) any partnership arrangements entered into by them under Article 7;

   (c) the results from the monitoring, review and assessment of the market surveillance strategy drawn up by their Member State;

   (d) ~~all~~ **relevant** complaints received by them and reports made by them about issues relating to non-compliant products;

   [*moved from Article 12(4)*]

   (da) the type, number and outcome of the checks performed by them;

   (db) the type and the number of non-compliances detected by them;

   (dc) the nature of the temporary measures taken by them against economic operators and of the corrective action taken by economic operators;

   (dd) details of the cases of non-compliance where penalties were imposed by them.

(e) in relation to products made available on the market in their territory, without prejudice to Article 12 of Directive 2001/95/EC and Article 19 of this Regulation, the following information:

(i) any non-compliance;

(ii) the identification of hazards and the economic operator concerned;

(iii) any possible risks not restricted to their territory;

(iv) the results of testing carried out by them or the concerned economic operator;

(v) details of voluntary measures taken by economic operators;

(vi) details of restrictive measures taken by that market surveillance authority, where applicable, the penalties imposed;

(vii) the outcome of contacts with an economic operator and the follow up by that economic operator;

(viii) failures by a person responsible for compliance information to comply with Article 4 (3);

(ix) failures by manufacturers to comply with Article 4(4)**;**

(x) any objection raised by a Member State in accordance with the applicable safeguard procedure in the Union harmonisation legislation applicable to the product and any subsequent follow-up.

(f) in relation to products entering the Union market for which the process for the release for free circulation has been suspended in accordance with Article 27, in their territory, the following information:

(i) any non-compliance;

(ii) the identification of any hazards and the economic operator concerned;

(iii) the results of testing carried out by them or the concerned economic operator;

(iv) details of restrictive measures taken by that market surveillance authority and, where applicable, the penalties imposed;

(v) the outcome of contacts with an economic operator and the follow up by that economic operator;

(vi) any other control or test reports carried out by or at the request of the market surveillance authority;

(vii) any objection raised by a Member State in accordance with the applicable safeguard procedure in the Union harmonisation legislation applicable to the product and any subsequent follow-up.

(fa) [*partly moved from paragraph 5*] information related to the recognition of the validity of test reports prepared by or for their counterparts in other Member States.

4. Where relevant for the enforcement of Union harmonisation legislation and for the purposes of minimising risk and combating fraud, customs authorities shall extract from national customs systems and transmit to the information and communication system data relating to the placing of products under the customs procedure 'release for free circulation' and the results of controls related to product safety.

   The Commission, in the context of the EU Single Window environment for customs, shall develop an electronic interface to enable the transmission of such data. This interface shall be in place [four years] from the date of adoption of the implementing acts.

~~5.~~ **[*moved to Article 12*]** ~~Market surveillance authorities shall recognise the validity of and shall make use of test reports prepared by or for their counterparts in other Member States and which have been entered into the information and communication system.~~

6. The Commission shall adopt implementing acts specifying the details of implementation arrangements for paragraphs 1 to 4 and defining the data to be transmitted in accordance with paragraph 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.

Article 35

International cooperation

1. The Commission may exchange confidential market surveillance related information with regulatory authorities of third countries or international organisations where it has concluded confidentiality arrangements based on reciprocity with those authorities or organisations.

2. The Commission may set up a framework for cooperation and exchange of selected information contained in the information exchange system provided for in Article 12 of Directive 2001/95/EC, with applicant countries, third countries or international organisations. The cooperation or exchange of information may relate, inter alia, to the following:

   (a) risk assessment methods used and the results of product-testing;

   (b) coordinated product recalls or other similar actions;

   (c) the measures taken by market surveillance authorities under Article 15.

3. The Commission may approve a specific system of product-related pre-export control carried out by a third country on products immediately prior to their export into the Union in order to verify that those products satisfy the requirements of the Union harmonisation legislation applicable to them. The approval may be granted in respect of one or more products, in respect of one or more categories of product or in respect of products or categories of product manufactured by certain manufacturers.

4. Where such an approval has been granted, the number and frequency of import controls for those products or categories of product entering the Union market, referred to in paragraph 3, may be reduced.

   Customs authorities may however carry out controls those products or categories of product entering the Union market, in order to ensure that the pre-export controls carried out by the third country are effective to determine compliance with Union harmonisation legislation.

5. Approval may only be granted to a third country under paragraph 3 following an audit within the Union demonstrating that the following conditions are satisfied:

   (a) products exported to the Union from that third country satisfy the requirements set out in Union harmonisation legislation;

   (b) the controls carried out in that third country are sufficiently effective and efficient to replace or reduce the documentary and physical controls laid down in such legislation.

6. The approval referred to in paragraph 3 shall specify the competent authority of the third country under whose responsibility the pre-export controls are to be performed and that competent authority shall be the counterpart for all contacts with the Union.

7. The competent authority, referred to in paragraph 6, shall ensure the official verification of the products prior to their entry into the Union.

8. Where controls on products entering the Union market referred to in paragraph 3 reveal significant non-compliance, the market surveillance authorities shall notify immediately the Commission through the system referred to in Article 34 and increase the number of controls on such products.

9. The Commission shall withdraw an approval granted under paragraph 3 where it is revealed that the products entering the Union market do not comply with Union harmonisation legislation in a significant number of instances.

10. The Commission shall adopt implementing acts for the implementation of the system of product-related pre-export controls, referred to in paragraph 3, for specifying a model for the certificates of compliance or verification to be used. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.

Chapter IX

Financial provisions

Article 36

Financing activities

1. The Union shall finance performance of the tasks of the Network referred to in Article 34.

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

   (a) the functioning of the Product Contact Points referred to in Article 6;

   (b) the establishment and functioning of Union testing facilities referred to in Article 20;

   (c) the development of instruments of international cooperation referred to in Article 35;

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

   (e) 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;

   (f) the implementation of national market surveillance strategies referred to in Article 13 and Member States' and Union market surveillance campaigns;

   (g) activities carried out under programmes providing technical assistance, cooperation with third countries and the promotion and enhancement of Union market surveillance policies and systems amongst interested parties at Union and international levels.

3. The financing of the electronic interface referred to in Article 34(4) shall be shared between the Union and the Member States. The Union shall be responsible for financing the central module and link to the Network. Member States shall be responsible for financing the adaptation of their national systems.

4. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council[39], either directly, or by delegating budget implementation tasks to the entities listed in Article 58(1)(c) of that Regulation.

5. 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.

6. The appropriations determined by the budgetary authority for the financing of market surveillance activities may also cover expenses relating to preparatory work, monitoring, control, audit and evaluation activities which are required for the management of the activities set out in this Regulation and for the achievement of their objectives. These expenses shall include the costs of conducting studies, arranging meetings of experts, information and communication actions, including corporate communication of the political priorities of the Union insofar 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 related technical and administrative assistance expenses incurred by the Commission.

[39] Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002(OJ L 298, 26.10.2012, p. 1).

Article 37

Protection of the Union's financial interests of the Union

1. The Commission shall take appropriate measures to ensure 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 controls and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.

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

3. The European Anti-fraud Office (OLAF) may carry out investigations, including on-the-spot controls and inspections, in accordance with the procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[40] and Council Regulation (Euratom, EC) No 2185/96[41] with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under this Regulation.

4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and with international organisations, contracts, grant agreements and grant decisions resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, in accordance with their respective competences.

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40 Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

41 OJ L292, 14.11.1996, p.2.

Chapter X

Final provisions

Article 38

Applicability of Regulation (EC) 765/2008 and amendments to Union harmonisation legislation

Articles 15 to 29 of Regulation (EC) 765/2008 shall not apply to Union harmonisation legislation set out in the Annex.

Article 39

Amendments to Directive 2004/42/EC

Articles 6 and 7 of Directive 2004/42/EC are deleted.

Article 40

Amendments to Directive 2009/48/EC

Directive 2009/48/EC is amended as follows:

(1) Article 40 is deleted;

(2) In Article 42, paragraph 1 is deleted;

(3) Article 44 is deleted.

Article 41

Amendments to Directive 2010/35/EU

Directive 2010/35/EU is amended as follows:

(1) Article 16 is deleted;

(2) In Article 30, paragraph 1 is deleted.

Article 42

Amendments to Regulation (EU) No 305/2011

In Article 56 of Regulation (EU) No 305/2011, paragraph 1 is deleted.

Article 43

Amendments to Regulation (EU) No 528/2012

In Article 65 of Regulation (EU) No 528/212 of the European Parliament and of the Council, the second sentence of paragraph 1 is replaced by the following:

> 'Regulation (EU) 2018/[XX Please insert number of this Regulation] of the European Parliament and of the Council* shall apply accordingly.'
>
> * Regulation (EU) 2018/[XX Please insert number of this Regulation] of the European Parliament and of the Council of [Please insert date and full title of this Regulation and the OJ reference in brackets].

Article 44

Amendments to Directive 2013/29/EU

Directive 2013/29/EUis amended as follows:

(1) In Article 38, paragraph 2 is deleted;

(2) In Article 39(1), the fourth subparagraph is deleted.

Article 45

Amendments to Directive 2013/53/EU

Directive 2013/53/EUis amended as follows:

(1) Article 43 is deleted;

(2) In Article 44(1), the fifth subparagraph is deleted.

Article 46

Amendments to Directive 2014/28/EU

Directive 2014/28/EUis amended as follows:

(1) In Article 41, the first paragraph is deleted;

(2) In Article 42(1), the fourth subparagraph is deleted.

Article 47

Amendments to Directive 2014/29/EU

Directive 2014/29/EU is amended as follows:

(1) Article 34 is deleted;

(2) In Article 35(1), the fourth subparagraph is deleted.

Article 48

Amendments to Directive 2014/30/EU

Directive 2014/30/EUis amended as follows:

(1) Article 37 is deleted;

(2) In Article 38(1), the fourth subparagraph is deleted.

Article 49

Amendments to Directive 2014/31/EU

Directive 2014/31/EU is amended as follows:

(1) Article 36 is deleted;

(2) In Article 37(1), the fourth subparagraph is deleted.

Article 50

Amendments to Directive 2014/32/EU

Directive 2014/32/EU is amended as follows:

(1) Article 41 is deleted;

(2) In Article 42(1), the fourth subparagraph is deleted.

Article 51

Amendments to Directive 2014/33/EU

Directive 2014/33/EU is amended as follows:

(1) Article 37 is deleted;

(2) In Article 38(1), the fifth subparagraph is deleted.

Article 52

Amendments to Directive 2014/34/EU

Directive 2014/34/EU is amended as follows:

(1) Article 34 is deleted;

(2) In Article 35(1), the fourth subparagraph is deleted.

Article 53

Amendments to Directive 2014/35/EU

Directive 2014/35/EU is amended as follows:

(1) Article 18 is deleted;

(2) In Article 19(1), the third subparagraph is deleted.

Article 54

Amendments to Directive 2014/53/EU

Directive 2014/53/EU is amended as follows:

(1) Article 39 is deleted;

(2) In Article 40(1), the fourth subparagraph is deleted.

Article 55

Amendments to Directive 2014/68/EU

Directive 2014/68/EU is amended as follows:

(1) Article 39 is deleted;

(2) In Article 40(1), the third subparagraph is deleted.

Article 56

Amendments to Directive 2014/90/EU

Directive 2014/90/EU is amended as follows:

(1) In Article 12, paragraph 10 is deleted;

(2) In Article 25, paragraph 1 is replaced by the following:

'As regards marine equipment, the Member States shall undertake market surveillance in accordance with the EU market surveillance framework laid down in Regulation [number of the new Enforcement Regulation], subject to paragraph 2 and 3 of this Article.'

(3) In Article 25, paragraph 4 is deleted;

(4) In Article 26(1), the fourth subparagraph is deleted.

Article 57

Amendments to Regulation (EU) 2016/424

Regulation (EU) 2016/424 is amended as follows:

(1) Article 39 is deleted;

(2) In Article 40(1), the fourth subparagraph is deleted.

Article 58

Amendments to Regulation (EU) 2016/425

Regulation (EU) 2016/425 is amended as follows:

(1) Article 37 is deleted;

(2) In Article 38(1), the fourth subparagraph is deleted.

Article 59

Amendments to Regulation (EU) 2016/426

Regulation (EU) 2016/426is amended as follows:

(1) Article 36 is deleted;

(2) In Article 37(1), the fourth subparagraph is deleted.

Article 60

Amendments to Regulation (EU) 2017/1369

Regulation (EU) 2017/1369 is amended as follows:

(1) In Article 8, paragraphs 1 and 3 are deleted;

(2) In Article 9(2), the second subparagraph is deleted.

Chapter XI

Penalties, evaluation, committee procedure and entry into force and application

Article 61

Penalties

1. 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 shall be effective, proportionate and dissuasive.

   The Member States shall notify those provisions to Commission, by [31 March 2020], notify the Commission of those rules and of those measures and shall notify it without delay of any subsequent amendment affecting them.

2. When a decision is being made whether to impose a penalty in each individual case, due regard shall be given to the following:

   (a) the financial situation of small and medium-sized enterprises;

   (b) the nature, gravity and duration of the non-compliance taking into account the harm caused to end-users;

   (c) the intentional or negligent character of the infringement;

   (d) the level of cooperation shown by the economic operator during the period of the investigation carried out by the market surveillance authorities;

   (e) any relevant similar infringements previously committed by the economic operator.

3. The penalties may be increased where the economic operator has previously committed a similar infringement and may include criminal penalties for serious infringements of Union harmonisation legislation.

4. The Member States shall ensure that financial penalties for intentional infringements of Union harmonisation legislation shall as a minimum offset the economic advantage arising from the infringement.

5. Member States shall ensure, in particular, that penalties can be imposed where the economic operator fails or refuses to cooperate during market surveillance controls and activities.

Article 62

Evaluation

By [31 December 2024] and every five years thereafter, the Commission shall carry out an evaluation of this Regulation against the objectives it pursues and present a report on the main findings to the European Parliament, to the Council and to the European Economic and Social Committee.

The report shall assess whether this Regulation achieved its objectives, in particular with regard to reducing the number of non-compliant products on the Union market, ensuring effective and efficient enforcement of Union harmonisation legislation within the Union, improving cooperation between competent authorities and strengthening the controls on products entering the Union market, whilst taking into account the impact on business and in particular on small and medium-sized enterprises. In addition, the evaluation should also assess the effectiveness of the market surveillance activities that receive Union financing in the light of the requirements of Union policies and legislation.

Article 63

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 64

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from [1 January 2020].

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

Done at Brussels,

For the European Parliament	For the Council
The President	The President

ANNEX

List of Union harmonisation legislation

1. Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (OJ L 326, 29.12.1969, p. 599);
2. Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (OJ L 042 , 23.02.1970, p. 16-20);
3. Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14–20);
4. Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 147, 9.6.1975, p. 40–47);
5. Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products (OJ L 46, 21.2.1976, p. 1–11);
6. Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40–50);
7. Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ L 167, 22.6.1992, p. 17–28);
8. Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer (OJ L 100, 19.4.1994, p. 37–41);
9. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10–23);
10. Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC (OJ L 350, 28.12.1998, p. 58–68);
11. Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1–78);
12. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34–43);
13. Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1–194);
14. ~~Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1–10);~~

15. Regulation (EC) No 552/2004 of the European Parliament and of the Council of 10 March 2004 on the interoperability of the European Air Traffic Management network (the interoperability Regulation) (OJ L 96, 31.3.2004, p. 26–42);

16. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1–35);

17. Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7–49);

18. Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC (OJ L 143, 30.4.2004, p. 87–96);

19. Directive 2004/52/EC of the European Parliament and of the Council of 29 April 2004 on the interoperability of electronic road toll systems in the Community (OJ L 200, 7.6.2004, p. 50–57);

20. Directive 2005/64/EC of the European Parliament and of the Council of 26 October 2005 on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC (OJ L 310, 25.11.2005, p. 10–27);

21. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery (OJ L 157, 9.6.2006, p. 24–86);

22. Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles and amending Council Directive 70/156/EEC (OJ L 161, 14.6.2006, p. 12–18);

23. Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (OJ L 266, 26.9.2006, p. 1–14);

24. Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p.1);

25. Regulation (EC) No 715/2007 of the European Parliament and of the Council of 20 June 2007 on type approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information (OJ L 171, 29.6.2007, p. 1–16);

26. Directive 2007/45/EC of the European Parliament and of the Council of 5 September 2007 laying down rules on nominal quantities for pre-packed products, repealing Council Directives 75/106/EEC and 80/232/EEC, and amending Council Directive 76/211/EEC (OJ L 247, 21.9.2007, p. 17–20);

27. Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (OJ L 263, 9.10.2007, p. 1–160);

28. Directive 2008/2/EC of the European Parliament and of the Council of 15 January 2008 on the field of vision and windscreen wipers for wheeled agricultural or forestry tractors (Codified version) (OJ L 24, 29.1.2008, p. 30–38);

29. 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1–1355);

30. Regulation (EC) No 78/2009 of the European Parliament and of the Council of 14 January 2009 on the type-approval of motor vehicles with regard to the protection of pedestrians and other vulnerable road users, amending Directive 2007/46/EC and repealing Directives 2003/102/EC and 2005/66/EC (OJ L 35, 4.2.2009, p. 1–31);

31. Regulation (EC) No 79/2009 of the European Parliament and of the Council of 14 January 2009 on type-approval of hydrogen-powered motor vehicles, and amending Directive 2007/46/EC (OJ L 35, 4.2.2009, p. 32–46);

32. Directive 2009/34/EC of the European Parliament and of the Council of 23 April 2009 relating to common provisions for both measuring instruments and methods of metrological control (OJ L 106, 28.4.2009, p. 7–24);

33. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1–37);

34. Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC (OJ L 188, 18.7.2009, p. 1–13);

35. Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning type-approval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor (OJ L 200, 31.7.2009, p. 1–24);

36. Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10–35);

37. Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer (OJ L 286, 31.10.2009, p. 1–30);

38. Regulation (EC) No 1222/2009 of the European Parliament and of the Council of 25 November 2009 on the labelling of tyres with respect to fuel efficiency and other essential parameters (OJ L 342, 22.12.2009, p. 46–58);

39. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59–209);

40. Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (OJ L 27, 30.1.2010, p. 1–19);

41. Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment (OJ L 165, 30.6.2010, p. 1–18);

42. Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC (OJ L 88, 4.4.2011, p. 5–43);

43. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88–110);

44. Regulation (EU) No 1007/2011 of the European Parliament and of the Council of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC of the European Parliament and of the Council (OJ L 272, 18.10.2011, p. 1–64);

45. 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 (OJ L 167, 27.6.2012, p. 1–123);

46. Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38–71);

47. Regulation (EU) No 167/2013 of the European Parliament and of the Council of 5 February 2013 on the approval and market surveillance of agricultural and forestry vehicles (OJ L 60, 2.3.2013, p. 1–51);

48. Regulation (EU) No 168/2013 of the European Parliament and of the Council of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles (OJ L 60, 2.3.2013, p. 52–128);

49. Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles (OJ L 178, 28.6.2013, p. 27–65);

50. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90–131);

51. Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (OJ L 96, 29.3.2014, p. 1–44);

52. Directive 2014/29/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of simple pressure vessels (OJ L 96, 29.3.2014, p. 45–78);

53. Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility (OJ L 96, 29.3.2014, p. 79–106);

54. Directive 2014/31/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of non-automatic weighing instruments (OJ L 96, 29.3.2014, p. 107–148);

55. Directive 2014/32/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of measuring instruments (OJ L 96, 29.3.2014, p. 149–250);

56. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251–308);

57. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309–356);

58. Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357–374);

59. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62–106);

60. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164–259);

61. Directive 2014/90/EU of the European Parliament and of the Council of 23 July 2014 on marine equipment and repealing Council Directive 96/98/EC (OJ L 257, 28.8.2014, p. 146–185);

62. Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 (OJ L 150, 20.5.2014, p. 195–230);

63. Regulation (EU) No 540/2014 of the European Parliament and of the Council of 16 April 2014 on the sound level of motor vehicles and of replacement silencing systems, and amending Directive 2007/46/EC and repealing Directive 70/157/EEC (OJ L 158, 27.5.2014, p. 131–195);

64. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1–50);

65. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51–98);

66. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99–147);

67. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1–175);

68. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176–332);

69. Regulation (EU) 2017/852 of the European Parliament and of the Council on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1–21);

70. Regulation (EU) 2017/1369 of the European Parliament and of the Council of 4 July 2017 setting a framework for energy labelling and repealing Directive 2010/30/EU (OJ L 198, 28.7.2017, p. 1–23).'