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INFORMATION NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee/Council

Subject: Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on market surveillance and compliance of products and amending Council Directive 2004/42/EC, Regulations (EC) No 765/2008 and (EU) No 305/2011 of the European Parliament and of the Council
- Outcome of the European Parliament's first reading
(Strasbourg, 15 to 18 April 2019)

I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the joint declaration on practical arrangements for the codecision procedure¹, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this dossier at first reading, thereby avoiding the need for second reading and conciliation.

¹ OJ C 145, 30.6.2007, p. 5.

In this context, the rapporteur, Nicola DANTI (S&D, IT), presented a compromise amendment (amendment number 214) to the proposal for a Regulation on behalf of the Committee on the Internal Market and Consumer Protection. This amendment had been agreed during the informal contacts referred to above.

In addition, the EFDD political group tabled five amendments (amendments numbered 215 to 219).

II. VOTE

When it voted on 17 April 2019, the plenary adopted the compromise amendment (amendment number 214) to the proposal for a Regulation. No other amendments were adopted. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto².

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

² The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in *bold and italics*. The symbol "■" indicates deleted text.

Market surveillance and compliance of products ***I

European Parliament legislative resolution of 17 April 2019 on the 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 (COM(2017)0795 – C8-0004/2018 – 2017/0353(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2017)0795),
 - having regard to Article 294(2) and Articles 33, 114 and 207 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0004/2018),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the reasoned opinion submitted, within the framework of Protocol No 2 on the application of the principles of subsidiarity and proportionality, by the Swedish Parliament, asserting that the draft legislative act does not comply with the principle of subsidiarity,
 - having regard to the opinion of the European Economic and Social Committee of 23 May 2018¹,
 - having regard to the provisional agreement approved by the committee responsible under Rule 69f(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 15 February 2019 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
 - having regard to Rule 59 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection and the opinion of the Committee on the Environment, Public Health and Food Safety (A8-0277/2018),
1. Adopts its position at first reading hereinafter set out;

¹ OJ C 283, 10.8.2018, p. 19.

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P8_TC1-COD(2017)0353

Position of the European Parliament adopted at first reading on 17 April 2019 with a view to the adoption of Regulation (EU) 2019/... of the European Parliament and of the Council *on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011*

(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 *and* 114 thereof,

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee¹,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C 283, 10.8.2018, p. 19.

² Position of the European Parliament of 17 April 2019.

Whereas:

- (1) In order to guarantee the free movement of products within the Union, it is necessary to ensure that products ***are compliant with Union harmonisation legislation and therefore*** 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, public security ***and protection of any other public interests protected by that legislation***. 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, ***regardless of whether products are placed on the market via offline or online means and regardless of whether they are manufactured in the Union or not.***

- (2) *Union harmonisation legislation covers a large share of manufactured products. Non-compliant and unsafe products put citizens at risk, and might distort competition with economic operators selling compliant products within the Union.*
- (3) 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 of 28 October 2015 entitled ‘Upgrading the Single Market: more opportunities for people and business’. This should be achieved by strengthening market surveillance, providing economic operators with *clear, transparent and comprehensive rules*, intensifying compliance controls and promoting closer cross-border cooperation among enforcement authorities, including through cooperation with customs authorities.

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- (4) The framework *for market surveillance* established by this Regulation should complement and strengthen existing provisions in Union harmonisation legislation relating to the ensuring of compliance of products and the framework for cooperation with *organisations representing* economic operators *or end users*, the market surveillance of products and controls on those products entering the Union market. 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 Union harmonisation legislation. The corresponding provisions of this Regulation should therefore not apply in the areas covered by such specific provisions, for instance those set out in Regulations (EC) No 1223/2009¹, (EU) 2017/745² and (EU) 2017/746³, *including as regards the use of the European database on medical devices (EUDAMED), and (EU) 2018/858⁴ of the European Parliament and of the Council.*

¹ 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).

² 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).

³ 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).

⁴ ***Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1).***

- (5) Directive 2001/95/EC of the European Parliament and of the Council¹ 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 Rapid Information Exchange System (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 should be made more effective.
- (6) ***The provisions on market surveillance of*** this Regulation should cover products that are subject to the Union harmonisation legislation listed in **■ Annex I** 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 ***and will help to increase the confidence of consumers and other end users in products placed on the Union market. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to specify whether this Regulation is also to apply to that legislation.***

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

- (7) *Articles 15 to 29 of Regulation (EC) No 765/2008 of the European Parliament and of the Council¹ laying down the Community market surveillance framework and controls of products entering the Community market should be deleted and the respective provisions should be replaced by this Regulation. That framework includes the provisions on controls of products entering the Community market, in Articles 27, 28 and 29 of Regulation (EC) No 765/2008, which apply not only to products covered by the market surveillance framework, but to all products in so far as other Union law does not contain specific provisions relating to the organisation of controls on products entering the Union market. It is therefore necessary that the scope of the provisions of this Regulation with regard to products entering the Union market extend to all products.*
- (8) In order to rationalise and simplify the overall legislative framework, while simultaneously pursuing the objectives of Better Regulation, the rules applicable to controls on products entering the Union market should be revised and integrated into a single legislative framework for controls on products at the Union's external borders.

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¹ *Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).*

- (9) Responsibility for enforcing Union harmonisation legislation should lie with the Member States, and their 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. ***In this regard, the methodology and criteria for assessing risks should be further harmonised in all Member States in order to ensure a level playing field for all economic operators.***
- (10) ***In order to assist market surveillance authorities to strengthen consistency in their activities related to the application of this Regulation, an effective peer review system should be established for those market surveillance authorities wishing to participate.***
- (11) Certain definitions currently set out in Regulation (EC) No 765/2008 should be aligned with definitions set out in other Union legal acts and, where appropriate, reflect the architecture of modern supply chains. ***The definition of ‘manufacturer’ in this Regulation should not relieve manufacturers of any obligations they might have under Union harmonisation legislation where specific definitions of manufacturer are applied, which might cover 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 might be affected and places it on the market, or any other natural or legal person who places a product on the market under its name or trade mark.***

- (12) 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 corresponding to the roles of each of the economic operators in the supply and distribution process pursuant to specific provisions in Union harmonisation legislation, and the manufacturer should retain ultimate responsibility for compliance of the product with requirements in the Union harmonisation legislation.

(13) *The challenges of the global market and increasingly complex supply chains, as well as the increase of products that are offered for sale online to end users within the Union, call for the strengthening of enforcement measures, to ensure the safety of consumers. Furthermore, practical experience of market surveillance has shown that such supply chains sometimes involve economic operators whose novel form means that they do not fit easily into the traditional supply chains according to the existing legal framework. Such is the case, in particular, with fulfilment service providers, which perform many of the same functions as importers but which might not always correspond to the traditional definition of importer in Union law. In order to ensure that market surveillance authorities can carry out their responsibilities effectively and to avoid a gap in the enforcement system, it is appropriate to include fulfilment service providers within the list of economic operators against whom it is possible for market surveillance authorities to take enforcement measures. By including fulfilment service providers within the scope of this Regulation, market surveillance authorities will be better able to deal with new forms of economic activity in order to ensure the safety of consumers and the smooth functioning of the internal market, including where the economic operator acts both as an importer as regards certain products and as a fulfilment service provider as regards other products.*

- (14) 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 roles 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 *Union harmonisation legislation listed in Annex I to this Regulation, such as the producer of an article and the downstream user as defined in Regulation (EC) No 1907/2006 of the European Parliament and of the Council¹ and in Regulation (EC) No 1272/2008 of the European Parliament and of the Council², the installer as defined in Directive 2014/33/EU of the European Parliament and of the Council³, the supplier as defined in Regulation (EC) No 1222/2009 of the European Parliament and of the Council⁴ or the dealer as defined in Regulation (EU) 2017/1369 of the European Parliament and of the Council⁵.*

¹ *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).*

² *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).*

³ *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).*

⁴ *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).*

⁵ *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).*

(15) *In the case of a product offered for sale online or through other means of distance sales, the product should be considered to have been made available on the market if the offer for sale is targeted at end users in the Union. In line with the applicable Union rules on private international law, a case-by-case analysis should be carried out in order to establish whether an offer is targeted at end users in the Union. An offer for sale should be considered to be targeted at end users in the Union if the relevant economic operator directs, by any means, its activities to a Member State. For the case-by-case analyses, relevant factors, such as the geographical areas to which dispatch is possible, the languages available, used for the offer or for ordering, or means of payment, need to be taken into consideration. In the case of online sales, the mere fact that the economic operators' or the intermediaries' website is accessible in the Member State in which the end user is established or domiciled is insufficient.*

- (16) The development of e-commerce is also due, to a great extent, to the proliferation of information society service providers, usually through platforms and for remuneration, which offer intermediary services by storing third party content, without exercising control over that content, and therefore not acting on behalf of an economic operator. Removal of content regarding non-compliant products or, where this is not feasible, *restricting* 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 Council¹. In particular, no general obligation should be imposed on information society 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.

¹ Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce) (OJ L 178, 17.7.2000, p. 1).

- (17) *While this Regulation does not deal with the protection of intellectual property rights, it should nevertheless be borne in mind that often counterfeit products do not comply with the requirements set out in the Union harmonisation legislation, present risks to health and safety of end users, distort competition, endanger public interests and support other illegal activities. Therefore, Member States should continue taking effective measures to prevent counterfeit products from entering the Union market pursuant to Regulation (EU) No 608/2013 of the European Parliament and of the Council¹.*
- (18) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this end, 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, *for certain products*, there should be *an economic operator* established in the Union so that market surveillance authorities have someone to whom *requests* can be addressed, *including requests for information* regarding a product's compliance with Union harmonisation legislation, *and who can cooperate with market surveillance authorities in making sure that immediate corrective action is taken to remedy instances of non-compliance. The economic operators who should perform those tasks are the manufacturer, or the importer when the manufacturer is not established in the Union, or an authorised representative mandated by the manufacturer for this purpose, or a fulfilment service provider established in the Union for products handled by it when no other economic operator is established in the Union.*

¹ *Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003 (OJ L 181, 29.6.2013, p. 15).*

- (19) *The development of e-commerce poses certain challenges for market surveillance authorities with regard to the ensuring of compliance of products offered for sale online and the effective enforcement of Union harmonisation legislation. The number of economic operators offering products directly to consumers by electronic means is increasing. Therefore, economic operators with tasks regarding products subject to certain Union harmonisation legislation perform an essential role by providing market surveillance authorities with an interlocutor established in the Union, and by performing specific tasks in a timely manner to make sure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, other end users and businesses within the Union.*
- (20) *The obligations of the economic operator with tasks regarding products subject to certain Union harmonisation legislation should be without prejudice to existing obligations and responsibilities of manufacturer, importer and authorised representative under the relevant Union harmonisation legislation.*

(21) Obligations of this Regulation requiring an economic operator to be established in the Union in order to place products on the Union's market should only apply to areas where the need for an economic operator to act as a liaison point with the market surveillance authorities has been identified, taking into account a risk-based approach, having regard to the principle of proportionality, and taking into account high level of protection of end users in the Union.

(22) *Moreover, those obligations should not apply where the specific requirements set out in certain legal acts on products achieve in effect the same result, namely Regulation (EC) No 648/2004 of the European Parliament and of the Council¹, Regulation (EC) No 1223/2009, Regulation (EU) No 167/2013 of the European Parliament and of the Council², Regulation (EU) No 168/2013 of the European Parliament and of the Council³, Directive 2014/28/EU of the European Parliament and of the Council⁴, Directive 2014/90/EU of the European Parliament and of the Council⁵, Regulation (EU) 2016/1628 of the European Parliament and of the Council⁶, Regulation (EU) 2017/745, Regulation (EU) 2017/746, Regulation (EU) 2017/1369 and Regulation (EU) 2018/858. Consideration should also be given to situations where potential risks or cases of non-compliance are low, or in which products are mainly traded through traditional supply chains, which is the case, for instance, for Directive 2014/33/EU, Regulation*

¹ *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).*

² *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).*

³ *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).*

⁴ *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).*

⁵ *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).*

⁶ *Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).*

(EU) 2016/424/EU of the European Parliament and of the Council¹ and Directive 2010/35/EU of the European Parliament and of the Council².

¹ ***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).***

² ***Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1).***

- (23) *Contact information of economic operators with tasks regarding products subject to certain Union harmonisation legislation should be indicated with the product in order to facilitate checks throughout the supply chain.*
- (24) Economic operators should fully cooperate with market surveillance authorities and other competent authorities to ensure the smooth performance of market surveillance and to enable the authorities to perform their tasks. *This includes, where requested by authorities, providing the contact information of the economic operators with tasks regarding products subject to certain Union harmonisation legislation where this information is available to them.*
- (25) *Economic operators should have easy access to high quality, comprehensive information. Since the single digital gateway established under Regulation (EU) 2018/1724 of the European Parliament and of the Council¹ provides for a single point of online access to information, it can be used in respect to providing relevant information on Union harmonisation legislation to economic operators. Nevertheless, Member States should put in place procedures for ensuring access to the Product Contact Points established under Regulation (EU) 2019/... of the European Parliament and of the Council²⁺ in order to assist the economic operators in addressing properly their requests for information. Guidance on issues relating to technical specifications or harmonised standards or design of a specific product should not be part of the obligations of Member States when providing such information.*

¹ *Regulation (EU) 2018/1724 of the European Parliament and of the Council of 2 October 2018 establishing a single digital gateway to provide access to information, to procedures and to assistance and problem-solving services and amending Regulation (EU) No 1024/2012 (OJ L 295, 21.11.2018, p. 1).*

² *Regulation (EU) 2019/... of the European Parliament and of the Council of ... on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 (OJ L ...).*

⁺ *OJ: please insert the number in the text, and the number, the date and the publication reference of the document in PE-CONS 70/18 - COD 2017/0354 in the footnote.*

- (26) *Market surveillance authorities might carry out joint activities with other authorities or organisations representing economic operators or end users, with a view to promoting compliance, identifying non-compliance, raising awareness and providing guidance on Union harmonisation legislation and with respect to specific categories of products, including those that are offered for sale online.*
- (27) Member States should designate their own market surveillance authorities. ***This Regulation should not prevent Member States from choosing the competent authorities to carry out the market surveillance tasks.*** In order to facilitate administrative assistance and cooperation, Member States should also ***appoint*** a single liaison office. Single liaison offices should ***at least represent the coordinated position of the market surveillance authorities and the authorities in charge of the control on products entering the Union market.***
- (28) *E-commerce poses certain challenges for market surveillance authorities regarding the protection of the health and safety of end users from non-compliant products. Therefore, Member States should ensure their market surveillance is organised with the same effectiveness for products made available online as it is for products made available offline.*

- (29) *While performing market surveillance of products offered for sale online, market surveillance authorities are facing numerous difficulties, such as tracing products offered for sale online, identifying the responsible economic operators, or conducting risk-assessments or tests due to the lack of physical access to products. In addition to the requirements introduced by this Regulation, Member States are encouraged to use complementary guidance and best practices for market surveillance and for communication with businesses and consumers.*
- (30) *Special attention should be given to emerging technologies, taking into account that consumers are increasingly using connected devices in their daily lives. The Union regulatory framework should therefore address the new risks to ensure the safety of the end users.*
- (31) *In the age of constant development of digital technologies new solutions that could contribute to the effective market surveillance within the Union should be explored.*

- (32) Market surveillance 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 ***on a risk-based approach***, taking ***the interests of those economic operators*** into account and limiting the said burden to what is necessary for the performance of efficient and effective controls. Furthermore, market surveillance 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. ***Uniform conditions for certain inspection activities carried out by the market surveillance authorities where products or categories of products present specific risks or seriously breach the applicable Union harmonisation legislation might be laid down by the Commission.***
- (33) ***Market surveillance authorities, when performing their duties, are confronted with different shortcomings in terms of resources, coordination mechanisms, as well as powers with regard to non-compliant products. Such differences lead to fragmented enforcement of Union harmonisation legislation and to market surveillance being more rigorous in some Member States than in others, potentially compromising the level playing field among businesses and creating also potential imbalances in the level of product safety throughout the Union.***

- (34) 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.
- (35) This Regulation should be without prejudice to the freedom of Member States to choose the enforcement system that they consider to be appropriate. Member States should be free to choose whether their market surveillance authorities can exercise investigation and enforcement directly under their own authority, *by recourse to other public authorities* or upon application to the competent courts.

- (36) 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.
- (37) 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, data or information 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 economic operators, including those in the digital value chain, to provide all the evidence, data and information necessary.
- (38) 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 its trade, business, craft or profession.
- (39) Market surveillance authorities should be able to require *a* representative or *a relevant* 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 *relevant* member of staff.

- (40) 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 acquire products and, where the evidence cannot be obtained by other means, to purchase products under a cover identity.
- (41) 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 its 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 **■** measures, *where duly justified and proportionate and* where there are no other means available to prevent or mitigate such harm, including, where necessary, *requiring the removal of content from the online interface or the display of a warning. When such a request is not observed, the relevant authority should have the power to require information society service providers to restrict access to the online interface. These measures should be taken* in accordance with the principles laid down in Directive 2000/31/EC. **■**

- (42) *The implementation of this Regulation and the exercise of powers in its application should also comply with other Union and national law, for example Directive 2000/31/EC, including with applicable procedural safeguards and principles of the fundamental rights. That implementation and that exercise of powers should also be proportionate and adequate in view of the nature and the overall actual or potential harm caused by the infringement. Competent authorities should take all facts and circumstances of the case into account and should choose the most appropriate measures, namely, those which are essential to address the infringement covered by this Regulation. Those measures should be proportionate, effective and dissuasive. Member States should remain free to set out conditions and limits for the exercise of the powers to fulfil duties in national law. Where, for example, in accordance with national law, prior authorisation to enter the premises of natural persons and legal persons is required from the judicial authority of the Member State concerned, the power to enter such premises should be used only after such prior authorisation has been obtained.*
- (43) Market surveillance authorities act in the interest of economic operators, of end users, and of the public, to ensure that public interests *covered by relevant* Union harmonisation legislation on products are consistently preserved and protected through appropriate enforcement *measures*, and that compliance with such legislation is ensured across the supply chain through appropriate *checks, taking into consideration the fact that administrative checks alone, in many cases, cannot replace physical and laboratory checks in order to verify the compliance of products with the relevant Union harmonisation legislation*. Consequently, market surveillance authorities should ensure *a high level of transparency while performing their activities and should make available to the public any information that they consider to be relevant in order to protect the interests of end users in the Union.*

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- (44) This Regulation should be without prejudice to the functioning of RAPEX in accordance with Directive 2001/95/EC █ .
- (45) 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 on the Functioning of the European Union. With a view to ensuring an equivalent level of protection throughout the Union, Member States are authorised to take █ measures in relation to products presenting a risk to health and safety, or other aspects of public interest protection. They are also required to notify those measures to other Member States and the Commission, allowing the Commission to take a position on *whether* national measures that restrict the free movement of products with a view to ensuring the functioning of the internal market are justified.
- (46) *The exchange of information* between market surveillance authorities, and the use of evidence and investigation findings should *respect the principle of confidentiality*. Information should be handled in accordance with applicable national law, in order to ensure that investigations are not compromised and that the reputation of the economic operator is not prejudiced.

- (47) 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 Council¹ and Regulation (EU) 2018/1725 of the European Parliament and of the Council², as applicable.
- (48) To ensure the *effectiveness* and consistency of testing across the Union in the market surveillance framework *with regard to specific products or a specific category or group of products or for specific risks related to a category or group of products*, the Commission *might designate testing facilities of its own or public testing facilities of a Member State as a Union testing facility. All Union testing facilities should be accredited in accordance with the requirements of Regulation (EC) No 765/2008. In order to avoid conflicts of interests, Union testing facilities should only provide services to market surveillance authorities, the Commission, the Union Product Compliance Network (the ‘Network’) and other government or intergovernmental entities.*

¹ 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).

² Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

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- (49) Member States should ensure that adequate financial resources are always available for the appropriate staffing and equipping of the market surveillance authorities. Efficient market surveillance is demanding in terms of resources, and stable resources should be provided, at a level appropriate to the enforcement needs at any given moment. ***Member States should have the possibility to supplement public financing by reclaiming from the relevant economic operators the costs incurred when performing market surveillance in relation to products that were found to be non-compliant █.***
- (50) ***Mechanisms for mutual assistance should be established, since it is imperative for the Union market for goods that the market surveillance authorities of the Member States cooperate with each other effectively. Authorities should act in good faith and, as a general principle, accept requests for mutual assistance, in particular those concerning access to EU declaration of conformity, declaration of performance and technical documentation.***
- (51) 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.

(52) 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. ■ Authorities ■ in charge of the control on products entering the ■ Union *market*, have a complete overview of trade flows across the Union's external borders, and should therefore be required to carry out adequate controls on a risk assessment basis, to contribute to a safer market place *which ensures a high level of protection of public interests. It is for Member States to designate the specific authorities that are to be responsible for the appropriate documentary and, where necessary, physical or laboratory checks of products before those products are released for free circulation.* A uniform enforcement of Union harmonisation legislation on products can only be achieved through systematic cooperation and exchange of information between market surveillance and *other authorities designated as authorities in charge of the control on products entering the Union market.* 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, ■ authorities *in charge of the control on products entering the customs territory of the Union* 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 presented by an imported product, it should inform the Member States about that risk in order to ensure coordinated and more effective compliance and enforcement controls at the first points of entry to the Union.

(53) *Importers should be reminded that Articles 220, 254, 256, 257 and 258 of Regulation (EU) No 952/2013 of the European Parliament and of the Council¹ provide that products entering the Union market that require further processing in order to be in compliance with the applicable Union harmonisation legislation shall be placed under the appropriate customs procedure allowing such processing by the importer. Generally, the release for free circulation should not be deemed to be proof of conformity with Union law, since such a release does not necessarily include a complete check of compliance.*

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

- (54) *In order to use the EU Single Window environment for customs and therefore to optimise and unburden the data transfer between customs and market surveillance authorities, it is necessary to set up electronic interfaces that allow automatic data transfer. Customs and market surveillance authorities should contribute to determine the data to be transmitted. Additional burden for customs authorities should be limited and the interfaces should be highly automated and easy-to-use.*
- (55) *It is necessary to establish the Network, hosted by the Commission, aimed at structured coordination and cooperation between enforcement authorities of the Member States and the Commission, and at streamlining the practices of market surveillance within the Union that facilitate 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 to deter infringements. The involvement of administrative cooperation groups (ADCOs) in the Network should not preclude the involvement of other, similar, groups involved in administrative cooperation. The Commission should provide the necessary administrative and financial support to the Network.*

- (56) *There should be effective, speedy and accurate exchange of information among the Member States and the Commission. A number of existing tools, such as the information and communication system for market surveillance (ICSMS) and RAPEX enable coordination among market surveillance authorities in the Union. These tools, together with the interface permitting data transfer from ICSMS into RAPEX should be maintained and further developed in order to exploit their full potential and help to increase the level of cooperation and exchange of information between Member States and the Commission.*
- (57) In that context, *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, **■** *customs and* market surveillance authorities **■** . Furthermore, an electronic interface should be developed to allow effective exchange of information between national **■** systems *of customs* and market surveillance authorities. *With regard to the cases of mutual assistance requests the single liaison offices should give any support necessary for cooperation between the relevant authorities. Therefore, ICSMS should provide the functions enabling an automated indication to the single liaison offices when deadlines are not met. When sectoral legislation already provides for electronic systems for cooperation and data exchange, as is the case for example of EUDAMED for medical devices, those systems should be kept in use, when appropriate.*

- (58) *In general, ICSMS should be used to exchange information considered helpful for other market surveillance authorities. This might include checks undertaken in the context of market surveillance projects, regardless of the outcome of the tests. The amount of data to be entered in ICSMS should strike a balance between imposing too great a burden, when the efforts for entering the data would exceed the work involved in doing the actual checks, and being comprehensive enough to support greater efficiency and effectiveness on the side of the authorities. Thus, the data entered in ICSMS should also cover simpler checks than laboratory tests only. Nevertheless, there should be no need to include brief visual checks. As a guideline, checks which are individually documented should also be entered in ICSMS.*
- (59) *Member States are encouraged to use ICSMS for interactions between customs and market surveillance authorities as an alternative to the national systems. This should not replace the Community Risk Management System (CRMS) used by customs authorities. These two systems could work in parallel since they fulfil different, complementary roles, with ICSMS facilitating communication between customs and market surveillance authorities in order to allow for a smooth treatment of customs declarations in the scope of the product safety and compliance framework while CRMS is for customs common risk management and controls.*

- (60) *Injuries caused by non-compliant products are important information for market surveillance authorities. ICSMS should therefore provide for related data fields so that market surveillance authorities can enter readily available reports provided for in the course of their investigations, thus facilitating later statistical evaluations.*
- (61) The Commission should be able to exchange market surveillance related information with regulatory authorities of third countries or international organisations *within the framework of agreements concluded between the Union and third countries or international organisations*, with a view to ensuring compliance of products prior to their export to the Union market.
- (62) *In order to achieve a high degree of compliance with applicable Union harmonisation legislation on products while at the same time ensuring an effective resource-allocation and a cost-efficient control of products entering the Union market, the Commission should be able to approve specific pre-export control systems. Products falling under such approved systems might, as part of the risk assessment performed by authorities in charge of controls on products entering the Union market, benefit from a higher level of confidence than comparable products which have not been subject to a pre-export control.*

- (63) The Commission should carry out an evaluation of this Regulation in light of the objective it pursues, ***and taking into consideration new technological, economic, commercial and legal developments***. Pursuant to point 22 of the Interinstitutional Agreement of 13 April 2016 on Better Law Making¹, the evaluation, based on efficiency, effectiveness, relevance, coherence and value added, should provide the basis for impact assessments of options for further action, ***particularly as regards the scope of this Regulation, the application and enforcement of the provisions related to the tasks of economic operators placing products on the market, and the system of product-related pre-export controls***.
- (64) 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.
- (65) 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. ■

¹ OJ L 123, 12.5.2016, p. 1.

(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission in relation to: ***determining the uniform conditions for checks, criteria for determination of the frequency of checks and amount of samples to be checked in relation to certain products or categories of products, where specific risks or serious breaches of Union harmonisation legislation have been continuously identified; specifying the*** procedures for the designation of Union testing facilities **■**; ***laying down benchmarks and techniques for checks on the basis of common risk analysis at the Union level***; specifying the details of statistical data covering controls performed by the designated authorities with respect to products subject to Union law; **■** specifying the details of implementation arrangements for the information and communication system and defining the data relating to the placing of products under the customs procedure ‘release for free circulation’ transmitted by customs authorities; and to the ***approval*** of specific ***systems*** of product-related pre-export controls ***and the withdrawal of such approvals*** **■**. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹.

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

- (67) Since the objective of this Regulation, namely to improve the functioning of the internal market by strengthening the market surveillance of products covered by 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.
- (68) This Regulation respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union ***and present in the constitutional traditions of Member States***. Accordingly, this Regulation ***should*** be interpreted and applied ***in accordance with*** those rights and principles, ***including those related to the freedom and pluralism of the media***. 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:

Chapter I
General provisions

Article 1
Subject matter

1. ***The objective of this Regulation is to improve the functioning of the internal market by strengthening the market surveillance of products covered by the Union harmonisation legislation referred to in Article 2, with a view to ensuring that only compliant products that 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, the protection of the environment and public security and any other public interests protected by that legislation, are made available on the Union market.***
2. ***This Regulation lays down rules and procedures for economic operators regarding products subject to certain Union harmonisation legislation and establishes a framework for cooperation with economic operators.***
3. This Regulation also provides a framework for controls on **■** products entering the Union market.

Article 2

Scope

1. This Regulation ***shall apply*** to **■** products that are subject to the Union harmonisation legislation listed in Annex ***I*** ('Union harmonisation legislation'), 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.
2. ***Articles 25 to 28 shall apply to products covered by Union law in so far as there are no specific provisions relating to the organisation of controls on products entering the Union market in Union law.***
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 to 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 authorities to ensure that products comply with the requirements *set out in the applicable* Union harmonisation legislation and to *ensure* protection *of the public interest covered by that legislation*;
- (4) ‘market surveillance authority’ means an authority designated by a Member State under Article 10 as *responsible for carrying out* market surveillance **■** 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 requirement under the Union harmonisation legislation *or under this Regulation*;
- (8) ‘manufacturer’ means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark;
- (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) ***‘fulfilment service provider’ means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the Council¹, parcel delivery services as defined in point 2 of Article 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council², and any other postal services or freight transport services;***
- (12) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer’s obligations under the relevant Union harmonisation legislation ***or under the requirements of this Regulation;***
- (13) ‘economic operator’ means the manufacturer, the authorised representative, the importer, the distributor, the ***fulfilment service provider or any other natural or legal person who is 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;***

¹ ***Directive 97/67/EC of the European Parliament and of the Council of 15 December 1997 on common rules for the development of the internal market of Community postal services and the improvement of quality of service (OJ L 15, 21.1.1998, p. 14).***

² ***Regulation (EU) 2018/644 of the European Parliament and of the Council of 18 April 2018 on cross-border parcel delivery services (OJ L 112, 2.5.2018, p. 19).***

- (14) *‘information society service provider’ means a provider of a service as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535 of the European Parliament and of the Council¹;*
- (15) *‘online interface’ means any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator, and which serves to give end users access to the economic operator’s products;*
- (16) *‘corrective action’ means any action taken by an economic operator to bring any non-compliance to an end where required by a market surveillance authority or on the economic operator's own initiative;*
- (17) *‘voluntary measure’ means a corrective action where not required by a market surveillance authority;*
- (18) *‘risk’ means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm;*

¹ *Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).*

- (19) *‘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;*
- (20) *‘product presenting a serious risk’ means a product presenting a risk, for which, based on a risk assessment and taking into account the normal and foreseeable use of the product, the combination of the probability of occurrence of a hazard causing harm and the degree of severity of the harm is considered to require rapid intervention by the market surveillance authorities, including cases where the effects of the risk are not immediate* ■ ;

- (21) 'end user' means any natural or legal person residing or established in the Union, to whom a product has been made available either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of its industrial or professional activities;
- (22) 'recall' means any measure aimed at achieving the return of a product that has already been made available to the end user;
- (23) 'withdrawal' means any measure aimed at preventing a product in the supply chain from being made available on the market;
- (24) 'customs authorities' means customs authorities as defined in point 1 of Article 5 of Regulation (EU) No 952/2013;
- (25) 'release for free circulation' means the procedure laid down in Article 201 of Regulation (EU) No 952/2013;
- (26) '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'.

■

Chapter II

Tasks of economic operators

Article 4

Tasks of economic operators regarding products subject to certain Union harmonisation legislation

1. *Notwithstanding any obligations set out in applicable Union harmonisation legislation, a product subject to legislation referred to in paragraph 5 may be placed on the market only if there is an economic operator established in the Union who is responsible for the tasks set out in paragraph 3 in respect of that product.*
2. *For the purposes of this Article, the economic operator referred to in paragraph 1 means any of the following:*
 - (a) a manufacturer established in the Union ■ ;
 - (b) an importer, *where the manufacturer is not established in the Union*;
 - (c) *an authorised representative who has a written mandate from the manufacturer designating the authorised representative to perform the tasks set out in paragraph 3 on the manufacturer's behalf*;

- (d) *a fulfilment service provider established in the Union with respect to the products it handles, where no other economic operator as mentioned in points (a), (b) and (c) is established in the Union.*

■

3. *Without prejudice to any obligations of economic operators under the applicable Union harmonisation legislation, the economic operator referred to in paragraph 1 shall perform the following tasks:*

- (a) if the Union harmonisation legislation applicable to the product provides for an EU declaration of conformity *or declaration of performance* and technical documentation, *verifying that the EU declaration of conformity or declaration of performance and technical documentation have been drawn up*, keeping the declaration *of conformity or declaration of performance* at the disposal of market surveillance authorities for the period required by that legislation *and ensuring that the technical documentation can be made available to those authorities upon request*;
- (b) further to a reasoned request from a market surveillance authority, providing that authority with all information and documentation necessary to demonstrate the conformity of the product in *a language which can be easily understood by that authority*;

- (c) *when having reason to believe that a product in question presents a risk, informing the market surveillance authorities thereof;*
- (d) *cooperating with the market surveillance authorities, including following a reasoned request making sure that the immediate, necessary, corrective action is taken to remedy any case of non-compliance with the requirements set out in Union harmonisation legislation applicable to the product in question, or, if that is not possible, to mitigate the risks presented by that product, when required to do so by the market surveillance authorities or on its own initiative, where the economic operator referred to in paragraph 1 considers or has reason to believe that the product in question presents a risk.*

4. *Without prejudice to the respective obligations of economic operators under the applicable Union harmonisation legislation, the name, registered trade name or registered trade mark, and contact details, including the postal address, of the economic operator referred to in paragraph 1 shall be indicated on the product or on its packaging, the parcel or an accompanying document.*

5. This Article *only* applies in relation to *products* that *are* subject to **Regulations (EU) No 305/2011¹, (EU) 2016/425² and (EU) 2016/426³ of the European Parliament and of the Council, and Directives 2000/14/EC⁴, 2006/42/EC⁵, 2009/48/EC⁶, 2009/125/EC⁷, 2011/65/EU⁸, 2013/29/EU⁹, 2013/53/EU¹⁰, 2014/29/EU¹¹, 2014/30/EU¹², 2014/31/EU¹³,**

¹ **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).**

² **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).**

³ **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).**

⁴ **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).**

⁵ **Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).**

⁶ **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).**

⁷ **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).**

⁸ **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).**

⁹ **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).**

¹⁰ **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).**

¹¹ **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).**

¹² **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).**

¹³ **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).**

2014/32/EU¹, 2014/34/EU², 2014/35/EU³, 2014/53/EU⁴ and 2014/68/EU⁵ of the European Parliament and of the Council.

¹ *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).*

² *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).*

³ *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).*

⁴ *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)*

⁵ *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).*

Article 5

Authorised representative

- 1. For the purposes of point (c) of Article 4(2), the authorised representative shall be mandated by the manufacturer to perform the tasks listed in Article 4(3), notwithstanding any other tasks mandated under the relevant Union harmonisation legislation.*

2. *The authorised representative shall perform the tasks specified in the mandate. It shall provide a copy of the mandate to the market surveillance authorities upon request, in an Union language determined by the market surveillance authority.*
3. *Authorised representatives shall have the appropriate means to be able to fulfil their tasks.*

Article 6

Distance sales

Products offered for sale online or through other means of distance sales shall be deemed to be made available on the market if the offer is targeted at end users in the Union. An offer for sale shall be considered to be targeted at end users in the Union if the relevant economic operator directs, by any means, its activities to a Member State.

Article 7

Obligation of cooperation

1. *Economic operators shall cooperate with market surveillance authorities regarding actions which could eliminate or mitigate risks that are presented by products made available on the market by those operators.*

2. *Information society service providers shall cooperate with the market surveillance authorities, at the request of the market surveillance authorities and in specific cases, to facilitate any action taken to eliminate or, if that is not possible, to mitigate the risks presented by a product that is or was offered for sale online through their services.*



Chapter III

Assistance to and cooperation with economic operators

Article 8

Information to economic operators

1. *The Commission, in accordance with Regulation (EU) 2018/1724, shall ensure that the Your Europe portal provides users with easy online access to information about the product requirements and rights, obligations and rules derived from the Union harmonisation legislation.*
2. *Member States shall put in place procedures for providing economic operators, at their request and free of charge, with information with respect to the national transposition and implementation of Union harmonisation legislation applicable to products. For this purpose, Article 9(1), (4) and (5) of Regulation (EU) 2019/...⁺ shall apply.*



⁺ *OJ: please insert the number in the text of the document in PE-CONS 70/18 - COD 2017/0354.*

Article 9

Joint activities to promote compliance

1. Market surveillance authorities may *agree* with *other relevant authorities or with* organisations representing *economic operators* or end users on the carrying out **■** of joint activities that have the aim of **■** promoting compliance, *identifying non-compliance, raising awareness and providing guidance in relation to the Union harmonisation legislation* with respect to specific categories of *products, in particular categories of products that are often found to present a serious risk, including products offered for sale online.*
2. *The market surveillance authority in question and the parties referred to in paragraph 1 shall ensure that the agreement on joint activities does not lead to unfair competition between economic operators and does not affect the objectivity, independence and impartiality of the parties.*
3. *A market surveillance authority may use any information resulting from joint activities carried out as part of any investigation regarding non-compliance that it undertakes.*
4. *The market surveillance authority in question shall make the agreement on joint activities, including the names of the parties involved, available to the public and shall enter that agreement in the information and communication system referred to in Article 34. At the request of a Member State, the Network established under Article 29 shall assist in the drawing up of the agreement on joint activities.*

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Chapter IV

Organisation, *activities* and *obligations* of market surveillance *authorities* and the single liaison office



Article 10

Designation of market surveillance authorities and the single liaison office

1. *Member States shall organise and carry out market surveillance as provided for in this Regulation.*
2. *For the purposes of paragraph 1 of this Article, each Member State shall designate one or more market surveillance authorities in its territory. Each Member State shall inform the Commission ■ and the other Member States of its market surveillance authorities ■ and the areas of competence of each of those authorities, using the information and communication system referred to in Article 34.*
3. Each Member State shall *appoint* a single liaison office.
4. The single liaison office ■ shall *at least* be responsible for *representing the coordinated position* of the market surveillance authorities *and the authorities* designated under *Article 25(1) and for communicating the national strategies as set out in Article 13. The single liaison office shall also assist in the cooperation between market surveillance authorities in different Member States, as set out in Chapter VI.*

5. ***In order to carry out market surveillance of products made available online and offline with the same effectiveness for all distribution channels***, Member States shall ensure that their market surveillance authorities and single liaison office have the necessary resources, including sufficient budgetary and other resources, ***such as a sufficient number of competent personnel***, expertise, procedures and other arrangements for the proper performance of their duties.
6. 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 ***appropriate communication and coordination mechanisms are established to enable those authorities to collaborate closely and exercise their duties effectively***.

Article 11

Activities of market surveillance authorities

1. Market surveillance authorities shall conduct their activities in order to ensure the following:
 - (a) effective ■ market ***surveillance*** within their territory ***of products made available online and offline*** with respect to ■ products that are subject to ■ Union harmonisation legislation ■ ;

(b) **█** the taking by economic operators of appropriate and proportionate corrective action in relation to compliance with that legislation and this Regulation;

(c) *the taking of appropriate and proportionate measures where the economic operator fails to take corrective action.*

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

3. *Market surveillance authorities, as part of their activities set out in paragraph 1 of this Article, shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks based on adequate samples, prioritising their resources and actions to ensure effective market surveillance and taking into account the national market surveillance strategy referred to in Article 13.*

In deciding on which checks to perform, on which types of products and on what scale, market surveillance authorities shall follow a risk-based approach taking into account the following factors:

(a) *possible hazards and non-compliance associated with the products and, where available, their occurrence on the market;*

■

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

(c) *the economic operator's past record of non-compliance;*

(d) *if relevant, the risk profiling performed by the authorities designated under Article 25(1);*

(e) *consumer complaints and other information received from other authorities, economic operators, media and other sources that might indicate non-compliance.*

4. *The Commission, after consulting the Network, may adopt implementing acts determining the uniform conditions of checks, criteria for determination of the frequency of checks and amount of samples to be checked in relation to certain products or categories of products, where specific risks or serious breaches of applicable Union harmonisation legislation have been continuously identified, in order to ensure high level of protection of health and safety or other public interests protected by that legislation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2).*

5. *Where economic operators present test reports or certificates attesting the conformity of their products with Union harmonisation legislation issued by a conformity assessment body accredited in accordance with Regulation (EC) No 765/2008, market surveillance authorities shall take due account of those reports or certificates.*
6. *Evidence 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.*
7. *Market surveillance authorities shall establish the following procedures in connection with products subject to the Union harmonisation legislation:*
 - (a) *procedures for following up on complaints or reports on issues relating to risks or non-compliance;*
 - (b) *procedures for verifying that the corrective action that was to be taken by economic operators has been taken.*

8. *With a view to ensuring communication and coordination with their counterparts in other Member States, market surveillance authorities shall actively participate in administrative cooperation groups (ADCOs) as referred to in Article 30(2).*
9. *Without prejudice to any Union safeguard procedure pursuant to the applicable Union harmonisation legislation, products that have been 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 other Member States, unless a relevant market surveillance authority in another Member State concluded the contrary on the basis of its own investigation, taking into account the input, if any, provided by an economic operator.*

Article 12

Peer reviews

1. *Peer reviews shall be organised for market surveillance authorities wishing to participate in such reviews, in order to strengthen consistency in market surveillance activities in relation to the application of this Regulation.*

2. *The Network shall develop the methodology and the rolling plan for peer reviews among participating market surveillance authorities. When establishing the methodology and the rolling plan, the Network shall take into consideration, at least, the number and the size of market surveillance authorities in the Member States, the number of personnel available and other resources for performing the peer review, and other relevant criteria.*
3. *Peer reviews shall cover best practices developed by some market surveillance authorities which may be of benefit for other market surveillance authorities, and other relevant aspects related to the effectiveness of market surveillance activities.*
4. *The outcome of the peer reviews shall be reported to the Network.*

Article 13

National market surveillance strategies

1. Each Member State shall draw up *an overarching* national market surveillance strategy, at least every *four* years. *Each Member State shall draw up the first such strategy by ... [three years after the date of entry into force of this Regulation].* The *national* strategy shall promote a consistent, comprehensive and integrated approach to market surveillance and to the enforcement of Union harmonisation legislation within the territory of the Member State. *When drawing up the national market surveillance strategy, all sectors covered by the Union harmonisation legislation and all stages of the product supply chain, including imports and digital supply chains, shall be considered. The priorities set out within the work programme of the Network may also be considered.*

2. The national market surveillance strategy shall include at least the following elements, *when this does not compromise market surveillance activities*:
- (a) *the available information* on the occurrence of non-compliant products, in particular taking into account the █ checks and controls referred to in Articles 11(3) and 25(3), respectively, and, *where applicable*, market trends that may affect non-compliance rates for the categories of products, *and possible threats and risks related to emerging technologies*;
 - (b) the areas identified *by the Member States* as priorities for the enforcement of Union harmonisation legislation;
 - (c) the enforcement *activities* planned in order to reduce non-compliance in those areas identified as priorities, including, where relevant, the minimum control levels envisaged for categories of products which have significant levels of non-compliance;
 - █
 - (d) an assessment of the cooperation with market surveillance authorities in other Member States, *as referred to in Article 11(8) and Chapter VI*.
 - █

3. Member States shall communicate their national market surveillance strategy *to the Commission and other Member States* through the information and communication system referred to in Article 34. Each *Member State shall publish a summary of its strategy.*

Chapter V

Market surveillance powers and measures

Article 14

Powers 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 **■** Union harmonisation legislation **■** .
2. *Market surveillance authorities shall exercise the powers set out in this Article efficiently and effectively, in accordance with the principle of proportionality, to the extent that such exercise relates to the subject matter and the purpose of the measures and the nature and the overall actual or potential harm resulting from the instance of non-compliance. Powers shall be conferred and exercised in accordance with Union and national law, including the principles of the Charter of Fundamental Rights of the European Union, as well as with principles of national law relating to freedom of expression and the freedom and pluralism of the media, with applicable procedural safeguards and with the Union rules on data protection, in particular Regulation (EU) 2016/679.*

3. When conferring powers under paragraph 1, 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 *in accordance with the division of powers and the institutional and administrative organisation of the Member State in question*;
 - (c) upon application to courts competent to grant the necessary decision to approve the exercise of that power, *including, where appropriate, on appeal, if the application to grant the necessary decision was not successful*.
4. The powers conferred on market surveillance authorities under paragraph 1 shall include *at least* the following :
- (a) *the power to require economic operators to provide relevant documents, technical specifications, data or information on compliance and technical aspects of the product, including access to embedded software in so far as such access is necessary for the purpose of assessing the product's compliance with applicable Union harmonisation legislation, in any form or format and irrespective of the medium of storage or the place where such documents, technical specifications, data or information are stored, and to take or obtain copies thereof*;

(b) *the power to require economic operators to provide relevant information on the supply chain, on the details of the distribution network, on quantities of products on the market and on other product models that have the same technical characteristics as the product in question, where relevant for compliance with the applicable requirements under Union harmonisation legislation;*

■

(c) *the power to require economic operators to provide relevant information required for the purpose of ascertaining the ownership of websites, where the information in question is related to the subject matter of the investigation;*

(d) *the power to carry out unannounced on-site inspections and physical checks of products;*

(e) *the power to enter any premises, land or means of transport that the economic operator in question uses for purposes related to the economic operator's trade, business, craft or profession, in order to identify non-compliance and to obtain evidence;*

(f) the *power* to start investigations ■ on market surveillance authorities' own initiative in order to *identify non-compliances and bring them to an end;*

- (g) *the power to require economic operators to take appropriate action to bring an instance of non-compliance to an end or to eliminate the risk;*
- (h) *the power to take appropriate measures where an economic operator fails to take appropriate corrective action or where the non-compliance or the risk persists, including the power to prohibit or restrict the making available of a product on the market or to order that the product is withdrawn or recalled;*
- (i) *the power to impose penalties in accordance with Article 41;*
- (j) *the power to acquire product samples, including under a cover identity, to inspect those samples and to reverse-engineer them in order to identify non-compliance and to obtain evidence;*
- (k) *the power, where no other effective means are available to eliminate a serious risk:*
 - (i) *to require the removal of content referring to the related products from an online interface or to require the explicit display of a warning to end users when they access an online interface; or*

(ii) where a request according to point (i) has not been complied with, to require information society service providers to restrict access to the online interface, including by requesting a relevant third party to implement such measures.

5. Market surveillance authorities may use any information, 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.

Article 15

Recovery of costs by market surveillance authorities

1. Member States may authorise their market surveillance authorities to reclaim from the relevant economic operator the totality of the costs of their activities with respect to instances of non-compliance.

2. The costs referred to in paragraph 1 of this Article may include the costs of carrying out testing, the costs of taking measures in accordance with Article 28(1) and (2), the costs of storage and the costs of activities relating to products that are found to be non-compliant and are subject to corrective action prior to their release for free circulation or their placing on the market.

Article 16

Market surveillance measures

1. *Market surveillance authorities shall take appropriate measures if a product subject to Union harmonisation legislation, when used in accordance with its intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained:*
 - (a) *is liable to compromise the health or safety of users; or*
 - (b) *does not conform to applicable Union harmonisation legislation.*
2. *Where market surveillance authorities make findings referred to in point (a) or (b) of paragraph 1, they shall without delay require the relevant economic operator to take appropriate and proportionate corrective action to bring the non-compliance to an end or to eliminate the risk within a period they specify.*
3. *For the purposes of paragraph 2, the corrective action required to be taken by the economic operator may include, inter alia:*
 - (a) *bringing the product into compliance, including by rectifying formal non-compliance as defined by the applicable Union harmonisation legislation, or by ensuring that the product no longer presents a risk;*

- (b) preventing the product from being made available on the market;*
- (c) withdrawing or recalling the product immediately and alerting the public to the risk presented;*
- (d) destroying the product or otherwise rendering it inoperable;*
- (e) affixing to the product suitable, clearly worded, easily comprehensible warnings of the risks that it might present, in the language or languages determined by the Member State in which the product is made available on the market;*
- (f) setting prior conditions for making the product concerned available on the market;*
- (g) alerting the end users at risk immediately and in an appropriate form, including by publication of special warnings in the language or languages determined by the Member State in which the product is made available on the market.*

4. Corrective actions referred to in points (e), (f) and (g) of paragraph 3 may only be required in cases where the product is liable to present a risk only in certain conditions or only to certain end users.

5. *If the economic operator fails to take corrective action referred to in paragraph 3 or where the non-compliance or the risk referred to in paragraph 1 persists, market surveillance authorities shall ensure that the product is withdrawn or recalled, or that its being made available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly.*
6. *The information to the Commission and the other Member States pursuant to paragraph 5 of this Article shall be communicated through the information and communication system referred to in Article 34. That communication of information shall also be deemed to fulfil notification requirements for the applicable safeguard procedures of Union harmonisation legislation.*
7. *Where a national measure is considered to be justified in accordance with the applicable safeguard procedure, or where no market surveillance authority of another Member State concluded the contrary as referred to in Article 11(9), the competent market surveillance authorities in the other Member States shall take the necessary measures in respect of the non-compliant product and shall enter the relevant information in the information and communication system referred to in Article 34.*

Article 17

Use of information, professional and commercial secrecy

Market surveillance authorities shall perform their activities with a high level of transparency and shall make available to the public any information that they consider to be relevant in order to protect the interests of end users. Market surveillance authorities shall *respect* the principles of confidentiality *and of* professional and commercial *secrecy and shall protect* personal data in accordance with *Union and* national law ■ .

Article 18

Procedural rights of economic operators

1. Any measure, decision or order taken or made by market surveillance authorities pursuant to Union harmonisation legislation or this Regulation ■ shall state the exact grounds on which it is based.
2. Any such measure, decision 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 it 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 **working** days, unless it is not possible to give the economic operator 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, the economic operator shall be given that opportunity as soon as possible thereafter and that measure, decision or order shall be reviewed promptly by the market surveillance authority.



Article 19

Products presenting a serious risk

1. Market surveillance authorities shall **ensure that products presenting a serious risk are withdrawn or recalled, where there is no other effective means available to eliminate the serious risk, or that their being made available on the market is prohibited**. Market surveillance authorities shall **notify** the Commission **thereof immediately**, in accordance with Article 20.

2. A decision whether or not a product presents a serious risk shall be based on an appropriate risk assessment that takes account of the nature of the hazard and the likelihood of its occurrence. The feasibility of obtaining higher levels of safety and 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 20

Rapid Information Exchange System

1. Where a market surveillance authority takes or intends to take a measure pursuant to Article 19 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. The market surveillance authority 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 ***immediately*** notify the Commission of any voluntary measures taken and communicated to the market surveillance authority 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 risk related to the product, 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 of this Article, the **Rapid Information Exchange System (RAPEX)** 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*.
5. ***The Commission shall provide and maintain a data interface between RAPEX and the information and communication system referred to in Article 34 so as to avoid double data entry.***

Article 21

Union testing facilities

1. ***The objective of the Union testing facilities is to contribute to enhancing laboratory capacity, as well as to ensuring the reliability and consistency of testing, for the purposes of market surveillance within the Union.***

2. *For the purposes of paragraph 1, the Commission may designate a public testing facility of a Member State as a Union testing facility for specific categories of products or for specific risks related to a category of products.*

The Commission may *also* designate *one of its own testing facilities as a* Union testing facility for specific *categories of* products or for specific risks related to a category *of products, or for products for which testing capacity is missing or is not sufficient.*

3. *Union testing facilities shall be accredited in accordance with Regulation (EC) No 765/2008.*
4. *The designation of Union testing facilities shall not affect the freedom of market surveillance authorities, the Network and the Commission to choose testing facilities for the purpose of their activities.*
5. *Designated Union testing facilities shall provide their services solely to market surveillance authorities, the Network, the Commission and other government or intergovernmental entities.*
6. *Union testing facilities shall, within the area of their competence, perform the following activities:*

(a) carry out *testing of products at the request of* market surveillance *authorities, the Network or the Commission*;

■

(b) *provide independent technical or scientific advice at the request of the Network*;

(c) *develop new techniques and methods of analysis*.

7. *The activities referred to in paragraph 6 of this Article shall be remunerated and may be financed by the Union in accordance with Article 36(2).*

8. *Union testing facilities may receive financing by the Union in accordance with Article 36(2) in order to increase their testing capacity or to create new testing capacity for specific categories of products or for specific risks related to a category of products for which the testing capacity is missing or is insufficient.*

9. The Commission shall adopt implementing acts specifying the procedures for *the designation of* Union testing facilities. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2).

■

Chapter VI
Cross-border mutual assistance



Article 22
Mutual Assistance

1. *There shall be efficient cooperation and exchange of information among the market surveillance authorities of the Member States, and between market surveillance authorities and the Commission and the relevant Union agencies.*
2. *When a market surveillance authority is unable to conclude its investigation because of its inability to access certain information, despite having made all appropriate efforts to obtain that information, it may submit a reasoned request to the market surveillance authority of another Member State where access to this information can be enforced. In this case the requested authority shall supply to the applicant authority without delay, and in any event within 30 days, any information that the requested authority considers to be relevant in order to establish whether a product is non-compliant.*

3. *The requested authority shall undertake appropriate investigations or take any other measures that are appropriate in order to gather the requested information. Where necessary, those investigations shall be carried out with the assistance of other market surveillance authorities.*
4. *The applicant authority shall remain responsible for any investigation that it has initiated, unless the requested authority agrees to take over responsibility.*
5. *In duly justified cases, a requested authority may refuse to comply with a request for information under paragraph 2 where:*
 - (a) *the applicant authority has not sufficiently substantiated that the requested information is necessary in order to establish non-compliance;*
 - (b) *the requested authority demonstrates reasonable grounds showing that complying with the request would substantially impair the execution of its own activities.*

Article 23

Requests for enforcement measures

1. ***Where bringing non-compliance with regard to a product to an end requires measures within the jurisdiction of another Member State and where such measures do not result from the requirements of Article 16(7), an applicant authority may submit a duly reasoned request for enforcement measures to a requested authority in that other Member State.***
2. The requested authority shall ***without delay*** take all appropriate and ***necessary*** enforcement measures ***using the powers conferred on it under this Regulation in order to bring the instance of non-compliance to an end by exercising the powers laid down in Article 14 and any additional powers granted to it under national law.***
3. The requested authority shall **■** inform **■** the applicant authority about the measures referred to in paragraph 2 that have been taken or which are intended to be taken.

A requested authority may refuse to comply with a request for enforcement measures in any of the following situations:

- (a) the requested authority concludes that the applicant authority has not provided sufficient information;*
- (b) the requested authority considers that the request is contrary to Union harmonisation legislation;*
- (c) the requested authority demonstrates reasonable grounds showing that complying with the request would substantially impair the execution of its own activities.*

Article 24

Procedure for mutual assistance requests

1. *Before submitting a request under Article 22 or 23, the applicant authority shall endeavour to carry out all reasonable possible investigations.*
2. *When submitting a request under Article 22 or 23, the applicant authority shall provide all available information in order to enable the requested authority to fulfil the request, including any necessary evidence obtainable only in the Member State of the applicant authority.*

3. Requests **■** under *Articles 22 and 23* and all communication related to them shall be made using electronic standard forms by means of the information and communication system referred to in Article 34.
4. ***Communication shall take place directly between the involved market surveillance authorities or through the single liaison offices of the Member States concerned.***
5. The languages to be used for requests **■** under *Articles 22 and 23* and for all communication linked to them shall be agreed upon by the market surveillance authorities concerned.
6. Where no agreement about the languages to be used can be reached between the market surveillance authorities concerned, the requests **■** under *Articles 22 and 23* shall be sent in the official language of the Member State of the applicant authority, and the replies to such requests shall be sent in the official language of the Member State of the requested authority. In such case, 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 authority.
7. ***The information and communication system referred to in Article 34 shall provide structured information on mutual assistance cases to the single liaison offices involved. Using this information, single liaison offices shall provide any support that is necessary to facilitate assistance.***

■

Chapter VII
Products entering the Union market

Article 25
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 information and communication 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 **■** law 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 of this Article. They shall perform those controls on the basis of risk analysis in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013 ***and, where relevant, on the basis of risk-based approach as referred to in the second subparagraph of Article 11(3) of this Regulation.***

■

4. Risk-related information shall be exchanged between:
- (a) the authorities designated under paragraph 1 of this Article in accordance with Article 47(2) of Regulation (EU) No 952/2013; and
 - (b) customs authorities in accordance with Article 46(5) of Regulation (EU) No 952/2013.

Where, in relation to products subject to Union law 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 *are not compliant with applicable Union law or* present a risk, they shall transmit all relevant information to the competent customs office of destination.

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

6. By 31 March of each year, Member States shall submit to the Commission *detailed* statistical data covering controls *performed by the authorities designated under paragraph 1 with respect to products subject to Union law* during the previous calendar year. *The statistical data shall cover* the number of interventions in the field of controls on such products *with regard to* product safety and compliance.

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The Commission shall draw up a report by 30 June of each year, containing the information provided by the Member States for the previous calendar year *and an analysis of the data submitted*. The report shall be published in the information and communication system referred to in Article 34.

7. Where the Commission becomes aware of a serious risk presented ■ by products subject to Union ■ law that are imported from a third country, it shall recommend to the Member State concerned *to take* appropriate market surveillance measures.

8. *The Commission, after consulting the Network, may adopt implementing acts laying down benchmarks and techniques for checks on the basis of common risk analysis on the Union level, in order to ensure a consistent enforcement of Union law, to strengthen the controls on products entering the Union market and to ensure an effective and uniform level of such controls. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2).*
9. The Commission shall adopt implementing acts further specifying the details of the data to be submitted ■ under paragraph 6 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2).

Article 26

Suspension of release for free circulation

1. Authorities designated under Article 25(1) shall suspend the release of a product for free circulation if in the course of controls *pursuant to* Article 25(3), it is established that:
- (a) the product is not accompanied by the documentation required by the Union ■ law applicable to it *or there is a reasonable doubt as to the authenticity, accuracy or completeness of such documentation*;

- (b) the product is not marked or labelled in accordance with the Union law applicable to it;
- (c) the product bears a CE marking or other marking required by the Union law applicable to it which has been affixed in a false or misleading manner;
- (d) the *name, registered trade name or registered trade mark and the contact details, including the postal address, of an economic operator with tasks regarding the product subject to certain Union harmonisation legislation* is not indicated or identifiable in accordance with Article 4(4); or
- (e) for any other reason, *when* there is cause to believe that the product *does* not comply with the Union law applicable to it or that it *presents* a serious risk *to health, safety, the environment or any other public interest referred to in Article 1*.

2. Authorities designated under Article 25(1) shall immediately notify the market surveillance authorities of any suspension of release referred to in paragraph 1 of this Article.

3. Where the market surveillance authorities have *reasonable grounds* to believe that a product *does* not comply with the Union law applicable to it or *presents* a serious risk, they shall *request* the authorities designated under Article 25(1) to suspend the process for its release for free circulation.
4. *Notifications under paragraph 2 and requests under paragraph 3 of this Article may take place by means of the information and communication system referred to in Article 34, including through the use of electronic interfaces between this system and systems used by customs authorities, when they are available.*

Article 27

Release for free circulation

Where the release of a product for free circulation ■ has been suspended in accordance with Article 26, that product shall be released for free circulation where all the other requirements and formalities relating to such a release have been fulfilled and where either of the following conditions is satisfied:

- (a) within *four* working days of the suspension, the authorities designated under Article 25(1) have not been requested by the market surveillance authorities to maintain the suspension;

- (b) the authorities designated under Article 25(1) have been informed by the market surveillance authorities *of its approval for release for free circulation*.

The release for free circulation shall not be deemed to be proof of conformity with Union law.



Article 28

Refusal to release for free circulation

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 25(1) not to release it for free circulation. They shall also require these authorities to include the following notice *in the customs data-processing system, and, where appropriate*, on the commercial invoice accompanying the product and on any other relevant accompanying document ■ :

‘Dangerous product – release for free circulation not authorised – Regulation (EU) 2019/...
+’.

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

+ OJ: please insert the number of the document in PE-CONS 45/19 - COD 2017/0353.

2. Where market surveillance authorities conclude that a product may not be placed on the market since it does not comply with the Union law 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 25(1) not to release it for free circulation. They shall also require those authorities to include the following notice *in the customs data-processing system, and, where appropriate*, on the commercial invoice accompanying the product and on any other relevant accompanying document :

‘Product not in conformity – release for free circulation not authorised – Regulation (EU) 2019/... +.’

Market surveillance authorities shall immediately enter that information in the information and communication 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 notice required by paragraph 1 or 2 shall also be included, under the same conditions as required by paragraph 1 or 2, *in* the documents used in connection with that procedure.

⁺ OJ: please insert the number of the document in PE-CONS 45/19 - COD 2017/0353.

4. Authorities designated under Article 25(1) may destroy or otherwise render inoperable a product which presents a risk to the health and safety of end users where the authority in question considers that it is necessary and proportionate to do so. The cost of such *measure* shall be borne by the *natural or legal* person declaring the product for free circulation.

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

Chapter VIII

Coordinated enforcement and international cooperation

Article 29

Union Product Compliance Network

1. A Union Product Compliance Network ('the Network') is hereby established.
2. *The purpose of the Network is to serve as a platform for structured coordination and cooperation between enforcement authorities of the Member States and the Commission, and to streamline the practices of market surveillance within the Union, thereby making market surveillance more effective.*

Article 30

Composition *and functioning* of the **EN** Network

1. The Network shall be composed of *representatives from each Member State, including a representative of each single liaison office referred to in Article 10 and an optional national expert, the chairs of ADCOs, and representatives from the Commission.*

2. *Separate or joint ADCOs shall be established for the uniform application of Union harmonisation legislation. ADCOs shall be composed of representatives of the national market surveillance authorities and, if appropriate, representatives of the single liaison offices.*

ADCOs meetings are intended only for representatives of market surveillance authorities and the Commission.

Relevant stakeholders, such as organisations representing the interests at Union level of industry, small and medium-sized enterprises (SMEs), consumers, testing laboratories, standardisation and conformity assessment bodies, may be invited to attend the ADCOs meetings depending on the subject matter of discussion.

3. *The Commission shall support and encourage cooperation between market surveillance authorities through the Network and participate in the meetings of the Network, its sub-groups and the ADCOs.*
4. *The Network shall meet at regular intervals and, where necessary, at the reasoned request of the Commission or a Member State.*
5. *The Network may establish standing or temporary sub-groups dealing with specific questions and tasks.*
6. *The Network may invite experts and other third parties, including the organisations representing the interests of industry, SMEs, consumers, testing laboratories, standardisation and conformity assessment bodies at Union level, to attend meetings as observers or to provide written contributions.*
7. *The Network shall use its best endeavours to reach consensus. Decisions taken by the Network shall be legally non-binding recommendations.*
8. *The Network shall establish its own rules of procedure.*

Article 31

Role and tasks of the Network

- 1. In carrying out the tasks set out in paragraph 2, the Network shall address general, horizontal issues of market surveillance with a view to facilitating the cooperation among single liaison offices, as well as the Commission.*
- 2. The Network shall have the following tasks:*
 - (a) to prepare, adopt and monitor the implementation of its work programme;*
 - (b) to facilitate the identification of common priorities for market surveillance activities and the exchange of information across sectors on evaluations of products, including risk assessment, test methods and results, recent scientific developments and new technologies, emerging risks and other aspects relevant to control activities and on the implementation of national market surveillance strategies and activities;*
 - (c) to coordinate ADCOs and their activities;*

- (d) to organise cross-sector joint market surveillance and testing projects and define their priorities;*
- (e) to exchange expertise and best practices, in particular regarding the implementation of national market surveillance strategies;*
- (f) to facilitate the organisation of training programmes and exchanges of personnel;*
- (g) in collaboration with the Commission, to organise information campaigns and voluntary mutual visit programmes between market surveillance authorities;*
- (h) to discuss questions arising from cross-border mutual assistance mechanisms;*
- (i) to contribute to the development of guidance to ensure the effective and uniform application of this Regulation;*
- (j) to propose the financing of activities referred to in Article 36;*
- (k) to contribute to uniform administrative practices with regard to market surveillance in the Member States;*

- (l) to provide advice and assist the Commission with issues related to the further development of RAPEX and the information and communication system referred to in Article 34;*
- (m) to promote the cooperation and exchange of expertise and best practices between market surveillance authorities and authorities in charge of controls at the Union's external borders;*
- (n) to promote and facilitate collaboration with other relevant networks and groups, with a view to explore possibilities for using new technologies for the purposes of market surveillance and traceability of products;*
- (o) to evaluate regularly the national market surveillance strategies, the first such evaluation taking place by ... [5 years after entry into force of this Regulation];*
- (p) to take up any other issues in activities within the remit of the Network, with the aim of contributing to the effective functioning of market surveillance within the Union.*

Article 32

Role and tasks of administrative cooperation groups

- 1. In carrying out the tasks set out in paragraph 2, ADCOs shall address specific matters related to market surveillance and sector specific issues.*
- 2. ADCOs shall have the following tasks:*
 - (a) to facilitate the uniform application of Union harmonisation legislation within their area of competence with a view to increasing the efficiency of market surveillance throughout the internal market;*
 - (b) to promote communication between market surveillance authorities and the Network and develop mutual confidence between market surveillance authorities;*
 - (c) to establish and coordinate common projects, such as cross-border joint market surveillance activities;*
 - (d) to develop common practices and methodologies for effective market surveillance;*

- (e) to inform each other of national market surveillance methods and activities and to develop and promote best practices;*
- (f) to identify issues of shared interest relating to market surveillance and suggest common approaches to be adopted;*
- (g) to facilitate sector-specific evaluations of products, including risk assessments, test methods and results, recent scientific developments and other aspects relevant to control activities.*

Article 33

Role and tasks of the Commission

1. The Commission shall have the following tasks:
 - (a) to assist the Network, its sub-groups, and the ADCOs by means of an executive secretariat that provides technical and logistic support;*
 - (b) to keep and make available to the single liaison offices and ADCO chairs an updated list of ADCO chairs, including their contact information;*
 - (c) to assist the Network in preparing and monitoring its work programme;*

- (d) to support the functioning of the Product Contact Points *having duties assigned by Member States in relation to Union harmonisation legislation*;
 - (e) *to determine, in consultation with the Network, the need for additional testing capacity and to propose solutions for that purpose, in accordance with Article 21*;
 - (f) to apply the instruments of international cooperation referred to in Article 35;
 - (g) *to provide support for the establishment of separate or joint ADCOs*;
 - (h) to develop and maintain the information and communication system referred to in Article 34, including the interface ■ referred to in Article 34(7), *as well as the interface with national market surveillance databases*, and provide information to the public by means of that system;
-
- (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, ■ comparative analyses, mutual joint visits *and visit programmes, exchange of personnel*, research work, ■ laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work ■ ;

- (j) to prepare and assist in the implementation of Union market surveillance campaigns and similar activities;
- (k) to organise *joint market surveillance and testing projects*, and common training programmes, to facilitate exchanges of personnel between market surveillance authorities and, where appropriate, with the market surveillance authorities of third countries or with international organisations, *and to organise information campaigns and voluntary mutual visit programmes between market surveillance authorities*;
- (l) 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 level;
- (m) to facilitate technical or scientific expertise for the purpose of implementing market surveillance administrative cooperation;
- (n) to examine, **█** at the request of the *Network or on its own initiative*, any question covering the application of this Regulation and issue guidelines, recommendations and best practices in order to encourage consistent application of this Regulation **█** .

█

Article 34

Information and communication system

1. The Commission shall further develop and maintain an information and communication system for the collection, ***processing*** and storage of information, in a structured form, on issues relating to the enforcement of Union harmonisation legislation, ***with the aim of improving the sharing of data among Member States, including for the purpose of requests for information, providing a comprehensive overview of market surveillance activities, results and trends.*** The Commission, ***market surveillance authorities***, single liaison offices, and authorities designated under Article 25(1) shall have access to that system. ***The Commission shall develop and maintain the public user interface of this system, where key information for end-users about market surveillance activities shall be provided.***
2. ***The Commission shall further develop and maintain electronic interfaces between the system referred to in paragraph 1 and national market surveillance systems.***
3. Single liaison offices shall enter the following information in the information and communication system:
 - (a) the identity of the market surveillance authorities in their Member State and areas of competence of those authorities pursuant to Article 10(2);

(b) the identity of the authorities designated under Article 25(1) ;

(c) *the national market surveillance strategy drawn up by their Member State under Article 13 and the results from the review and assessment of the market surveillance strategy.*

4. Market surveillance authorities shall enter into the information and communication system **■** in relation to products made available on the market *for which an in-depth check of compliance has been carried out*, without prejudice to Article 12 of Directive 2001/95/EC and Article 20 of this Regulation, *and where applicable, 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 26 of this Regulation, in their territory*, the following information *concerning*:

(a) *measures according to Article 16(5) taken by that market surveillance authority;*

(b) *reports of testing carried out by them;*

- (c) *corrective action taken by economic operators concerned;*
- (d) *readily available reports on injuries caused by the product in question;*
- (e) *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) *where available, failures by authorised representatives to comply with Article 5(2);*
- (g) *where available, failures by manufacturers to comply with Article 5(1).*

■

5. *Where market surveillance authorities consider it useful, they may enter into the information and communication system any additional information related to the checks they perform and results of testing carried out by them or at their request.*
6. Where relevant for the enforcement of Union harmonisation legislation and for the purpose of minimising risk ■, customs authorities shall extract from national customs systems ■ information ■ on *products* placed under the customs procedure ‘release for free circulation’ ■ related to *the enforcement of Union harmonisation legislation and transmit it to the information and communication system.*

7. ***The Commission shall develop an electronic interface to enable the transmission of data between national customs systems and the information and communication system. This interface shall be in place within four years from the date of adoption of the relevant implementing act referred to in paragraph 8.***
8. The Commission shall adopt implementing acts specifying the details of implementation arrangements for paragraphs 1 to 7 ***of this Article, and in particular the data processing to be applied on data collected in accordance with paragraph 1 of this Article***, and defining the data to be transmitted in accordance with ***paragraphs 6 and 7 of this Article***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2).

Article 35

International cooperation

1. ***In order to improve the efficiency of market surveillance in the Union***, the Commission may ***cooperate with and*** exchange **█** market surveillance related information with regulatory authorities of third countries or international organisations ***within the framework of agreements concluded between the Union and third countries or international organisations. Any such agreements shall be based on reciprocity, include provisions on confidentiality corresponding to those applicable in the Union, and ensure that any exchange of information is in accordance with applicable Union law.***

2. ■ 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 16.
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 products or in respect of products or categories of products manufactured by certain manufacturers.
4. *The Commission shall produce and maintain a list of those products or categories of products with regard to which approval has been granted as referred to in paragraph 3 and shall make this list available to the public.*
5. *Approval may only be granted to a third country under paragraph 3 if following conditions are satisfied:*

- (a) *the third country possesses an efficient verification system of the compliance of products exported to the Union, and the controls carried out in that third country are sufficiently effective and efficient to replace or reduce import controls;*
- (b) *audits within the Union and, if relevant, in the third country demonstrate that products exported from that third country to the Union satisfy the requirements set out in Union harmonisation legislation.*

6. Where such an approval has been granted, the **risk assessment applied to** import controls for those products or categories of products entering the Union market, referred to in paragraph 3, **shall include the granted approvals.**

■ Authorities **designated under Article 25(1)** may however carry out controls **on** those products or categories of products entering the Union market, **including** in order to ensure that the pre-export controls carried out by the third country are effective to determine compliance with Union harmonisation legislation.

■

7. 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.
8. The competent authority, referred to in paragraph 7, shall ensure the official verification of the products prior to their entry into the Union.
9. Where controls on products entering the Union market referred to in paragraph 3 of this Article reveal significant non-compliance, the market surveillance authorities shall notify immediately the Commission through the information and communication system referred to in Article 34 and *adapt the level* of controls on such products.
10. ***The Commission shall adopt implementing acts approving each specific system of product-related pre-export controls, referred to in paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2).***

11. The Commission shall *regularly monitor the correct functioning of the approval* granted under paragraph 3 of this Article. *The Commission shall adopt implementing acts* withdrawing that approval where it is revealed that the products entering the Union market do not comply with Union harmonisation legislation in a significant number of instances. *Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2). The Commission shall immediately inform the third country concerned thereof.*
12. *The system of product-related pre-export control shall be evaluated in accordance with Article 42(4).*

Chapter IX

Financial provisions

Article 36

Financing activities

1. The Union shall finance performance of the tasks of the Network referred to in Article **31** *and the peer reviews referred to in Article 12.*

2. The Union may finance the following activities in relation to the application of this Regulation:
- (a) the functioning of the Product Contact Points **■** ;
 - (b) the establishment and functioning of Union testing facilities referred to in Article 21;
 - (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;
 - (g) Member States' and Union market surveillance campaigns *and associated activities, including resources and equipment, IT tools and training*;

(h) the performance of preliminary or ancillary work in connection with market surveillance activities related to the application of Union harmonisation legislation, such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits and visit programmes, exchange of personnel, research work, training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work;

(i) 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 level.

3. The ***Union shall finance*** the electronic interface referred to in Article 34(7), ***including the development of the information and communication system referred to in Article 34 to enable it to receive automatic flows of electronic data from the national customs systems.***

■

4. ***The Union shall finance the electronic interfaces referred to in Article 34(2) enabling the exchange of data between the information and communication system referred to in Article 34 and the national market surveillance systems.***

5. The Union's financial assistance with respect to the activities in support of this Regulation shall be implemented in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council¹, either directly, or by entrusting budget implementation tasks to the entities listed in point (c) of Article 62(1) of that Regulation.
6. 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.
7. 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 *activities*, including corporate communication of the political priorities of the Union in so 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.

¹ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

Article 37

Protection of the financial interests of the Union

1. The Commission shall take appropriate measures to ensure that, when *activities* 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 provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council¹ and Council Regulation (Euratom, EC) No 2185/96² 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.

¹ 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).

² Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p.2).

Chapter X
Amendments



Article 38

Amendments to Directive 2004/42/EC

Articles 6 and 7 of Directive 2004/42/EC of the European Parliament and of the Council¹ are deleted.

Article 39

Amendments to Regulation (EC) No 765/2008

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

-(1) the title is replaced by the following:

“Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and repealing Regulation (EEC) No 339/93”;

¹ Directive 2004/42/EC 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).

- (2) in Article 1, paragraphs 2 and 3 are deleted;*
- (3) in Article 2, points 1, 2, 14, 15, 17, 18 and 19 are deleted;*
- (4) Chapter III, containing Articles 15 to 29, is deleted;*
- (5) paragraph 1 of Article 32 is amended as follows:*
 - (a) point (c) is replaced by the following:*

“(c) the drawing up and updating of contributions to guidelines in the fields of accreditation, notification to the Commission of conformity assessment bodies and conformity assessment;”;
 - (b) points (d) and (e) are deleted;*

(c) points (f) and (g) are replaced by the following:

“(f) the performance of preliminary or ancillary work in connection with the implementation of the conformity assessment, metrology and accreditation activities linked to the implementation of Community 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;

(g) activities carried out under programmes of technical assistance, cooperation with third countries and the promotion and enhancement of European conformity assessment and accreditation policies and systems among interested parties in the Community and at international level.”

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

Article 40

Amendments to Regulation (EU) No 305/2011

In Article 56(1) of Regulation (EU) No 305/2011, the first subparagraph is replaced by the following:

1. ***Where the market surveillance authorities of one Member State have sufficient reason to believe that a construction product covered by a harmonised standard or for which a European Technical Assessment has been issued does not achieve the declared performance and presents a risk for the fulfilment of the basic requirements for construction works covered by this Regulation, they shall carry out an evaluation in relation to the product concerned covering the respective requirements laid down by this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.***

Chapter XI

Final provisions

Article 41

Penalties

1. The Member States shall lay down the rules on penalties applicable to infringements of this Regulation ***and of*** Union harmonisation legislation ***listed in Annex II*** that impose obligations on economic operators **■** and shall take all measures necessary to ensure that they are implemented ***in accordance with national law***.
2. The penalties provided for shall be effective, proportionate and dissuasive.
3. The Member States shall, by ... ***[27 months after the date of entry into force of this Regulation]***, notify those provisions to ***the*** Commission, ***where they have not previously***

been notified, and shall notify it, without delay, of any subsequent amendment affecting them.

Article 42

Evaluation, *review and guidelines*

1. By 31 December **2026** and every five years thereafter, the Commission shall carry out an evaluation of this Regulation in light of the objectives that it pursues and shall present a report thereon to the European Parliament, to the Council and to the European Economic and Social Committee.
2. The report shall assess whether this Regulation achieved its objective, 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, while taking into account the impact on business and in particular on SMEs. In addition, the evaluation shall also assess *the scope of this Regulation*, the effectiveness of *the peer review system and of* the market surveillance activities that receive Union financing in the light of the requirements of Union policies and law *and the possibilities to further improve the cooperation between the market surveillance authorities and customs authorities*.

3. *By ... [four years after the date of entry into force of this Regulation], the Commission shall prepare an evaluation report on the implementation of Article 4. The report shall in particular evaluate the scope of that Article, its effects and its costs and benefits. The report shall be accompanied, where appropriate, by a legislative proposal.*
4. *Within four years after the first approval of a specific system of product-related pre-export control referred to in Article 35(3), the Commission shall carry out an evaluation of its effects and cost efficiency.*
5. *In order to facilitate the implementation of this Regulation, the Commission shall draw up guidelines for the practical implementation of Article 4 for the purposes of market surveillance authorities and economic operators.*

Article 43

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.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act in respect of the implementing powers referred to in Article 11(4), Article 21(9), Article 25(8), Article 35(10) and Article 35(11) of this Regulation, and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 44

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 ... [***two years after the date of entry into force of this Regulation***]. ***However, Articles 29, 30, 31, 32, 33 and 36 shall apply from 1 January 2021.***

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

Done at ...,

For the European Parliament

For the Council

The President

The President

ANNEX I

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. 36);
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 42, 23.2.1970, p. 16);
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);

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);
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);
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);
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);

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);
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);
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);
11. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1);12. 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);

13. 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);
14. 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);
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15. 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);
16. 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);
17. 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);

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18. 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);
 19. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);
 20. 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);

21. 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);
22. 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);

23. 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);
24. 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);

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25. 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);
 26. 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);
 27. 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);

28. 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);
29. 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);
30. 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);
31. 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);

32. 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);
33. 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);
34. 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);
35. 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);

36. 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);
37. Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1);
38. 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);
39. 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);

40. 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);
41. 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);
42. 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);
43. 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);

44. 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);
45. 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);
46. 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);

47. 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);
48. 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);
49. 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);
50. 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);

51. 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);
52. 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);
53. 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);
54. 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);

55. *Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (OJ L 127, 29.4.2014, p. 1);*
56. 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);
57. 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);

58. 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);
59. 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);
60. 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);
61. 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);

62. 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);
63. 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);
64. ***Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53);***

65. 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);
66. 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);
67. 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);
68. 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);
69. ***Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p. 1);***

70. *Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1), in so far as the design, production and placing on the market of aircrafts referred to in points (a) and (b) of Article 2(1) thereof, where it concerns unmanned aircraft and their engines, propellers, parts and equipment to control them remotely, are concerned.*

ANNEX II

List of Union harmonisation legislation without provisions on penalties

- 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. 36);***
- 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 42, 23.2.1970, p. 16);***
- 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);***

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);*
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);*
6. *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);*
7. *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);*

8. *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);*
9. *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);*
10. *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);*
11. *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);*

12. *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);*
13. *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);*
14. *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);*
15. *Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1);*

16. *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);*
17. *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);*
18. *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);*
19. *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).*

ANNEX III

Correlation table

Regulation (EC) No 765/2008	This Regulation
Article 1(2)	Article 1(1)
Article 1(3)	Article 1(3)
Article 2, point 1	Article 3, point 1
Article 2, point 2	Article 3, point 2
Article 2, point 14	Article 3, point 22
Article 2, point 15	Article 3, point 23
Article 2, point 17	Article 3, point 3
Article 2, point 18	Article 3, point 4
Article 2, point 19	Article 3, point 25
Article 15(1) and (2)	Article 2(1)
Article 15(3)	Article 2(3)
Article 15(4)	-
Article 15(5)	Article 2(2)
Article 16(1)	Article 10(1)
Article 16(2)	Article 16(5)
Article 16(3)	-
Article 16(4)	-

Article 17(1)	Article 10(2)
Article 17(2)	Article 34(1), last sentence and Article 34(3), point (a)
Article 18(1)	Article 10(6)
Article 18(2), point (a)	Article 11(7), point (a)
Article 18(2), point (b)	-
Article 18(2), point (c)	Article 11(7), point (b)
Article 18(2), point (d)	-
Article 18(3)	Articles 10(5) and 14(1)
Article 18(4)	Article 14(2)
Article 18(5)	Article 13
Article 18(6)	Article 31(2), point (o)
Article 19(1), first subparagraph	Article 11(3)
Article 19(1), second subparagraph	Article 14(4), points (a), (b), (e) and (j)
Article 19(1), third subparagraph	Article 11(5)
Article 19(2)	Article 16(3), point (g)
Article 19(3)	Article 18(2)
Article 19(4)	Article 11(2)
Article 19(5)	Article 17
Article 20(1)	Article 19(1)
Article 20(2)	Article 19(2)

Article 21(1)	Article 18(1)
Article 21(2)	Article 18(2)
Article 21(3)	Article 18(3)
Article 21(4)	-
Article 22(1)	Article 20(1)
Article 22(2)	Article 20(2)
Article 22(3)	Article 20(3)
Article 22(4)	Article 20(4)
Article 23(1) and (3)	Article 34(1)
Article 23(2)	Article 34(4)
Article 24(1)	Article 22(1)
Article 24(2)	Article 22(2) to (5)
Article 24(3)	-
Article 24(4)	-
Article 25(1)	-
Article 25(2), point (a)	Article 31(2), point (f) and Article 33(1), points (i) and (k)
Article 25(2), point (b)	Article 31(2), points (g) and (m) and Article 33(1), points (i) and (k)
Article 25(3)	-
Article 26	-

Article 27(1), first sentence	Article 25(2)
Article 27(1), second sentence	Article 25(3)
Article 27(2)	Article 25(4)
Article 27(3), first subparagraph	Article 26(1)
Article 27(3), second subparagraph	Article 26(2)
Article 27(4)	-
Article 27(5)	-
Article 28(1)	Article 27, first paragraph, point (a)
Article 28(2)	Article 27, first paragraph, point (b)
Article 29(1)	Article 28(1)
Article 29(2)	Article 28(2)
Article 29(3)	Article 28(3)
Article 29(4)	Article 28(4)
Article 29(5)	Article 25(5)
Article 32(1), point (d)	-
Article 32(1), point (e)	Article 36(2), point (e)
