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**NOTE**

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From:	Presidency
To:	Permanent Representatives Committee
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 - Analysis of the final compromise text with a view to agreement

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**I. INTRODUCTION**

1. On 19 December 2017, the Commission transmitted the above-mentioned proposal for a Regulation to the European Parliament and to the Council.
2. In the European Parliament, this proposal was referred to the Internal Market and Consumer Protection (IMCO) Committee. The IMCO Committee adopted its report on the proposal on 3 September 2018. The report was confirmed in the plenary meeting on 12 September 2018.
3. On 23 November 2018, the Permanent Representatives Committee mandated the Presidency to start negotiations with the European Parliament, with a view to reaching an agreement in the first reading.

4. Five trilogues took place:
  - on 10 and 18 December 2018 under the Austrian Presidency, and
  - on 17 and 30 January, as well as 7 February 2019 under the Romanian Presidency.
5. In the trilogue on 7 February 2019, the co-legislators reached a provisional agreement. On 8 February 2019, the Permanent Representatives Committee was debriefed by the Presidency on the outcome of the trilogue.

## **II. STATE OF PLAY**

6. On 8 February 2019, a technical meeting with the European Parliament took place, in order to examine recitals and to agree on outstanding technical issues.
7. On 11 and 12 February 2019, two Working Party meetings took place, in order to inform delegations about the outcome of the technical meeting of 8 February and to make a number of technical adjustments to recitals and articles.
8. On this basis, the Presidency submits to the Permanent Representatives Committee the final compromise text set out in the Annex to this note.

## **III. CONCLUSION**

9. The Permanent Representatives Committee is invited to endorse the compromise text and to mandate the Presidency to inform the European Parliament that should the Parliament adopt in a forthcoming plenary meeting the text of the proposal in the exact form as set out in the Annex (subject to legal-linguistic revision), the Council would adopt the proposed Regulation thus amended.

**2017/353(COD)**

**REGULATION (EU) 2019/...**  
**OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**of ...**

**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**

**(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 Committee<sup>1</sup>,

Acting in accordance with the ordinary legislative procedure<sup>2</sup>,

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<sup>1</sup> OJ C 283, 10.8.2018, p. 19.

<sup>2</sup> Position of the European Parliament of ... (not yet published in the Official Journal) and decision of the Council of ... .

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 produced in the Union or not.

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

- (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. However, in accordance with the principle of *lex specialis*, this Regulation should apply only in so far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of Union harmonisation legislation. The corresponding provisions of this Regulation should not therefore apply in the areas covered by such specific provisions, for instance those set out in Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products<sup>3</sup>, Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices<sup>4</sup> and Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices<sup>5</sup>, including the use of EUDAMED, and Regulation (EU) 2018/858 of the European Parliament and of the Council<sup>6</sup>.

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<sup>3</sup> 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).

<sup>4</sup> 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).

<sup>5</sup> 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).

<sup>6</sup> 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 Council<sup>7</sup> lays down the general safety requirements for all consumer products and provides for specific obligations and powers of the Member States in relation to dangerous products as well as for the exchange of information to that effect through the Union Rapid Alert System for dangerous non-food products (RAPEX). Market surveillance authorities should have the possibility of taking the more specific measures available to them under that Directive. In order to achieve a higher level of safety for consumer products, the mechanisms for exchanges of information and rapid intervention situations provided for in Directive 2001/95/EC 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 consumer and other end-users confidence in products placed on the Union market. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to provide whether this Regulation is also to apply to that legislation.

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<sup>7</sup> 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 Council<sup>8</sup> laying down the Community market surveillance framework and controls of products entering the Community market will be replaced by this Regulation. That framework includes also the provisions on controls of products entering the Union market in Articles 27, 28 and 29, which apply not only to products covered by the market surveillance framework as outlined above, but to all Union legislation in so far as other Union legislation does not contain specific provisions relating to the organisation of controls on products entering the Union market. It is therefore necessary to extend the scope of the provisions of this Regulation on products entering the Union market to all Union legislation as well.
- (8) In order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of Better Regulation, the rules applicable to controls on products entering the Union market should be revisited and integrated into a single legislative framework for controls on products at the external borders.

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<sup>8</sup> Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).



- (9) Responsibility for enforcing Union harmonisation legislation should lie with the Member States, whose market surveillance authorities should be required to ensure that the legislation is fully complied with. The Member States should, therefore, establish systematic approaches to ensure effectiveness of market surveillance and other enforcement activities. With 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 in relation 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 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 may have in Union harmonisation legislation where specific definitions of manufacturer are applied, which may include any natural or legal person who modifies a product already placed on the market in such a way that compliance with the applicable Union harmonisation legislation may be affected and places it on the market, or any other natural or legal person who places a product on the market under his 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 which correspond to the role of each economic operator in the supply and distribution process pursuant to specific provisions in Union harmonisation legislation, with the manufacturer retaining ultimate responsibility for compliance of the product with requirements in the Union harmonisation legislation.

- (13) The challenges of the global market and an increasingly complex supply chain, as well as the increase of products that are offered for sale online to end-users within the Union, call for the strengthening and enforcement measures, to ensure the safety of consumers. Furthermore, practical experience of market surveillance has shown that this supply chain sometimes involves 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 enforcement measures may be taken by market surveillance authorities. By including fulfilment centres within the scope of the 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 but 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 role in the supply chain, and the extent to which they contribute to the making available of products on the Union market. Therefore, it is necessary to apply this Regulation to economic operators that are directly concerned by Union harmonisation legislation as listed in Annex I, such as the producer of an article and the downstream user as defined in each case in Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>9</sup> and Regulation (EC) No 1272/2008 of the European Parliament and of the Council<sup>10</sup>, the installer as defined in Directive 2014/33/EU of the European Parliament and of the Council<sup>11</sup>, the supplier as defined in Regulation (EC) No 1222/2009 of the European Parliament and of the Council<sup>12</sup> or the dealer as defined in Regulation (EU) 2017/1369 of the European Parliament and of the Council<sup>13</sup>.

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<sup>9</sup> 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).

<sup>10</sup> 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).

<sup>11</sup> 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).

<sup>12</sup> 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).

<sup>13</sup> 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 being sold online or through other means of distance sales, the product should be considered made available on the market if the offer is targeted at end-users in the Union. In line with the applicable Union legislation on international private law a case-by-case analysis, taking into account the relevant circumstances, should be applied to establish whether an offer is targeted at end-users in the Union. An offer should be considered targeted if the relevant economic operator directs, by any means, his or her activities to a Member State of the European Union. 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 payment possibilities, need to be taken into consideration. In case of online sales the mere accessibility of the economic operators' or the intermediaries' website 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, normally through platforms and for remuneration, which offer intermediary services by storing third party content, but without exercising any control over such content, thus not acting on behalf of an economic operator. Removal of content regarding non-compliant products or where it is not feasible 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 Council<sup>14</sup>. In particular, no general obligation should be imposed on service providers to monitor the information which they transmit or store, nor should a general obligation be imposed upon them to actively seek facts or circumstances indicating illegal activity. Furthermore, hosting service providers should not be held liable as long as they do not have actual knowledge of illegal activity or information and are not aware of the facts or circumstances from which the illegal activity or information is apparent.

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<sup>14</sup> Directive 2000/31/EC of the European Parliament and of the Council on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce) (OJ L 178, 17.07.2000, p. 1).

- (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, pose 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 in preventing the entry of counterfeit products to the Union's market pursuant to Regulation (EU) No 608/2013 of the European Parliament and of the Council<sup>15</sup>.
- (18) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this purpose, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers and the market surveillance authorities is a key element allowing immediate intervention and corrective action in relation to the product. It is important that 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 for providing information regarding a product's compliance with Union harmonisation legislation and who can cooperate with market surveillance authorities making sure that immediate corrective action is taken to remedy instances of non-compliance. Economic operators who should perform these tasks should be the manufacturer, or the importer when the manufacturer is not established in the Union, or an authorised representative designated by the manufacturer for this purpose, or a fulfilment service provider established in the Union for consignments handled by it when no other economic operator is established in the Union.

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<sup>15</sup> 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 ensuring the compliance of products sold online and effectively enforcing the Union harmonisation legislation. The number of economic operators offering products directly to consumers by electronic means is increasing. Therefore, the role of economic operator with tasks regarding certain products is essential for providing market surveillance authorities with an interlocutor established in the Union, and for 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, 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 instruments on products achieve the same result in effect, namely Regulation (EC) No 648/2004 of the European Parliament and of the Council<sup>16</sup>, Regulation (EC) No 1223/2009, Regulation (EU) No 167/2013 of the European Parliament and of the Council<sup>17</sup>, Regulation (EU) No 168/2013 of the European Parliament and of the Council<sup>18</sup>, Directive 2014/28/EU of the European Parliament and of the Council<sup>19</sup>, Directive 2014/90/EU of the European Parliament and of the Council<sup>20</sup>, Regulation (EU) 2016/1628 of the European Parliament and of the Council<sup>21</sup>, 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 of the European Parliament and of the Council<sup>22</sup>,

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<sup>16</sup> 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).

<sup>17</sup> 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).

<sup>18</sup> 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).

<sup>19</sup> Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses (recast) (OJ L 96, 29.3.2014, p. 1).

<sup>20</sup> 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).

<sup>21</sup> 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).

<sup>22</sup> 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).

Regulation (EU) 2016/424/EU of the European Parliament and of the Council<sup>23</sup> and Directive 2010/35/EU of the European Parliament and of the Council<sup>24</sup>.

- (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 activities 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 Council<sup>25</sup> provides for a single point of 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 Point established under Regulation (EU) 2019/... of the European Parliament and of the Council<sup>26+</sup> in order to facilitate 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.

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<sup>23</sup> 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).

<sup>24</sup> 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).

<sup>25</sup> 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).

<sup>26</sup> 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 ...).

<sup>+</sup> 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, 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 online.
- (27) Member States should designate their own market surveillance authorities. This Regulation should not prevent Member States from choosing the competent national 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. Liaison offices should at least represent a 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 the organisation of their market surveillance with the same effectiveness for products made available online and offline.

- (29) While performing market surveillance of products offered 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 safety tests due to the lack of physical access to products. In addition to the mandatory requirements introduced by this Regulation, Member States are encouraged to use complementary guidance and good 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 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 activities should be thorough and effective, to ensure that Union harmonisation legislation on products is applied correctly. Given that controls may represent a burden for economic operators, market surveillance authorities should organise and conduct inspection activities on a risk based approach, taking the interests of those operators into account and limiting the said burden to what is necessary for the performance of efficient and effective controls. Furthermore, market surveillance activities should be performed with the same level of care by the competent authorities of the Member State irrespective of whether non-compliance of the given product is relevant on the territory of that Member State or is likely to have an impact on the market of another Member State. Uniform conditions for certain inspection activities carried out by the market surveillance authorities when products or categories of products present specific risks or seriously breach the applicable Union harmonisation legislation might be laid down.
- (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 deem 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, as appropriate or by 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, information or data in question and regardless of where it is located and of the format in which it is held. Market surveillance authorities should be able to request third parties in the digital value chain to provide all the evidence, data and information necessary.
- (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 his 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 competent staff member.



- (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 make test purchases 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 his identity or relocates within the Union or to a third country in order to avoid enforcement. In cases where there is a risk of serious and irreparable harm to end-users due to non-compliance, market surveillance authorities should be able to take 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 display a warning. When such a request is not observed, the respective authority should have the power to require information society service provider 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 and exercise of powers in the application of this Regulation 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. The implementation and exercise of powers should also be proportionate and adequate in view of the nature and the overall actual or potential harm of the infringement. Competent authorities should take all facts and circumstances of the case into account and should choose the most appropriate measures, 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 and 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, end-users, and of the general public, to ensure that public interests covered by respective 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 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 deem relevant in order to protect the interests of end-users in the Union.

- (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 should be authorised to take measures in relation to products presenting a risk to health and safety, or other aspects of public interest protection. They should also be required to notify those measures to other Member States and the Commission, allowing the Commission to take a position on the justification of national measures that restrict the free movement of products with a view to ensuring the functioning of the internal market.
- (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 according to applicable national law, in order to ensure that investigations are not compromised and that the reputation of the economic operator is not prejudiced.

- (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 Council<sup>27</sup> and Regulation (EC) No 45/2001 of the European Parliament and of the Council<sup>28</sup>, as the case may be.
- (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 (EU) 765/2008. In order to avoid conflict of interests, Union testing facilities should only provide services to market surveillance authorities, the Commission, the Network and other government or intergovernmental entities. Procedures for the designation of Union testing facilities should be set up by implementing acts.

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<sup>27</sup> 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).

<sup>28</sup> Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

- (49) Member States should be required to ensure that adequate financial resources are always available in order to staff and equip the market surveillance authorities appropriately. An efficient market surveillance activity is demanding in terms of resources, and stable resources should be provided, at a level appropriate to the enforcement needs at any given moment. Member States should have the possibility to supplement public financing by reclaiming the costs incurred when performing market surveillance activities in relation to products that were found to be non-compliant.
- (50) Mechanisms for mutual assistance should be established, as 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 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, enjoy a complete overview of trade flows across the external borders, and should therefore be required to carry out adequate controls on a risk assessment basis, to contribute to a safer market place, which ensures a high level of protection of public interests. It is for Member States to designate the specific authorities that should be responsible for the appropriate documentary and, where necessary, physical or laboratory checks of products before those products are released for free circulation. 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 posed by an imported product, it should inform the Member States about those risks in order to ensure coordinated and more effective compliance and enforcement controls at the first points of entry to the Union.

- (53) Importers should be reminded that Articles 220, 254 and 256-258 of Regulation (EU) No 952/2013 of the European Parliament and of the Council<sup>29</sup> foresee that products entering the Union market that require further processing in order to be in compliance with Union harmonisation legislation applicable to them shall be placed under the appropriate customs procedure allowing such processing by the importer. Generally, the release for free circulation should not be deemed as proof of conformity with Union legislation, as such release does not necessarily include a complete check of compliance.

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<sup>29</sup> 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 allowing 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 be used.
- (55) It is necessary to establish a Union Product Compliance 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 facilitating the implementation of joint enforcement activities by Member States, such as joint investigations. This administrative support structure should allow the pooling of resources and maintain a communication and information system between Member States and the Commission, thereby helping to strengthen enforcement of Union harmonisation legislation on products and deter infringements. The involvement of Administrative Cooperation Groups (ADCOs) in the Network should not preclude the involvement of other similar groups performing 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 Information and Communication System for Market Surveillance (ICSMS) and Rapid Alert System for dangerous non-food products (RAPEX) enable coordination among market surveillance authorities in the Union. These tools, together with 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, market surveillance and customs 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 foresees electronic systems for cooperation and data exchange, as is the case for example for medical devices by the EUDAMED system, 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 may 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 becoming too burdensome, 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 just 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 risk management system used by customs (CRMS). 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 prior to their export of products 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 against the objectives it pursues, also 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 Making<sup>30</sup>, 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 to 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.

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<sup>30</sup> 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 the process of determining the uniform conditions for certain inspection activities, where specific risks or serious breaches of Union harmonisation legislation have been continuously identified, to the procedures for designating Union testing facilities, to statistical data covering controls performed by customs authorities with respect to products subject to Union harmonisation legislation, to details of implementation arrangements for the information and communication system and data relating to the placing of products under the customs procedure ‘release for free circulation’ transmitted by customs authorities, to the process of determining benchmarks and techniques with regard to the controls on products entering the Union market, and to approval and withdrawal of systems of product-related pre-export controls. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council<sup>31</sup>.

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<sup>31</sup> 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 ensure that products placed on the Union market fulfil the requirements of Union harmonisation legislation cannot be sufficiently achieved by the Member States given the need for a very high degree of cooperation, interaction and coherent action of all of the competent authorities in all Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.
- (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 Union harmonisation legislation referred to in Article 2, with a view to ensure 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, protection of the environment and public security and any other public interests protected by that legislation, are made available on the Union market.
2. It also 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 set out in the Annex I to this Regulation ('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, 26, 27 and 28 shall apply to products covered by Union legislation in so far as other Union legislation does not contain specific provisions relating to the organisation of controls on products entering the Union market.
3. The application of this Regulation shall not prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC.
4. This Regulation is without prejudice to Articles 12, 13, 14 and 15 of Directive 2000/31/EC.



## Article 3 Definitions

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

- (1) ‘making available on the market’ means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;
- (2) ‘placing on the market’ means the first making available of a product on the Union market;
- (3) ‘market surveillance’ means the activities carried out and measures taken by market surveillance authorities to ensure that products comply with the requirements set out in the applicable Union harmonisation legislation and 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 of the requirements under the Union harmonisation legislation or the requirements of 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 his 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 of warehousing, packaging, addressing and dispatching without having ownership of the products involved excluding services provided according to Article 2(1) of Directive 97/67/EC of the European Parliament and of the Council<sup>32</sup>, Article 2(2) of Regulation (EU) 2018/644 of the European Parliament and of the Council<sup>33</sup>, 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 his behalf in relation to specified tasks with regards to the manufacturer’s obligations under the relevant Union harmonisation legislation or the requirements of this Regulation;
- (13) ‘economic operator’ means the manufacturer, the authorised representative, the importer, the distributor, fulfilment service providers and any other natural or legal person subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant Union harmonisation legislation;

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<sup>32</sup> 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 015 21.1.1998, p. 14).

<sup>33</sup> 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 within the meaning of point (b) of Article 1(1) of Directive 2015/1535/EU of the European Parliament and of the Council<sup>34</sup>;
- (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 his 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;

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<sup>34</sup> 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 was made available either as a consumer, outside any trade, business, craft or profession, or as a professional end-user in the course of his industrial or professional activities;
- (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 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 to this product.
2. For the purpose of this Article, the economic operator referred to in paragraph 1 means any of the following:
  - (a) the manufacturer is established in the Union;
  - (b) an importer, when the manufacturer is not established in the Union;
  - (c) an authorised representative who has a written mandate from the manufacturer designating him to perform tasks listed in paragraph 3 on the manufacturer's behalf;

(d) a fulfilment service provider established in the Union with respect to products handled by it when 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 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 the 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, inform the market surveillance authorities;
  - (d) cooperating with the market surveillance authorities, including further to 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, mitigate the risks posed by that product when required to do so by the market surveillance authorities or at their own initiative when they consider or have reason to believe that the product in question presents a risk.
4. Without prejudice to the respective obligations of the economic operators under the applicable Union harmonisation legislation, the name, registered trade name or registered trade mark and the 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 shall only apply in relation to products that are subject to [Regulations](#) (EU) No 305/2011<sup>35</sup>, (EU) 2016/425<sup>36</sup> and (EU) 2016/426<sup>37</sup> of the European Parliament and of the Council and Directives 2000/14/EC<sup>38</sup>, 2006/42/EC<sup>39</sup>, 2009/48/EC<sup>40</sup>, 2009/125/EC<sup>41</sup>, 2011/65/EU<sup>42</sup>, 2013/29/EU, 2013/53/EU<sup>43</sup>, 2014/29/EU<sup>44</sup>, 2014/30/EU<sup>45</sup>, 2014/31/EU<sup>46</sup>, 2014/32/EU<sup>47</sup>, 2014/34/EU<sup>48</sup>, 2014/35/EU<sup>49</sup>, 2014/53/EU<sup>50</sup>, 2014/68/EU<sup>51</sup> of the European Parliament and of the Council.

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<sup>35</sup> 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).

<sup>36</sup> 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).

<sup>37</sup> 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).

<sup>38</sup> 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).

<sup>39</sup> Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery (OJ L 157, 9.6.2006, p. 24).

<sup>40</sup> 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).

<sup>41</sup> 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).

<sup>42</sup> 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).

<sup>43</sup> 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).

<sup>44</sup> 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).

<sup>45</sup> 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).

<sup>46</sup> 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)

<sup>47</sup> 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).

## Article 5

### Authorised representative

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

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<sup>48</sup> 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).

<sup>49</sup> 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).

<sup>50</sup> 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)

<sup>51</sup> 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).

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

## Article 6

### Distance sale

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 targeted at end-users in the Union, if the relevant economic operator directs, by any means, his or her activities to a Member State.

## Article 7

### Obligation of cooperation

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

2. Information society service providers shall cooperate with the market surveillance authorities, at their request and in specific cases, to facilitate any action taken to eliminate or, if that is not possible, mitigate the risks posed 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 shall, in accordance with Regulation (EU) 2018/1724, ensure that the Your Europe portal provides users with easy, online access to information regarding 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/...<sup>+</sup> shall apply.

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<sup>+</sup> 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, organisations representing operators or end-users on the carrying out joint activities aimed at promoting compliance, identifying non-compliance, raising awareness and providing guidance in relation to the Union harmonisation legislation and with respect to specific categories of products, in particular the ones that are often found to be presenting a serious risk, including the products sold 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 create unfair competition between economic operators, 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 undertaken by it into non-compliance.
4. The market surveillance authority in question shall make the agreement on joint activities, including the names of the parties involved, available to the general public and shall enter it in the system referred to in Article 34. The Network established under Article 29 shall, at the request of a Member State, assist in the drawing up of the agreement on joint activities.

## Chapter IV

### Organisation, activities and obligations of market surveillance authorities

#### 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 purpose of paragraph 1, each Member State shall designate one or more market surveillance authorities in its territory. It 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. It 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, including 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) the 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 if 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, 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 the effective market surveillance and taking into account the national market surveillance strategy referred to in Article 13.

In deciding what checks to perform, on what 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-compliances associated with the product and when available, its occurrence on the market;
  - (b) activities and operations under the control of 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. For certain products or category of products, where specific risks or serious breaches with applicable Union harmonisation legislation have been continuously identified, and in order to ensure high level of protection of health and safety or other public interests protected by that legislation, the Commission, after consultation of the Network established under Article 29, may adopt implementing acts in accordance with the examination procedure referred to in Article 43(2) determining the uniform conditions of checks, criteria for determination of the frequency of checks and amount of samples to be checked in relation to these products or category of products on the Union level.

5. Where economic operators present test reports or certificates attesting conformity of their products with Union harmonisation legislation issued by a conformity assessment body, accredited pursuant to Regulation (EC) No 765/2008, market surveillance authorities shall take due account of such reports or certificates.
6. The 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 of complaints or reports on issues relating to risks or non-compliances;
  - (b) procedures for verifying that corrective action 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 coordination groups referred to in Article 30(2).
9. Without prejudice to any Union safeguard procedure pursuant to the applicable Union harmonisation legislation, products deemed to be non-compliant on the basis of a decision of a market surveillance authority in one Member State, shall be presumed to be non-compliant by market surveillance authorities in another Member State, unless a relevant market surveillance authority in another Member State concluded the contrary based on its own investigation taking into account the input provided by an economic operator, if any.

## 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 implementation of this Regulation.

2. The Network shall develop the methodology and the rolling plan for peer reviews among participating Member States. 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 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 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, as a minimum, every 4 years, at first by ... ***[3 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 enforcement of Union harmonisation legislation within the territory of the Member State. When drawing up the strategy, all sectors falling within the Union harmonisation legislation and 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 established under Article 29 may also be considered.

2. The national market surveillance strategy shall include at least the following elements when this information does not compromise market surveillance activities:
- (a) the available information of the occurrence of non-compliant products, in particular taking into account the controls referred to in Articles 11(3) and 25(3), and, where applicable, market trends that may affect non-compliance rates in the categories of product, and possible threats and risks related to emerging technologies;
  - (b) the areas identified by the Member States as a priority for the enforcement of Union harmonisation legislation;
  - (c) the enforcement activities planned in order to reduce the occurrence of non-compliance in those areas identified as a priority, including, where relevant, the minimum control levels envisaged for categories of product which have significant levels of non-compliance;
  - (d) an assessment of the 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 system referred to under Article 34. Member States shall publish the summary of the strategies.

## Chapter V

### Market surveillance powers and measures

#### Article 14

##### Powers and duties of market surveillance authorities

1. Member States shall confer on their market surveillance authorities the powers of market surveillance, investigation and enforcement necessary for the application of this Regulation and for the application of Union harmonisation legislation.
2. Market surveillance authorities shall exercise their powers and duties set out in this Article efficiently and effectively and in accordance with the principle of proportionality, to the extent that relates to the subject matter, and the purpose of the measures and the nature and the overall actual or potential harm of the instance of non-compliance. Powers shall be implemented 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 principles in national law relating to freedom of expression and the freedom and pluralism of the media, applicable procedural safeguards and 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) where appropriate, 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) by application to courts competent to grant the necessary decision to approve the exercise of that power, including, where appropriate, by appeal, if the application to grant the necessary decision is not successful.
  
4. The powers conferred on market surveillance authorities under paragraph 1 shall include at least the following:
  - (a) the powers 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 insofar as necessary to assess compliance of the product with applicable Union harmonisation legislation, in any form or format and irrespective of its storage medium or the place where it is stored, and to take or obtain copies of this information;



- (b) the powers to require economic operators to provide relevant information on the supply chain, the details of distribution network, on quantities of products on the market and on other product models, that have the same technical characteristics as a product in question, where relevant for compliance with the applicable requirements under Union harmonisation legislation;
- (c) the powers to require economic operators to provide relevant information required for the purpose of ascertaining the ownership of websites, when the information in question is related to the subject matter of the investigation;
- (d) the powers to carry out, without prior announcement, on-site inspections and physical checks;
- (e) the powers to enter any premises, land or means of transport that the economic operator in question uses for purposes related to his trade, business, craft or profession, in order to detect non-compliance and obtain evidence;
- (f) the powers to start investigations on their own initiative in order to identify non-compliances and bring them to an end;

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

- (ii) where a request according to point (i) is not observed, 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 these instances of non-compliance.
2. Those costs may include the costs of carrying out testing, the costs of taking measures in accordance with Article 28(1) and (2) and the costs for storage and of activities relating to products that are found to be non-compliant and 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 requirements set out in 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 action to bring, as applicable, the non-compliance or the risk to an end within a period they specify.
3. For the purpose of paragraph 2, the action required to be taken by the economic operator may include inter alia:
  - (a) bringing the product into compliance, including rectifying formal non-compliance as defined by the applicable Union harmonisation legislation, or ensuring that the product no longer presents a risk;

- (b) preventing the product from being made available on the market;
- (c) withdrawing or recalling immediately the product 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 it may 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. Actions referred to in points (e), (f) and (g) of paragraph 3 may only be required in cases where a product is liable to present a risk only in certain conditions or only to certain persons.

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 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 shall be communicated through the system referred to in Article 34. This information also fulfils notification requirements for the applicable safeguard procedures of Union harmonisation legislation.
7. If a national measure is considered justified according to the applicable safeguard procedure, or no market surveillance authority of another Member State concluded the contrary pursuant to Article 11(9), the competent market surveillance authorities in the other Member States shall take the measures necessary in respect to the non-compliant product and shall enter the related information in the 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 general public any information that they deem relevant in order to protect the interests of end-users in the Union. Market surveillance authorities shall respect the principle of confidentiality and of professional and commercial secrecy and shall protect personal data pursuant to Union and national legislation.

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

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

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

## Article 19

### Products presenting a serious risk

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



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

## Article 20

### Union Rapid Alert System (RAPEX)

1. Where a market surveillance authority takes or intends to take a measure in accordance with 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. It shall also inform the Commission without delay of the modification or withdrawal of any such measure.
2. If a product presenting a serious risk has been made available on the market, market surveillance authorities shall immediately notify the Commission of any voluntary measures taken and communicated by an economic operator.

3. The information provided in accordance with paragraphs 1 and 2 shall include all available details, in particular the data necessary for the identification of the product, the origin and the supply chain of the product, the related risk, the nature and the duration of the national measure taken and any voluntary measures taken by economic operators.
4. For the purposes of paragraphs 1, 2 and 3 of this Article, the market surveillance and information exchange system provided for in Article 12 of Directive 2001/95/EC shall be used. Paragraphs 2, 3 and 4 of Article 12 of that Directive shall apply *mutatis mutandis*.
5. The Commission shall provide and maintain a data interface between the RAPEX system to the system referred to in Article 34 so that the need for double data entry is reliably avoided.

## Article 21

### Union testing facilities

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

2. For the purpose 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 facilities 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 Chapter II of Regulation (EC) No 765/2008.
4. The designation of Union testing facilities shall not affect the freedom of the market surveillance authorities, the Network and the Commission to choose testing facilities for the purpose of their market surveillance activities.
5. Designated Union testing facilities shall offer 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 tasks:

- (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 on request of the Network established under Article 29;
  - (c) develop new techniques and methods of analysis.
7. 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) of this Regulation.
8. Union testing facilities may receive financing by the Union in accordance with Article 36(2) in order to increase their testing capacity or 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 has undertaken all appropriate efforts to obtain information itself, and nevertheless cannot conclude its investigations, it may submit a motivated 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 deems relevant 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 remains responsible for the investigation it has initiated, unless the requested authority agrees to take over responsibility.
5. In well justified cases, a requested authority may refuse to comply with a request for information under paragraph 2:
  - (a) when the applicant authority has not sufficiently substantiated that the requested information is necessary to establish non-compliance;
  - (b) when the requested authority demonstrates reasonable grounds showing that the request would substantially impair the execution of its own activities.

## Article 23

### Requests for enforcement measures

1. In case where bringing a non-compliance with regard to the 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), a duly motivated request for enforcement measures may be made by an applicant authority to a requested authority in that Member State.
2. The requested authority shall without delay determine and take all appropriate 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 the 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 if one or more of the following applies:

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

## Article 24

### Procedure for mutual assistance requests

1. Before launching a request under Articles 22 and 23 the applicant authority shall endeavour to carry out itself all reasonable possible investigations.
2. The applicant authority shall provide all available information, in the case of requests under Articles 22 and 23, 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 linked to them shall be made using electronic standard forms by means of the the system referred to in Article 34.
4. Communication shall take place directly between the involved authorities or through the single liaison office 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 competent authorities concerned.
6. Where no agreement about the languages to be can be reached between the competent 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 in the official language of the Member State of the requested authority. In that instance, the applicant authority and the requested authority shall arrange for the translation of the requests, replies or other documents that it receives from the other.
7. The system referred to in Article 34 shall provide structured information on mutual assistance cases to the single liaison offices involved. Utilising this information, single liaison offices shall give any support 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 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 legislation that are to be placed under the customs procedure ‘release for free circulation’ shall be subject to controls performed by the authorities designated under paragraph 1. They shall perform those controls on the basis of risk analysis in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013 and where relevant on the basis of risk-based approach as referred to in 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;
  - (b) customs authorities in accordance with Article 46(5) of Regulation (EU) No 952/2013.

Where, in relation to products subject to Union legislation that are either in temporary storage or placed under a customs procedure other than release for free circulation, customs authorities at the first point of entry have reason to believe that those products are not compliant with applicable Union legislation 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 product or the identity of economic operators where a higher risk of non-compliance has been identified.

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

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

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

8. In order to ensure a consistent enforcement of Union harmonisation legislation, to strengthen the controls on products entering the Union market and to ensure an effective and uniform level of such controls, the Commission, after consultation of the Network established under Article 29, may adopt implementing acts in accordance with the examination procedure referred to in Article 43(2) determining benchmarks and techniques for checks on the basis of common risk analysis on the Union level.
9. The Commission shall specify further by means of implementing acts 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 legislation 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 that Union legislation;
- (c) the product bears a CE marking or other marking required by that Union legislation 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);
- (e) for any other reason, when there is cause to believe that the product does not comply with the requirements set out in the Union harmonisation legislation applicable to it or that it poses 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 harmonisation legislation applicable to it or poses 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 according to paragraph 2 and requests according to paragraph 3 may take place by means of the system referred to in Article 34 including utilisation of electronic interfaces between this system and systems used by customs, when they are available.

### Article 27

#### Release of products

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 if any 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 as proof of conformity with Union legislation.

## Article 28

### Refusal to release

1. Where the market surveillance authorities conclude that a product presents a serious risk, they shall take measures to prohibit the placing of the product on the market and shall require the authorities designated under Article 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/... of the European Parliament and of the Council of ... 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<sup>+</sup>’;

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

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<sup>+</sup> OJ: please insert the number and the date in the text, of the document in COD 2017/0354.



2. Where market surveillance authorities conclude that a product may not be placed on the market as it does not comply with the Union legislation applicable to it, they shall take measures to prohibit the placing of the product on the market and shall require the authorities designated under Article 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:

‘Product not in conformity – release for free circulation not authorised – Regulation (EU) 2019/... of the European Parliament and of the Council of ... 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<sup>+</sup>.’

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

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

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<sup>+</sup> OJ: please insert the number and the date in the text, of the document in COD 2017/0354.

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 it is deemed, by the authority in question, 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. An 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 making market surveillance activities more effective.

## Article 30

### Composition and functioning of the Network

1. The Network shall be composed of representatives from each Member State, including a representative of the single liaison offices referred to in Article 10, and an optional national expert, the chairs of administrative coordination groups (ADCOs), and representatives from the Commission.
2. Separate or joint administrative coordination groups (ADCOs) shall be established for implementation of Union harmonisation legislation. Administrative coordination groups shall be composed of representatives of the national market surveillance authorities and, if appropriate, representatives of the single liaison offices.

ADCO meetings are intended only for representatives of market surveillance authorities.

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

3. The Commission shall support and encourage cooperation between market surveillance authorities via 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 duly motivated 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, small and medium enterprises, consumers, laboratories and conformity assessment bodies at Union level, to attend meetings as observers or 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 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 cross-sector 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 market surveillance strategies and activities;
  - (c) to provide coordination of 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 market surveillance strategies;
- (f) to facilitate the organisation of training programmes and exchanges of national officials;
- (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 mechanism;
- (i) to contribute to the development of guidance to ensure the effective and uniform implementation of this Regulation;
- (j) to propose the financing of activities foreseen 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 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 external borders;
- (n) to promote and facilitate collaboration with other relevant networks and groups, with a view to explore possibilities on 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 under the purview of the Network aimed at contributing to the effective functioning of market surveillance within the Union.

## Article 32

### Role and tasks of administrative coordination groups

1. In carrying out the tasks set out in paragraph 2, ADCOs shall address specific matters of 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 single market;
  - (b) to promote communication between national market surveillance authorities and the Network and develop mutual confidence between national 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 assessment, 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 this 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 for the instruments of Union harmonisation legislation;
- (h) to develop and maintain the system referred to in Article 34, including the interface referred to in paragraph 7 of that Article, as well as the interface with national market surveillance databases, and provide information to the general 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, common training programmes, facilitate exchanges of personnel between market surveillance authorities and, where appropriate, with the market surveillance authorities of third countries or with international organisations, 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 levels;
- (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 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 in accordance with 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 systems.
3. Single liaison offices shall enter the following information in the system:
  - (a) the identity of the market surveillance authorities in their Member State and areas of competence of those authorities pursuant to Article 10(2);

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

4. Market surveillance authorities shall enter the following information into the 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, 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) when applicable, failures by authorised representatives to comply with Article 5(2);
  - (g) when available, failures by manufacturers to comply with Article 5(1).
5. Where market surveillance authorities consider it useful, they may enter 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 purposes of minimising risk, customs authorities shall extract from national customs systems information relating to 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 custom 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, in particular on the data processing that will be applied on data collected in accordance with paragraph 1 and defining the data to be transmitted in accordance with paragraphs 6 and 7. 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 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 legislation.

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 product or in respect of products or categories of product 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 to the Union from that third country 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 product 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 product 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 reveal significant non-compliance, the market surveillance authorities shall notify immediately the Commission through the system referred to in Article 34 and adapt the level of controls on such products.
10. The Commission shall adopt implementing acts to approve 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 and, by means of an implementing act withdraw an approval granted under paragraph 3 where it is revealed that the products entering the Union market do not comply with Union harmonisation legislation in a significant number of instances. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2). The Commission shall immediately inform the affected third country of the outcome of the decision of the committee accordingly.
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 29 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 the implementation of market surveillance activities linked to the application of Union harmonisation legislation such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits 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 levels.
3. The Union shall finance the electronic interface referred to in Article 34(7) including the development enabling the system referred to in Article 34 to receive automatic flows of electronic data from national customs systems according to Article 34(7).
  4. The Union shall finance the interface according to Article 34(2) allowing the exchange of data with national market surveillance systems.

5. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council<sup>52</sup>, either directly, or by delegating budget implementation tasks to the entities listed in point (c) of Article 58(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 insofar as far as they are related to the general objectives of market surveillance activities, expenses linked to information technology networks focusing on information processing and exchange together with all other related technical and administrative assistance expenses incurred by the Commission.

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<sup>52</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

## Article 37

### Protection of the Union's financial interests of the Union

1. The Commission shall take appropriate measures to ensure that, when 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 procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council<sup>53</sup> and Council Regulation (Euratom, EC) No 2185/96<sup>54</sup> with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant agreement or grant decision or a contract funded under this Regulation.
4. Without prejudice to paragraphs 1, 2 and 3, cooperation agreements with third countries and with international organisations, contracts, grant agreements and grant decisions resulting from the implementation of this Regulation shall contain provisions expressly empowering the Commission, the Court of Auditors and OLAF to conduct such audits and investigations, in accordance with their respective competences.

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<sup>53</sup> 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).

<sup>54</sup> OJ L292, 14.11.1996, p.2.



Chapter X  
Amendments

Article 38  
Amendments to Directive 2004/42/EC

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

Article 39  
Amendments to Regulation (EC) No 765/2008

1. The words in the title "and market surveillance relating to the marketing of products", Article 1(2) and (3), Article 2(1), 2(2), 2(14), 2(15), 2(17), 2(18) and 2(19), Articles 15 to 29, the words "and market surveillance" in point (c) of Article 32(1), point (d) of Article 32(1), point (e) of Article 32(1), the words "and market surveillance activities" and ", as well as European market surveillance campaigns and similar activities" in point (f) of Article 32(1), and the words ' , market surveillance' in point (g) of Article 32(1) of Regulation (EC) No 765/2008 are deleted.
2. References to the repealed articles shall be construed as references to the respective articles of this Regulation and shall be read in accordance with the correlation table in Annex III.

## Article 40

### Amendments to Regulation (EU) No 305/2011

In the first subparagraph of Article 56(1), the words "have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they" are deleted.

## Chapter XI

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

## Article 41

### Penalties

1. The Member States shall lay down the rules on penalties applicable to infringements of the provisions 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 according to national legislation.
2. The penalties provided for shall be effective, proportionate and dissuasive.
3. The Member States shall notify those provisions to the Commission, where they have not previously been notified, by ... [27 months after the date of entry into force of this Regulation] 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 against the objectives it pursues and present a report on the main findings to the European Parliament, to the Council and to the European Economic and Social Committee.
2. The report shall assess whether this Regulation achieved its objectives, in particular with regard to reducing the number of non-compliant products on the Union market, ensuring effective and efficient enforcement of Union harmonisation legislation within the Union, improving cooperation between competent authorities and strengthening the controls on products entering the Union market, whilst taking into account the impact on business and in particular on small and medium-sized enterprises. In addition, the evaluation should also assess the 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 legislation and the possibilities to further improve the cooperation between the market surveillance authorities and custom 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 the provisions on Article 4. The report shall particularly evaluate the scope of application of that Article, its effects and the costs and benefits of the related provisions. The report shall be accompanied, where appropriate, by a legislative proposal for its review.
4. Within four years after the first approval of a system for product-related pre-export control according to 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), 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 ... [2 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*  
*The President*

*For the Council*  
*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. 599);
2. Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (OJ L 042 , 23.02.1970, p. 16);
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. 400);
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 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);



12. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34);
13. Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1);
14. 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);
15. 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);
16. 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);

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

20. 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);
21. 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);

22. 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);
23. 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);
24. 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);

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 (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) 2018/1139 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), insofar as the design, production and placing on the market of aircrafts referred to in point (a) and (b) of Article 2(1), where it concerns unmanned aircraft, and their engines, propellers, parts and equipment to control them remotely is concerned.

## ANNEX II

### 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. 599);
2. Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (OJ L 042 , 23.02.1970, p. 16);
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 (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

<b>Regulation EC No. 765/2008</b>	<b>This Regulation</b>
Article 1(2)	Article 1(1)
Article 1(3)	Article 1(3)
Article 2(1)	Article 3(1)
Article 2(2)	Article 3(2)
Article 2(14)	Article 3(17)
Article 2(15)	Article 3(18)
Article 2(17)	Article 3(3)
Article 2(18)	Article 3(4)
Article 2(19)	Article 3(20)
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 18(1)	Article 10(6)
Article 18(2)(a)	Article 11(7)(a)
Article 18(2)(b)	-
Article 18(2)(c)	Article 11(7)(b)
Article 18(2)(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 19(1), first subparagraph	Article 11(3)
Article 19(1), second subparagraph	Article 14(4)(a), (b) and (e)
Article 19(1), third subparagraph	Article 11(5)
Article 19(2)	Article 16(3)(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)	Articles 22(2) to (4)
Article 24(3)	-
Article 24(4)	-

Article 25(1)	-
Article 25(2)(a)	Articles 31(2)(f), 33(1)(i) and (k)
Article 25(2)(b)	Articles 31(2)(g) and (k) and 33(1)(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(a)
Article 28(2)	Article 27(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)(e)	Article 36(2)(e)

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