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[1] Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2019/1020 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 June 2019

on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

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

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

Whereas:

(1) In order to guarantee the free movement of products within the Union, it is necessary to ensure that products are compliant with Union harmonisation legislation and therefore fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety in the workplace, protection of consumers, protection of the environment, public security and protection of any other public interests protected by that legislation. Robust enforcement of these requirements is essential to the proper protection of these interests and to create the conditions in which fair competition in the Union market for goods can thrive. Rules are therefore necessary to ensure this enforcement, regardless of whether products are placed on the market via offline or online means and regardless of whether they are manufactured in the Union or not.

(2) Union harmonisation legislation covers a large share of manufactured products. Non-compliant and unsafe products put citizens at risk, and might distort competition with economic operators selling compliant products within the Union.

(3) Strengthening the single market for goods through further enhancing efforts to keep non-compliant products from being placed on the Union market was identified as a priority in the Communication from the Commission of 28 October 2015 entitled 'Upgrading the Single Market: more opportunities for people and business'. This should be achieved by strengthening market surveillance, providing economic operators with clear, transparent and comprehensive rules, intensifying compliance controls and promoting closer cross-border cooperation among enforcement authorities, including through cooperation with customs authorities.

([1]) OJ C 283, 10.8.2018, p. 19.
([2]) Position of the European Parliament of 17 April 2019 (not yet published in the Official Journal) and decision of the Council of 14 June 2019.

(4) The framework for market surveillance established by this Regulation should complement and strengthen existing provisions in Union harmonisation legislation relating to the ensuring of compliance of products and the framework for cooperation with organisations representing economic operators or end users, the market surveillance of products and controls on those products entering the Union market. However, in accordance with the principle of *lex specialis*, this Regulation should apply only in so far as there are no specific provisions with the same objective, nature or effect in Union harmonisation legislation. The corresponding provisions of this Regulation should therefore not apply in the areas covered by such specific provisions, for instance those set out in Regulations (EC) No 1223/2009 ([3]), (EU) 2017/745 ([4]) and (EU) 2017/746 ([5]), including as regards the use of the European database on medical devices (EUDAMED), and (EU) 2018/858 ([6]) of the European Parliament and of the Council.

(5) Directive 2001/95/EC of the European Parliament and of the Council ([7]) lays down the general safety requirements for all consumer products and provides for specific obligations and powers of the Member States in relation to dangerous products as well as for the exchange of information to that effect through the Rapid Information Exchange System (RAPEX). Market surveillance authorities should have the possibility of taking the more specific measures available to them under that Directive. In order to achieve a higher level of safety for consumer products, the mechanisms for exchanges of information and rapid intervention situations provided for in Directive 2001/95/EC should be made more effective.

(6) The provisions on market surveillance of this Regulation should cover products that are subject to the Union harmonisation legislation listed in Annex I concerning manufactured products other than food, feed, medicinal products for human and veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. This will ensure a uniform framework for market surveillance of those products at Union level and will help to increase the confidence of consumers and other end users in products placed on the Union market. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to specify whether this Regulation is also to apply to that legislation.

(7) Articles 15 to 29 of Regulation (EC) No 765/2008 of the European Parliament and of the Council ([8]) laying down the Community market surveillance framework and controls of products entering the Community market should be deleted and the respective provisions should be replaced by this Regulation. That framework includes the provisions on controls of products entering the Community market, in Articles 27, 28 and 29 of Regulation (EC) No 765/2008, which apply not only to products covered by the market surveillance framework, but to all products in so far as other Union law does not contain specific provisions relating to the organisation of controls on products entering the Union market. It is therefore necessary that the scope of the provisions of this Regulation with regard to products entering the Union market extend to all products.

(8) In order to rationalise and simplify the overall legislative framework, while simultaneously pursuing the objectives of Better Regulation, the rules applicable to controls on products entering the Union market should be revised and integrated into a single legislative framework for controls on products at the Union's external borders.

(9) Responsibility for enforcing Union harmonisation legislation should lie with the Member States, and their market surveillance authorities should be required to ensure that the legislation is fully complied with. The Member States should, therefore, establish systematic approaches to ensure effectiveness of market surveillance and other enforcement activities. In this regard, the methodology and criteria for assessing risks should be further harmonised in all Member States in order to ensure a level playing field for all economic operators.

([3]) 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).

([4]) 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).

([5]) 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).

([6]) 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).

([7]) 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).

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

(10) In order to assist market surveillance authorities to strengthen consistency in their activities related to the application of this Regulation, an effective peer review system should be established for those market surveillance authorities wishing to participate.

(11) Certain definitions currently set out in Regulation (EC) No 765/2008 should be aligned with definitions set out in other Union legal acts and, where appropriate, reflect the architecture of modern supply chains. The definition of 'manufacturer' in this Regulation should not relieve manufacturers of any obligations they might have under Union harmonisation legislation where specific definitions of manufacturer are applied, which might cover any natural or legal person who modifies a product already placed on the market in such a way that compliance with the applicable Union harmonisation legislation might be affected and places it on the market, or any other natural or legal person who places a product on the market under its name or trade mark.

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

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

(14) Modern supply chains encompass a wide variety of economic operators who should all be subject to enforcement of Union harmonisation legislation, while taking due consideration of their respective roles in the supply chain, and the extent to which they contribute to the making available of products on the Union market. Therefore, it is necessary to apply this Regulation to economic operators that are directly concerned by Union harmonisation legislation listed in Annex I to this Regulation, such as the producer of an article and the downstream user as defined in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([9]) and in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([10]), the installer as defined in Directive 2014/33/EU of the European Parliament and of the Council ([11]), the supplier as defined in Regulation (EC) No 1222/2009 of the European Parliament and of the Council ([12]) or the dealer as defined in Regulation (EU) 2017/1369 of the European Parliament and of the Council ([13]).

([9]) 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).

([10]) 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).

([11]) 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).

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

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

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

(16) The development of e-commerce is also due, to a great extent, to the proliferation of information society service providers, usually through platforms and for remuneration, which offer intermediary services by storing third party content, without exercising control over that content, and therefore not acting on behalf of an economic operator. Removal of content regarding non-compliant products or, where this is not feasible, restricting access to non-compliant products offered through their services should be without prejudice to the rules laid down in Directive 2000/31/EC of the European Parliament and of the Council ([14]). In particular, no general obligation should be imposed on information society service providers to monitor the information which they transmit or store, nor should a general obligation be imposed upon them to actively seek facts or circumstances indicating illegal activity. Furthermore, hosting service providers should not be held liable as long as they do not have actual knowledge of illegal activity or information and are not aware of the facts or circumstances from which the illegal activity or information is apparent.

(17) While this Regulation does not deal with the protection of intellectual property rights, it should nevertheless be borne in mind that often counterfeit products do not comply with the requirements set out in the Union harmonisation legislation, present risks to health and safety of end users, distort competition, endanger public interests and support other illegal activities. Therefore, Member States should continue taking effective measures to prevent counterfeit products from entering the Union market pursuant to Regulation (EU) No 608/2013 of the European Parliament and of the Council ([15]).

(18) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this end, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers and the market surveillance authorities is a key element, allowing immediate intervention and corrective action in relation to the product. It is important that, for certain products, there should be an economic operator established in the Union so that market surveillance authorities have someone to whom requests can be addressed, including requests for information regarding a product's compliance with Union harmonisation legislation, and who can cooperate with market surveillance authorities in making sure that immediate corrective action is taken to remedy instances of non-compliance. The economic operators who should perform those tasks are the manufacturer, or the importer when the manufacturer is not established in the Union, or an authorised representative mandated by the manufacturer for this purpose, or a fulfilment service provider established in the Union for products handled by it when no other economic operator is established in the Union.

(19) The development of e-commerce poses certain challenges for market surveillance authorities with regard to the ensuring of compliance of products offered for sale online and the effective enforcement of Union harmonisation legislation. The number of economic operators offering products directly to consumers by electronic means is increasing. Therefore, economic operators with tasks regarding products subject to certain Union harmonisation legislation perform an essential role by providing market surveillance authorities with an interlocutor established in the Union, and by performing specific tasks in a timely manner to make sure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, other end users and businesses within the Union.

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

([15]) 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).

(20) The obligations of the economic operator with tasks regarding products subject to certain Union harmonisation legislation should be without prejudice to existing obligations and responsibilities of manufacturer, importer and authorised representative under the relevant Union harmonisation legislation.

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

(22) Moreover, those obligations should not apply where the specific requirements set out in certain legal acts on products achieve in effect the same result, namely Regulation (EC) No 648/2004 of the European Parliament and of the Council ([16]), Regulation (EC) No 1223/2009, Regulation (EU) No 167/2013 of the European Parliament and of the Council ([17]), Regulation (EU) No 168/2013 of the European Parliament and of the Council ([18]), Directive 2014/28/EU of the European Parliament and of the Council ([19]), Directive 2014/90/EU of the European Parliament and of the Council ([20]), Regulation (EU) 2016/1628 of the European Parliament and of the Council ([21]), Regulation (EU) 2017/745, Regulation (EU) 2017/746, Regulation (EU) 2017/1369 and Regulation (EU) 2018/858.

Consideration should also be given to situations where potential risks or cases of non-compliance are low, or in which products are mainly traded through traditional supply chains, which is the case, for instance, for Directive 2014/33/EU, Regulation (EU) 2016/424 of the European Parliament and of the Council ([22]) and Directive 2010/35/EU of the European Parliament and of the Council ([23]).

(23) Contact information of economic operators with tasks regarding products subject to certain Union harmonisation legislation should be indicated with the product in order to facilitate checks throughout the supply chain.

(24) Economic operators should fully cooperate with market surveillance authorities and other competent authorities to ensure the smooth performance of market surveillance and to enable the authorities to perform their tasks. This includes, where requested by authorities, providing the contact information of the economic operators with tasks regarding products subject to certain Union harmonisation legislation where this information is available to them.

(25) Economic operators should have easy access to high quality, comprehensive information. Since the single digital gateway established under Regulation (EU) 2018/1724 of the European Parliament and of the Council ([24]) provides for a single point of online access to information, it can be used in respect to providing relevant information on Union harmonisation legislation to economic operators. Nevertheless, Member States should put

([16]) Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1).
([17]) 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).
([18]) 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).
([19]) 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).
([20]) 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).
([21]) 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).
([22]) 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).
([23]) 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).
([24]) 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).

in place procedures for ensuring access to the Product Contact Points established under Regulation (EU) 2019/515 of the European Parliament and of the Council ([25]) in order to assist the economic operators in addressing properly their requests for information. Guidance on issues relating to technical specifications or harmonised standards or design of a specific product should not be part of the obligations of Member States when providing such information.

(26) Market surveillance authorities might carry out joint activities with other authorities or organisations representing economic operators or end users, with a view to promoting compliance, identifying non-compliance, raising awareness and providing guidance on Union harmonisation legislation and with respect to specific categories of products, including those that are offered for sale online.

(27) Member States should designate their own market surveillance authorities. This Regulation should not prevent Member States from choosing the competent authorities to carry out the market surveillance tasks. In order to facilitate administrative assistance and cooperation, Member States should also appoint a single liaison office. Single liaison offices should at least represent the coordinated position of the market surveillance authorities and the authorities in charge of the control on products entering the Union market.

(28) E-commerce poses certain challenges for market surveillance authorities regarding the protection of the health and safety of end users from non-compliant products. Therefore, Member States should ensure their market surveillance is organised with the same effectiveness for products made available online as it is for products made available offline.

(29) While performing market surveillance of products offered for sale online, market surveillance authorities are facing numerous difficulties, such as tracing products offered for sale online, identifying the responsible economic operators, or conducting risk-assessments or tests due to the lack of physical access to products. In addition to the requirements introduced by this Regulation, Member States are encouraged to use complementary guidance and best practices for market surveillance and for communication with businesses and consumers.

(30) Special attention should be given to emerging technologies, taking into account that consumers are increasingly using connected devices in their daily lives. The Union regulatory framework should therefore address the new risks to ensure the safety of the end users.

(31) In the age of constant development of digital technologies new solutions that could contribute to the effective market surveillance within the Union should be explored.

(32) Market surveillance should be thorough and effective, to ensure that Union harmonisation legislation on products is applied correctly. Given that controls may represent a burden for economic operators, market surveillance authorities should organise and conduct inspection activities on a risk-based approach, taking the interests of those economic operators into account and limiting the said burden to what is necessary for the performance of efficient and effective controls. Furthermore, market surveillance should be performed with the same level of care by the competent authorities of the Member State irrespective of whether non-compliance of the given product is relevant on the territory of that Member State or is likely to have an impact on the market of another Member State. Uniform conditions for certain inspection activities carried out by the market surveillance authorities where products or categories of products present specific risks or seriously breach the applicable Union harmonisation legislation might be laid down by the Commission.

(33) Market surveillance authorities, when performing their duties, are confronted with different shortcomings in terms of resources, coordination mechanisms, as well as powers with regard to non-compliant products. Such differences lead to fragmented enforcement of Union harmonisation legislation and to market surveillance being more rigorous in some Member States than in others, potentially compromising the level playing field among businesses and creating also potential imbalances in the level of product safety throughout the Union.

([25]) Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008 (OJ L 91, 29.3.2019, p. 1).

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

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

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

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

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

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

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

(41) In the digital environment in particular, market surveillance authorities should be able to bring non-compliance to an end quickly and effectively, notably where the economic operator selling the product conceals its identity or relocates within the Union or to a third country in order to avoid enforcement. In cases where there is a risk of serious and irreparable harm to end users due to non-compliance, market surveillance authorities should be able to take measures, where duly justified and proportionate and where there are no other means available to prevent or mitigate such harm, including, where necessary, requiring the removal of content from the online interface or the display of a warning. When such a request is not observed, the relevant authority should have the power to require information society service providers to restrict access to the online interface. These measures should be taken in accordance with the principles laid down in Directive 2000/31/EC.

(42) The implementation of this Regulation and the exercise of powers in its application should also comply with other Union and national law, for example Directive 2000/31/EC, including with applicable procedural safeguards and principles of the fundamental rights. That implementation and that exercise of powers should also be proportionate and adequate in view of the nature and the overall actual or potential harm caused by the infringement. Competent authorities should take all facts and circumstances of the case into account and should choose the

most appropriate measures, namely, those which are essential to address the infringement covered by this Regulation. Those measures should be proportionate, effective and dissuasive. Member States should remain free to set out conditions and limits for the exercise of the powers to fulfil duties in national law. Where, for example, in accordance with national law, prior authorisation to enter the premises of natural persons and legal persons is required from the judicial authority of the Member State concerned, the power to enter such premises should be used only after such prior authorisation has been obtained.

(43) Market surveillance authorities act in the interest of economic operators, of end users, and of the public, to ensure that public interests covered by relevant Union harmonisation legislation on products are consistently preserved and protected through appropriate enforcement measures, and that compliance with such legislation is ensured across the supply chain through appropriate checks, taking into consideration the fact that administrative checks alone, in many cases, cannot replace physical and laboratory checks in order to verify the compliance of products with the relevant Union harmonisation legislation. Consequently, market surveillance authorities should ensure a high level of transparency while performing their activities and should make available to the public any information that they consider to be relevant in order to protect the interests of end users in the Union.

(44) This Regulation should be without prejudice to the functioning of RAPEX in accordance with Directive 2001/95/EC.

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

(46) The exchange of information between market surveillance authorities, and the use of evidence and investigation findings should respect the principle of confidentiality. Information should be handled in accordance with applicable national law, in order to ensure that investigations are not compromised and that the reputation of the economic operator is not prejudiced.

(47) Where, for the purposes of this Regulation, it is necessary to process personal data, this should be carried out in accordance with Union law on the protection of personal data. Any processing of personal data under this Regulation is subject to Regulation (EU) 2016/679 of the European Parliament and of the Council ([26]) and Regulation (EU) 2018/1725 of the European Parliament and of the Council ([27]), as applicable.

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

(49) Member States should ensure that adequate financial resources are always available for the appropriate staffing and equipping of the market surveillance authorities. Efficient market surveillance is demanding in terms of resources, and stable resources should be provided at a level appropriate to the enforcement needs at any given moment. Member States should have the possibility to supplement public financing by reclaiming from the relevant economic operators the costs incurred when performing market surveillance in relation to products that were found to be non-compliant.

(50) Mechanisms for mutual assistance should be established, since it is imperative for the Union market for goods that the market surveillance authorities of the Member States cooperate with each other effectively. Authorities should act in good faith and, as a general principle, accept requests for mutual assistance, in particular those concerning access to EU declaration of conformity, declaration of performance and technical documentation.

([26]) 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).

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

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

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

(53) Importers should be reminded that Articles 220, 254, 256, 257 and 258 of Regulation (EU) No 952/2013 of the European Parliament and of the Council ([28]) provide that products entering the Union market that require further processing in order to be in compliance with the applicable Union harmonisation legislation shall be placed under the appropriate customs procedure allowing such processing by the importer. Generally, the release for free circulation should not be deemed to be proof of conformity with Union law, since such a release does not necessarily include a complete check of compliance.

(54) In order to use the EU Single Window environment for customs and therefore to optimise and unburden the data transfer between customs and market surveillance authorities, it is necessary to set up electronic interfaces that allow automatic data transfer. Customs and market surveillance authorities should contribute to determine the data to be transmitted. Additional burden for customs authorities should be limited and the interfaces should be highly automated and easy-to-use.

(55) It is necessary to establish the Network, hosted by the Commission, aimed at structured coordination and cooperation between enforcement authorities of the Member States and the Commission, and at streamlining the practices of market surveillance within the Union that facilitate the implementation of joint enforcement activities by Member States, such as joint investigations. This administrative support structure should allow the pooling of resources and maintain a communication and information system between Member States and the Commission, thereby helping to strengthen enforcement of Union harmonisation legislation on products and to deter infringements. The involvement of administrative cooperation groups (ADCOs) in the Network should not preclude the involvement of other, similar, groups involved in administrative cooperation. The Commission should provide the necessary administrative and financial support to the Network.

(56) There should be effective, speedy and accurate exchange of information among the Member States and the Commission. A number of existing tools, such as the information and communication system for market surveillance (ICSMS) and RAPEX enable coordination among market surveillance authorities in the Union. These tools, together with the interface permitting data transfer from ICSMS into RAPEX should be maintained and further developed in order to exploit their full potential and help to increase the level of cooperation and exchange of information between Member States and the Commission.

([28]) 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).

(57) In that context, for the purpose of collecting information relating to the enforcement of Union harmonisation legislation on products, ICSMS should be upgraded and be accessible to the Commission, single liaison offices, customs and market surveillance authorities. Furthermore, an electronic interface should be developed to allow effective exchange of information between national systems of customs and market surveillance authorities. With regard to the cases of mutual assistance requests, the single liaison offices should give any support necessary for cooperation between the relevant authorities. Therefore, ICSMS should provide the functions enabling an automated indication to the single liaison offices when deadlines are not met. When sectoral legislation already provides for electronic systems for cooperation and data exchange, as is the case for example of EUDAMED for medical devices, those systems should be kept in use, when appropriate.

(58) In general, ICSMS should be used to exchange information considered helpful for other market surveillance authorities. This might include checks undertaken in the context of market surveillance projects, regardless of the outcome of the tests. The amount of data to be entered in ICSMS should strike a balance between imposing too great a burden, when the efforts for entering the data would exceed the work involved in doing the actual checks, and being comprehensive enough to support greater efficiency and effectiveness on the side of the authorities. Thus, the data entered in ICSMS should also cover simpler checks than laboratory tests only. Nevertheless, there should be no need to include brief visual checks. As a guideline, checks which are individually documented should also be entered in ICSMS.

(59) Member States are encouraged to use ICSMS for interactions between customs and market surveillance authorities as an alternative to the national systems. This should not replace the Community Risk Management System (CRMS) used by customs authorities. These two systems could work in parallel since they fulfil different, complementary roles, with ICSMS facilitating communication between customs and market surveillance authorities in order to allow for a smooth treatment of customs declarations in the scope of the product safety and compliance framework while CRMS is for customs common risk management and controls.

(60) Injuries caused by non-compliant products are important information for market surveillance authorities. ICSMS should therefore provide for related data fields so that market surveillance authorities can enter readily available reports provided for in the course of their investigations, thus facilitating later statistical evaluations.

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

(62) In order to achieve a high degree of compliance with applicable Union harmonisation legislation on products while at the same time ensuring an effective resource-allocation and a cost-efficient control of products entering the Union market, the Commission should be able to approve specific pre-export control systems. Products falling under such approved systems might, as part of the risk assessment performed by authorities in charge of controls on products entering the Union market, benefit from a higher level of confidence than comparable products which have not been subject to a pre-export control.

(63) The Commission should carry out an evaluation of this Regulation in light of the objective it pursues, and taking into consideration new technological, economic, commercial and legal developments. Pursuant to point 22 of the Interinstitutional Agreement of 13 April 2016 on Better L aw Making ([29]), the evaluation, based on efficiency, effectiveness, relevance, coherence and value added, should provide the basis for impact assessments of options for further action, particularly as regards the scope of this Regulation, the application and enforcement of the provisions related to the tasks of economic operators placing products on the market, and the system of product-related pre-export controls.

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

([29]) OJ L 123, 12.5.2016, p. 1.

(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.

(66) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission in relation to: determining the uniform conditions for checks, criteria for determination of the frequency of checks and amount of samples to be checked in relation to certain products or categories of products, where specific risks or serious breaches of Union harmonisation legislation have been continuously identified; specifying the procedures for the designation of Union testing facilities; laying down benchmarks and techniques for checks on the basis of common risk analysis at the Union level; specifying the details of statistical data covering controls performed by the designated authorities with respect to products subject to Union law; specifying the details of implementation arrangements for the information and communication system and defining the data relating to the placing of products under the customs procedure 'release for free circulation' transmitted by customs authorities; and to the approval of specific systems of product-related pre-export controls and the withdrawal of such approvals. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([30]).

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

(68) This Regulation respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and present in the constitutional traditions of Member States. Accordingly, this Regulation should be interpreted and applied in accordance with those rights and principles, including those related to the freedom and pluralism of the media. In particular, this Regulation seeks to ensure full respect for consumer protection, the freedom to conduct a business, the freedom of expression and information, the right to property and the protection of personal data,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

1. The objective of this Regulation is to improve the functioning of the internal market by strengthening the market surveillance of products covered by the Union harmonisation legislation referred to in Article 2, with a view to ensuring that only compliant products that fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety in the workplace, the protection of consumers, the protection of the environment and public security and any other public interests protected by that legislation, are made available on the Union market.

2. This Regulation lays down rules and procedures for economic operators regarding products subject to certain Union harmonisation legislation and establishes a framework for cooperation with economic operators.

3. This Regulation also provides a framework for controls on products entering the Union market.

([30]) 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).

Article 2

Scope

1. This Regulation shall apply to products that are subject to the Union harmonisation legislation listed in Annex I ('Union harmonisation legislation'), in so far as there are no specific provisions with the same objective in the Union harmonisation legislation, which regulate in a more specific manner particular aspects of market surveillance and enforcement.

2. Articles 25 to 28 shall apply to products covered by Union law in so far as there are no specific provisions relating to the organisation of controls on products entering the Union market in Union law.

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

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

Article 3

Definitions

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

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

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

(3) 'market surveillance' means the activities carried out and measures taken by market surveillance authorities to ensure that products comply with the requirements set out in the applicable Union harmonisation legislation and to ensure protection of the public interest covered by that legislation;

(4) 'market surveillance authority' means an authority designated by a Member State under Article 10 as responsible for carrying out market surveillance in the territory of that Member State;

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

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

(7) 'non-compliance' means any failure to comply with any requirement under the Union harmonisation legislation or under this Regulation;

(8) 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under its name or trademark;

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

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

(11) 'fulfilment service provider' means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the Council ([31]), parcel delivery services as defined in point 2 of Article 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council ([32]), and any other postal services or freight transport services;

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

([32]) 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).

(12) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks with regard to the manufacturer's obligations under the relevant Union harmonisation legislation or under the requirements of this Regulation;

(13) 'economic operator' means the manufacturer, the authorised representative, the importer, the distributor, the fulfilment service provider or any other natural or legal person who is subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant Union harmonisation legislation;

(14) 'information society service provider' means a provider of a service as defined in point (b) of Article 1(1) of Directive (EU) 2015/1535 of the European Parliament and of the Council ([33]);

(15) 'online interface' means any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator, and which serves to give end users access to the economic operator's products;

(16) 'corrective action' means any action taken by an economic operator to bring any non-compliance to an end where required by a market surveillance authority or on the economic operator's own initiative;

(17) 'voluntary measure' means a corrective action where not required by a market surveillance authority;

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

(19) 'product presenting a risk' means a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, protection of consumers, the environment, public security and other public interests, protected by the applicable Union harmonisation legislation, to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

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

(21) 'end user' means any natural or legal person residing or established in the Union, to whom a product has been made available either as a consumer outside of any trade, business, craft or profession or as a professional end user in the course of its industrial or professional activities;

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

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

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

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

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

([33]) 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).

CHAPTER II

TASKS OF ECONOMIC OPERATORS

Article 4

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

1. Notwithstanding any obligations set out in applicable Union harmonisation legislation, a product subject to legislation referred to in paragraph 5 may be placed on the market only if there is an economic operator established in the Union who is responsible for the tasks set out in paragraph 3 in respect of that product.

2. For the purposes of this Article, the economic operator referred to in paragraph 1 means any of the following:

(a) a manufacturer established in the Union;

(b) an importer, where the manufacturer is not established in the Union;

(c) an authorised representative who has a written mandate from the manufacturer designating the authorised representative to perform the tasks set out in paragraph 3 on the manufacturer's behalf;

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

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

(a) if the Union harmonisation legislation applicable to the product provides for an EU declaration of conformity or declaration of performance and technical documentation, verifying that the EU declaration of conformity or declaration of performance and technical documentation have been drawn up, keeping the declaration of conformity or declaration of performance at the disposal of market surveillance authorities for the period required by that legislation and ensuring that the technical documentation can be made available to those authorities upon request;

(b) further to a reasoned request from a market surveillance authority, providing that authority with all information and documentation necessary to demonstrate the conformity of the product in a language which can be easily understood by that authority;

(c) when having reason to believe that a product in question presents a risk, informing the market surveillance authorities thereof;

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

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

5. This Article only applies in relation to products that are subject to Regulations (EU) No 305/2011 ([34]), (EU) 2016/425 ([35]) and (EU) 2016/426 ([36]) of the European Parliament and of the Council, and Directives 2000/14/EC ([37]), 2006/42/EC ([38]), 2009/48/EC ([39]), 2009/125/EC ([40]), 2011/65/EU ([41]), 2013/29/EU ([42]), 2013/53/EU ([43]), 2014/29/EU ([44]), 2014/30/EU ([45]), 2014/31/EU ([46]), 2014/32/EU ([47]), 2014/34/EU ([48]), 2014/35/EU ([49]), 2014/53/EU ([50]) and 2014/68/EU ([51]) of the European Parliament and of the Council.

Article 5

Authorised representative

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

2. The authorised representative shall perform the tasks specified in the mandate. It shall provide a copy of the mandate to the market surveillance authorities upon request, in a Union language determined by the market surveillance authority.

3. Authorised representatives shall have the appropriate means to be able to fulfil their tasks.

Article 6

Distance sales

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

([34]) 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).
([35]) 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).
([36]) 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).
([37]) 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).
([38]) Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24).
([39]) 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).
([40]) 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).
([41]) 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).
([42]) 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).
([43]) 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).
([44]) 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).
([45]) 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).
([46]) 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).
([47]) 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).
([48]) 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).
([49]) 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).
([50]) 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).
([51]) Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164).

Article 7

Obligation of cooperation

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

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

CHAPTER III

ASSISTANCE TO AND COOPERATION WITH ECONOMIC OPERATORS

Article 8

Information to economic operators

1. The Commission, in accordance with Regulation (EU) 2018/1724, shall ensure that the Your Europe portal provides users with easy online access to information about the product requirements and rights, obligations and rules derived from the Union harmonisation legislation.

2. Member States shall put in place procedures for providing economic operators, at their request and free of charge, with information with respect to the national transposition and implementation of Union harmonisation legislation applicable to products. For this purpose, Article 9(1), (4) and (5) of Regulation (EU) 2019/515 shall apply.

Article 9

Joint activities to promote compliance

1. Market surveillance authorities may agree with other relevant authorities or with organisations representing economic operators or end users on the carrying out of joint activities that have the aim of promoting compliance, identifying non-compliance, raising awareness and providing guidance in relation to the Union harmonisation legislation with respect to specific categories of products, in particular categories of products that are often found to present a serious risk, including products offered for sale online.

2. The market surveillance authority in question and the parties referred to in paragraph 1 shall ensure that the agreement on joint activities does not lead to unfair competition between economic operators and does not affect the objectivity, independence and impartiality of the parties.

3. A market surveillance authority may use any information resulting from joint activities carried out as part of any investigation regarding non-compliance that it undertakes.

4. The market surveillance authority in question shall make the agreement on joint activities, including the names of the parties involved, available to the public and shall enter that agreement in the information and communication system referred to in Article 34. At the request of a Member State, the Network established under Article 29 shall assist in the drawing up of the agreement on joint activities.

CHAPTER IV

ORGANISATION, ACTIVITIES AND OBLIGATIONS OF MARKET SURVEILLANCE AUTHORITIES AND THE SINGLE LIAISON OFFICE

Article 10

Designation of market surveillance authorities and the single liaison office

1. Member States shall organise and carry out market surveillance as provided for in this Regulation.

2. For the purposes of paragraph 1 of this Article, each Member State shall designate one or more market surveillance authorities in its territory. Each Member State shall inform the Commission and the other Member States of its market surveillance authorities and the areas of competence of each of those authorities, using the information and communication system referred to in Article 34.

3. Each Member State shall appoint a single liaison office.

4. The single liaison office shall at least be responsible for representing the coordinated position of the market surveillance authorities and the authorities designated under Article 25(1) and for communicating the national strategies as set out in Article 13. The single liaison office shall also assist in the cooperation between market surveillance authorities in different Member States, as set out in Chapter VI.

5. In order to carry out market surveillance of products made available online and offline with the same effectiveness for all distribution channels, Member States shall ensure that their market surveillance authorities and single liaison office have the necessary resources, including sufficient budgetary and other resources, such as a sufficient number of competent personnel, expertise, procedures and other arrangements for the proper performance of their duties.

6. Where there is more than one market surveillance authority in their territory, Member States shall ensure that the respective duties of those authorities are clearly defined and that appropriate communication and coordination mechanisms are established to enable those authorities to collaborate closely and exercise their duties effectively.

Article 11

Activities of market surveillance authorities

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

(a) effective market surveillance within their territory of products made available online and offline with respect to products that are subject to Union harmonisation legislation;

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

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

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

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

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

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

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

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

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

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

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

5. Where economic operators present test reports or certificates attesting the conformity of their products with Union harmonisation legislation issued by a conformity assessment body accredited in accordance with Regulation (EC) No 765/2008, market surveillance authorities shall take due account of those reports or certificates.

6. Evidence that is used by a market surveillance authority in one Member State may be used as part of investigations to verify product compliance carried out by market surveillance authorities in another Member State, without any further formal requirements.

7. Market surveillance authorities shall establish the following procedures in connection with products subject to the Union harmonisation legislation:

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

(b) procedures for verifying that the corrective action that was to be taken by economic operators has been taken.

8. With a view to ensuring communication and coordination with their counterparts in other Member States, market surveillance authorities shall actively participate in administrative cooperation groups (ADCOs) as referred to in Article 30(2).

9. Without prejudice to any Union safeguard procedure pursuant to the applicable Union harmonisation legislation, products that have been deemed to be non-compliant on the basis of a decision of a market surveillance authority in one Member State shall be presumed to be non-compliant by market surveillance authorities in other Member States, unless a relevant market surveillance authority in another Member State concluded the contrary on the basis of its own investigation, taking into account the input, if any, provided by an economic operator.

Article 12

Peer reviews

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

2. The Network shall develop the methodology and the rolling plan for peer reviews among participating market surveillance authorities. When establishing the methodology and the rolling plan, the Network shall take into consideration, at least, the number and the size of market surveillance authorities in the Member States, the number of personnel available and other resources for performing the peer review, and other relevant criteria.

3. Peer reviews shall cover best practices developed by some market surveillance authorities which may be of benefit for other market surveillance authorities, and other relevant aspects related to the effectiveness of market surveillance activities.

4. The outcome of the peer reviews shall be reported to the Network.

Article 13

National market surveillance strategies

1. Each Member State shall draw up an overarching national market surveillance strategy, at least every four years. Each Member State shall draw up the first such strategy by 16 July 2022. The national strategy shall promote a consistent, comprehensive and integrated approach to market surveillance and to the enforcement of Union harmonisation legislation within the territory of the Member State. When drawing up the national market surveillance strategy, all sectors covered by the Union harmonisation legislation and all stages of the product supply chain, including imports and digital supply chains, shall be considered. The priorities set out within the work programme of the Network may also be considered.

2. The national market surveillance strategy shall include at least the following elements, when this does not compromise market surveillance activities:

(a) the available information on the occurrence of non-compliant products, in particular taking into account the checks and controls referred to in Articles 11(3) and 25(3), respectively, and, where applicable, market trends that may affect non-compliance rates for the categories of products, and possible threats and risks related to emerging technologies;

(b) the areas identified by the Member States as priorities for the enforcement of Union harmonisation legislation;

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

(d) an assessment of the cooperation with market surveillance authorities in other Member States, as referred to in Article 11(8) and Chapter VI.

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

CHAPTER V

MARKET SURVEILLANCE POWERS AND MEASURES

Article 14

Powers of market surveillance authorities

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

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

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

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

(b) by recourse to other public authorities in accordance with the division of powers and the institutional and administrative organisation of the Member State in question;

(c) upon application to courts competent to grant the necessary decision to approve the exercise of that power, including, where appropriate, on appeal, if the application to grant the necessary decision was not successful.

4. The powers conferred on market surveillance authorities under paragraph 1 shall include at least the following:

(a) the power to require economic operators to provide relevant documents, technical specifications, data or information on compliance and technical aspects of the product, including access to embedded software in so far as such access is necessary for the purpose of assessing the product's compliance with applicable Union harmonisation legislation, in any form or format and irrespective of the medium of storage or the place where such documents, technical specifications, data or information are stored, and to take or obtain copies thereof;

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

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

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

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

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

(g) the power to require economic operators to take appropriate action to bring an instance of non-compliance to an end or to eliminate the risk;

(h) the power to take appropriate measures where an economic operator fails to take appropriate corrective action or where the non-compliance or the risk persists, including the power to prohibit or restrict the making available of a product on the market or to order that the product is withdrawn or recalled;

(i) the power to impose penalties in accordance with Article 41;

(j) the power to acquire product samples, including under a cover identity, to inspect those samples and to reverse-engineer them in order to identify non-compliance and to obtain evidence;

(k) the power, where no other effective means are available to eliminate a serious risk:

(i) to require the removal of content referring to the related products from an online interface or to require the explicit display of a warning to end users when they access an online interface; or

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

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

Article 15

Recovery of costs by market surveillance authorities

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

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

Article 16

Market surveillance measures

1. Market surveillance authorities shall take appropriate measures if a product subject to Union harmonisation legislation, when used in accordance with its intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained:

(a) is liable to compromise the health or safety of users; or

(b) does not conform to applicable Union harmonisation legislation.

2. Where market surveillance authorities make findings referred to in point (a) or (b) of paragraph 1, they shall without delay require the relevant economic operator to take appropriate and proportionate corrective action to bring the non-compliance to an end or to eliminate the risk within a period they specify.

3. For the purposes of paragraph 2, the corrective action required to be taken by the economic operator may include, inter alia:

(a) bringing the product into compliance, including by rectifying formal non-compliance as defined by the applicable Union harmonisation legislation, or by ensuring that the product no longer presents a risk;

(b) preventing the product from being made available on the market;

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

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

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

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

(g) alerting the end users at risk immediately and in an appropriate form, including by publication of special warnings in the language or languages determined by the Member State in which the product is made available on the market.

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

5. If the economic operator fails to take corrective action referred to in paragraph 3 or where the non-compliance or the risk referred to in paragraph 1 persists, market surveillance authorities shall ensure that the product is withdrawn or recalled, or that its being made available on the market is prohibited or restricted, and that the public, the Commission and the other Member States are informed accordingly.

6. The information to the Commission and the other Member States pursuant to paragraph 5 of this Article shall be communicated through the information and communication system referred to in Article 34. That communication of information shall also be deemed to fulfil notification requirements for the applicable safeguard procedures of Union harmonisation legislation.

7. Where a national measure is considered to be justified in accordance with the applicable safeguard procedure, or where no market surveillance authority of another Member State concluded the contrary as referred to in Article 11(9), the competent market surveillance authorities in the other Member States shall take the necessary measures in respect of the non-compliant product and shall enter the relevant information in the information and communication system referred to in Article 34.

Article 17

Use of information, professional and commercial secrecy

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

Article 18

Procedural rights of economic operators

1. Any measure, decision or order taken or made by market surveillance authorities pursuant to Union harmonisation legislation or this Regulation shall state the exact grounds on which it is based.

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

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

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

Article 19

Products presenting a serious risk

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

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

Article 20

Rapid Information Exchange System

1. Where a market surveillance authority takes or intends to take a measure pursuant to Article 19 and considers that the reasons which prompted the measure or the effects of the measure go beyond the territory of its Member State, it shall immediately notify the Commission of that measure in accordance with paragraph 4 of this Article. The market surveillance authority shall also inform the Commission without delay of the modification or withdrawal of any such measure.

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

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

4. For the purposes of paragraphs 1, 2 and 3 of this Article, the Rapid Information Exchange System (RAPEX) provided for in Article 12 of Directive 2001/95/EC shall be used. Paragraphs 2, 3 and 4 of Article 12 of that Directive shall apply *mutatis mutandis*.

5. The Commission shall provide and maintain a data interface between RAPEX and the information and communication system referred to in Article 34 so as to avoid double data entry.

Article 21

Union testing facilities

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

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

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

3. Union testing facilities shall be accredited in accordance with Regulation (EC) No 765/2008.

4. The designation of Union testing facilities shall not affect the freedom of market surveillance authorities, the Network and the Commission to choose testing facilities for the purpose of their activities.

5. Designated Union testing facilities shall provide their services solely to market surveillance authorities, the Network, the Commission and other government or intergovernmental entities.

6. Union testing facilities shall, within the area of their competence, perform the following activities:

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

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

(c) develop new techniques and methods of analysis.

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

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

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

CHAPTER VI

CROSS-BORDER MUTUAL ASSISTANCE

Article 22

Mutual Assistance

1. There shall be efficient cooperation and exchange of information among the market surveillance authorities of the Member States, and between market surveillance authorities and the Commission and the relevant Union agencies.

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

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

4. The applicant authority shall remain responsible for any investigation that it has initiated, unless the requested authority agrees to take over responsibility.

5. In duly justified cases, a requested authority may refuse to comply with a request for information under paragraph 2 where:

(a) the applicant authority has not sufficiently substantiated that the requested information is necessary in order to establish non-compliance;

(b) the requested authority demonstrates reasonable grounds showing that complying with the request would substantially impair the execution of its own activities.

Article 23

Requests for enforcement measures

1. Where bringing non-compliance with regard to a product to an end requires measures within the jurisdiction of another Member State and where such measures do not result from the requirements of Article 16(7), an applicant authority may submit a duly reasoned request for enforcement measures to a requested authority in that other Member State.

2. The requested authority shall without delay take all appropriate and necessary enforcement measures using the powers conferred on it under this Regulation in order to bring the instance of non-compliance to an end by exercising the powers laid down in Article 14 and any additional powers granted to it under national law.

3. The requested authority shall inform the applicant authority about the measures referred to in paragraph 2 that have been taken or which are intended to be taken.

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

(a) the requested authority concludes that the applicant authority has not provided sufficient information;

(b) the requested authority considers that the request is contrary to Union harmonisation legislation;

(c) the requested authority demonstrates reasonable grounds showing that complying with the request would substantially impair the execution of its own activities.

Article 24

Procedure for mutual assistance requests

1. Before submitting a request under Article 22 or 23, the applicant authority shall endeavour to carry out all reasonable possible investigations.

2. When submitting a request under Article 22 or 23, the applicant authority shall provide all available information in order to enable the requested authority to fulfil the request, including any necessary evidence obtainable only in the Member State of the applicant authority.

3. Requests under Articles 22 and 23 and all communication related to them shall be made using electronic standard forms by means of the information and communication system referred to in Article 34.

4. Communication shall take place directly between the involved market surveillance authorities or through the single liaison offices of the Member States concerned.

5. The languages to be used for requests under Articles 22 and 23 and for all communication linked to them shall be agreed upon by the market surveillance authorities concerned.

6. Where no agreement about the languages to be used can be reached between the market surveillance authorities concerned, the requests under Articles 22 and 23 shall be sent in the official language of the Member State of the applicant authority, and the replies to such requests shall be sent in the official language of the Member State of the requested authority. In such case, the applicant authority and the requested authority shall arrange for the translation of the requests, replies or other documents that it receives from the other authority.

7. The information and communication system referred to in Article 34 shall provide structured information on mutual assistance cases to the single liaison offices involved. Using this information, single liaison offices shall provide any support that is necessary to facilitate assistance.

CHAPTER VII

PRODUCTS ENTERING THE UNION MARKET

Article 25

Controls on products entering the Union market

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

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

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

3. Products subject to Union law that are to be placed under the customs procedure 'release for free circulation' shall be subject to controls performed by the authorities designated under paragraph 1 of this Article. They shall perform those controls on the basis of risk analysis in accordance with Articles 46 and 47 of Regulation (EU) No 952/2013 and, where relevant, on the basis of risk-based approach as referred to in the second subparagraph of Article 11(3) of this Regulation.

4. Risk-related information shall be exchanged between:

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

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

Where, in relation to products subject to Union law that are either in temporary storage or placed under a customs procedure other than 'release for free circulation', customs authorities at the first point of entry have reason to believe that those products are not compliant with applicable Union law or present a risk, they shall transmit all relevant information to the competent customs office of destination.

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

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

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

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

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

9. The Commission shall adopt implementing acts further specifying the details of the data to be submitted under paragraph 6 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2).

Article 26

Suspension of release for free circulation

1. Authorities designated under Article 25(1) shall suspend the release of a product for free circulation if in the course of controls pursuant to Article 25(3), it is established that:

(a) the product is not accompanied by the documentation required by the Union law applicable to it or there is a reasonable doubt as to the authenticity, accuracy or completeness of such documentation;

(b) the product is not marked or labelled in accordance with the Union law applicable to it;

(c) the product bears a CE marking or other marking required by the Union law applicable to it which has been affixed in a false or misleading manner;

(d) the name, registered trade name or registered trade mark and the contact details, including the postal address, of an economic operator with tasks regarding the product subject to certain Union harmonisation legislation is not indicated or identifiable in accordance with Article 4(4); or

(e) for any other reason, when there is cause to believe that the product does not comply with the Union law applicable to it or that it presents a serious risk to health, safety, the environment or any other public interest referred to in Article 1.

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

3. Where the market surveillance authorities have reasonable grounds to believe that a product does not comply with the Union law applicable to it or presents a serious risk, they shall request the authorities designated under Article 25(1) to suspend the process for its release for free circulation.

4. Notifications under paragraph 2 and requests under paragraph 3 of this Article may take place by means of the information and communication system referred to in Article 34, including through the use of electronic interfaces between this system and systems used by customs authorities, when they are available.

Article 27

Release for free circulation

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

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

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

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

Article 28

Refusal to release for free circulation

1. Where the market surveillance authorities conclude that a product presents a serious risk, they shall take measures to prohibit the placing of the product on the market and shall require the authorities designated under Article 25(1) not to release it for free circulation. They shall also require these authorities to include the following notice in the customs data-processing system, and, where appropriate, on the commercial invoice accompanying the product and on any other relevant accompanying document:

'Dangerous product — release for free circulation not authorised — Regulation (EU) 2019/1020'.

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

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

'Product not in conformity — release for free circulation not authorised — Regulation (EU) 2019/1020'.

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

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

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

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

CHAPTER VIII

COORDINATED ENFORCEMENT AND INTERNATIONAL COOPERATION

Article 29

Union Product Compliance Network

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

2. The purpose of the Network is to serve as a platform for structured coordination and cooperation between enforcement authorities of the Member States and the Commission, and to streamline the practices of market surveillance within the Union, thereby making market surveillance more effective.

Article 30

Composition and functioning of the Network

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

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

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

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

3. The Commission shall support and encourage cooperation between market surveillance authorities through the Network and participate in the meetings of the Network, its sub-groups and the ADCOs.

4. The Network shall meet at regular intervals and, where necessary, at the reasoned request of the Commission or a Member State.

5. The Network may establish standing or temporary sub-groups dealing with specific questions and tasks.

6. The Network may invite experts and other third parties, including the organisations representing the interests of industry, SMEs, consumers, testing laboratories, standardisation and conformity assessment bodies at Union level, to attend meetings as observers or to provide written contributions.

7. The Network shall use its best endeavours to reach consensus. Decisions taken by the Network shall be legally non-binding recommendations.

8. The Network shall establish its own rules of procedure.

Article 31

Role and tasks of the Network

1. In carrying out the tasks set out in paragraph 2, the Network shall address general, horizontal issues of market surveillance with a view to facilitating the cooperation among single liaison offices, as well as the Commission.

2. The Network shall have the following tasks:

(a) to prepare, adopt and monitor the implementation of its work programme;

(b) to facilitate the identification of common priorities for market surveillance activities and the exchange of information across sectors on evaluations of products, including risk assessment, test methods and results, recent scientific developments and new technologies, emerging risks and other aspects relevant to control activities and on the implementation of national market surveillance strategies and activities;

(c) to coordinate ADCOs and their activities;

(d) to organise cross-sector joint market surveillance and testing projects and define their priorities;

(e) to exchange expertise and best practices, in particular regarding the implementation of national market surveillance strategies;

(f) to facilitate the organisation of training programmes and exchanges of personnel;

(g) in collaboration with the Commission, to organise information campaigns and voluntary mutual visit programmes between market surveillance authorities;

(h) to discuss questions arising from cross-border mutual assistance mechanisms;

(i) to contribute to the development of guidance to ensure the effective and uniform application of this Regulation;

(j) to propose the financing of activities referred to in Article 36;

(k) to contribute to uniform administrative practices with regard to market surveillance in the Member States;

(l) to provide advice and assist the Commission with issues related to the further development of RAPEX and the information and communication system referred to in Article 34;

(m) to promote the cooperation and exchange of expertise and best practices between market surveillance authorities and authorities in charge of controls at the Union's external borders;

(n) to promote and facilitate collaboration with other relevant networks and groups, with a view to explore possibilities for using new technologies for the purposes of market surveillance and traceability of products;

(o) to evaluate regularly the national market surveillance strategies, the first such evaluation taking place by 16 July 2024;

(p) to take up any other issues in activities within the remit of the Network, with the aim of contributing to the effective functioning of market surveillance within the Union.

Article 32

Role and tasks of administrative cooperation groups

1. In carrying out the tasks set out in paragraph 2, ADCOs shall address specific matters related to market surveillance and sector specific issues.

2. ADCOs shall have the following tasks:

(a) to facilitate the uniform application of Union harmonisation legislation within their area of competence with a view to increasing the efficiency of market surveillance throughout the internal market;

(b) to promote communication between market surveillance authorities and the Network and develop mutual confidence between market surveillance authorities;

(c) to establish and coordinate common projects, such as cross-border joint market surveillance activities;

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

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

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

(g) to facilitate sector-specific evaluations of products, including risk assessments, test methods and results, recent scientific developments and other aspects relevant to control activities.

Article 33

Role and tasks of the Commission

The Commission shall have the following tasks:

(a) to assist the Network, its sub-groups, and the ADCOs by means of an executive secretariat that provides technical and logistic support;

(b) to keep and make available to the single liaison offices and ADCO chairs an updated list of ADCO chairs, including their contact information;

(c) to assist the Network in preparing and monitoring its work programme;

(d) to support the functioning of the Product Contact Points having duties assigned by Member States in relation to Union harmonisation legislation;

(e) to determine, in consultation with the Network, the need for additional testing capacity and to propose solutions for that purpose, in accordance with Article 21;

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

(g) to provide support for the establishment of separate or joint ADCOs;

(h) to develop and maintain the information and communication system referred to in Article 34, including the interface referred to in Article 34(7), as well as the interface with national market surveillance databases, and provide information to the public by means of that system;

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

(j) to prepare and assist in the implementation of Union market surveillance campaigns and similar activities;

(k) to organise joint market surveillance and testing projects, and common training programmes, to facilitate exchanges of personnel between market surveillance authorities and, where appropriate, with the market surveillance authorities of third countries or with international organisations, and to organise information campaigns and voluntary mutual visit programmes between market surveillance authorities;

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

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

(n) to examine, at the request of the Network or on its own initiative, any question covering the application of this Regulation and issue guidelines, recommendations and best practices in order to encourage consistent application of this Regulation.

Article 34

Information and communication system

1. The Commission shall further develop and maintain an information and communication system for the collection, processing and storage of information, in a structured form, on issues relating to the enforcement of Union harmonisation legislation, with the aim of improving the sharing of data among Member States, including for the purpose of requests for information, providing a comprehensive overview of market surveillance activities, results and trends. The Commission, market surveillance authorities, single liaison offices, and authorities designated under Article 25(1) shall have access to that system. The Commission shall develop and maintain the public user interface of this system, where key information for end-users about market surveillance activities shall be provided.

2. The Commission shall further develop and maintain electronic interfaces between the system referred to in paragraph 1 and national market surveillance systems.

3. Single liaison offices shall enter the following information in the information and communication system:

(a) the identity of the market surveillance authorities in their Member State and areas of competence of those authorities pursuant to Article 10(2);

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

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

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

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

(b) reports of testing carried out by them;

(c) corrective action taken by economic operators concerned;

(d) readily available reports on injuries caused by the product in question;

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

(f) where available, failures by authorised representatives to comply with Article 5(2);

(g) where available, failures by manufacturers to comply with Article 5(1).

5. Where market surveillance authorities consider it useful, they may enter into the information and communication system any additional information related to the checks they perform and results of testing carried out by them or at their request.

6. Where relevant for the enforcement of Union harmonisation legislation and for the purpose of minimising risk, customs authorities shall extract from national customs systems information on products placed under the customs procedure 'release for free circulation' related to the enforcement of Union harmonisation legislation and transmit it to the information and communication system.

7. The Commission shall develop an electronic interface to enable the transmission of data between national customs systems and the information and communication system. This interface shall be in place within four years from the date of adoption of the relevant implementing act referred to in paragraph 8.

8. The Commission shall adopt implementing acts specifying the details of implementation arrangements for paragraphs 1 to 7 of this Article, and in particular the data processing to be applied on data collected in accordance with paragraph 1 of this Article, and defining the data to be transmitted in accordance with paragraphs 6 and 7 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2).

Article 35

International cooperation

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

2. The cooperation or exchange of information may relate, inter alia, to the following:

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

(b) coordinated product recalls or other similar actions;

(c) the measures taken by market surveillance authorities under Article 16.

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

4. The Commission shall produce and maintain a list of those products or categories of products with regard to which approval has been granted as referred to in paragraph 3 and shall make this list available to the public.

5. Approval may only be granted to a third country under paragraph 3 if following conditions are satisfied:

(a) the third country possesses an efficient verification system of the compliance of products exported to the Union, and the controls carried out in that third country are sufficiently effective and efficient to replace or reduce import controls;

(b) audits within the Union and, if relevant, in the third country demonstrate that products exported from that third country to the Union satisfy the requirements set out in Union harmonisation legislation.

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

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

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

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

9. Where controls on products entering the Union market referred to in paragraph 3 of this Article reveal significant non-compliance, the market surveillance authorities shall notify immediately the Commission through the information and communication system referred to in Article 34 and adapt the level of controls on such products.

10. The Commission shall adopt implementing acts approving each specific system of product-related pre-export controls, referred to in paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 43(2).

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

12. The system of product-related pre-export control shall be evaluated in accordance with Article 42(4).

CHAPTER IX

FINANCIAL PROVISIONS

Article 36

Financing activities

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

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

(a) the functioning of the Product Contact Points;

(b) the establishment and functioning of Union testing facilities referred to in Article 21;

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

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

(e) the making available to the Commission of technical or scientific expertise for the purpose of assisting the Commission in its implementation of market surveillance administrative cooperation;

(f) the implementation of national market surveillance strategies referred to in Article 13;

(g) Member States' and Union market surveillance campaigns and associated activities, including resources and equipment, IT tools and training;

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

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

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

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

5. The Union's financial assistance with respect to the activities in support of this Regulation shall be implemented in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ([52]), either directly, or by entrusting budget implementation tasks to the entities listed in point (c) of Article 62(1) of that Regulation.

6. The appropriations allocated to activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the financial framework in force.

7. The appropriations determined by the budgetary authority for the financing of market surveillance activities may also cover expenses relating to preparatory work, monitoring, control, audit and evaluation activities which are required for the management of the activities set out in this Regulation and for the achievement of their objectives. These expenses shall include the costs of conducting studies, arranging meetings of experts, information and communication activities, including corporate communication of the political priorities of the Union in so far as they are related to the general objectives of market surveillance activities, expenses linked to information technology networks focusing on information processing and exchange together with all other related technical and administrative assistance expenses incurred by the Commission.

Article 37

Protection of the financial interests of the Union

1. The Commission shall take appropriate measures to ensure that, when activities financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective controls and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.

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

3. The European Anti-Fraud Office (OLAF) may carry out investigations, including on-the-spot controls and inspections, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council ([53]) and Council Regulation (Euratom, EC) No 2185/96 ([54]) 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.

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

([53]) 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).

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

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.

CHAPTER X

AMENDMENTS

Article 38

Amendments to Directive 2004/42/EC

Articles 6 and 7 of Directive 2004/42/EC of the European Parliament and of the Council ([55]) are deleted.

Article 39

Amendments to Regulation (EC) No 765/2008

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

(1) the title is replaced by the following:

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

(2) in Article 1, paragraphs 2 and 3 are deleted;

(3) in Article 2, points 1, 2, 14, 15, 17, 18 and 19 are deleted;

(4) Chapter III, containing Articles 15 to 29, is deleted;

(5) paragraph 1 of Article 32 is amended as follows:

(a) point (c) is replaced by the following:

'(c) the drawing up and updating of contributions to guidelines in the fields of accreditation, notification to the Commission of conformity assessment bodies and conformity assessment;';

(b) points (d) and (e) are deleted;

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

'(f) the performance of preliminary or ancillary work in connection with the implementation of the conformity assessment, metrology and accreditation activities linked to the implementation of Community legislation, such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits, research work, the development and maintenance of databases, training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work;

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

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

Article 40

Amendments to Regulation (EU) No 305/2011

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

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

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

CHAPTER XI

FINAL PROVISIONS

Article 41

Penalties

1. The Member States shall lay down the rules on penalties applicable to infringements of this Regulation and of Union harmonisation legislation listed in Annex II that impose obligations on economic operators and shall take all measures necessary to ensure that they are implemented in accordance with national law.

2. The penalties provided for shall be effective, proportionate and dissuasive.

3. The Member States shall, by 16 October 2021, notify those provisions to the Commission, where they have not previously been notified, and shall notify it, without delay, of any subsequent amendment affecting them.

Article 42

Evaluation, review and guidelines

1. By 31 December 2026 and every five years thereafter, the Commission shall carry out an evaluation of this Regulation in light of the objectives that it pursues and shall present a report thereon to the European Parliament, to the Council and to the European Economic and Social Committee.

2. The report shall assess whether this Regulation achieved its objective, in particular with regard to reducing the number of non-compliant products on the Union market, ensuring effective and efficient enforcement of Union harmonisation legislation within the Union, improving cooperation between competent authorities and strengthening the controls on products entering the Union market, while taking into account the impact on business and in particular on SMEs. In addition, the evaluation shall also assess the scope of this Regulation, the effectiveness of the peer review system and of the market surveillance activities that receive Union financing in the light of the requirements of Union policies and law and the possibilities to further improve the cooperation between the market surveillance authorities and customs authorities.

3. By 16 July 2023, the Commission shall prepare an evaluation report on the implementation of Article 4. The report shall in particular evaluate the scope of that Article, its effects and its costs and benefits. The report shall be accompanied, where appropriate, by a legislative proposal.

4. Within four years after the first approval of a specific system of product-related pre-export control referred to in Article 35(3), the Commission shall carry out an evaluation of its effects and cost efficiency.

5. In order to facilitate the implementation of this Regulation, the Commission shall draw up guidelines for the practical implementation of Article 4 for the purposes of market surveillance authorities and economic operators.

Article 43

Committee procedure

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

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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

Article 44

Entry into force and application

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

It shall apply from 16 July 2021. 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 Brussels, 20 June 2019.

For the European Parliament	*For the Council*
The President	*The President*
A. TAJANI	G. CIAMBA

ANNEX I

List of Union harmonisation legislation

1. Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (OJ L 326, 29.12.1969, p. 36);

2. Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (OJ L 42, 23.2.1970, p. 16);

3. Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14);

4. Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 147, 9.6.1975, p. 40);

5. Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products (OJ L 46, 21.2.1976, p. 1);

6. Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40);

7. Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ L 167, 22.6.1992, p. 17);

8. Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer (OJ L 100, 19.4.1994, p. 37);

9. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10);

10. Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC (OJ L 350, 28.12.1998, p. 58);

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

12. Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1);

13. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles (OJ L 269, 21.10.2000, p. 34);

14. Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1);

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

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

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

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

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

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

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

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

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

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

25. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

41. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1);

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

67. Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017, p. 1);

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

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

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

ANNEX II

List of Union harmonisation legislation without provisions on penalties

1. Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (OJ L 326, 29.12.1969, p. 36);

2. Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (OJ L 42, 23.2.1970, p. 16);

3. Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14);

4. Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 147, 9.6.1975, p. 40);

5. Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products (OJ L 46, 21.2.1976, p. 1);

6. Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ L 167, 22.6.1992, p. 17);

7. Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer (OJ L 100, 19.4.1994, p. 37);

8. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10);

9. Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1);

10. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34);

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

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

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

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

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

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

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

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

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

ANNEX III

Correlation table

Regulation (EC) No 765/2008	This Regulation
Article 1(2)	Article 1(1)
Article 1(3)	Article 1(3)
Article 2, point 1	Article 3, point 1
Article 2, point 2	Article 3, point 2
Article 2, point 14	Article 3, point 22
Article 2, point 15	Article 3, point 23
Article 2, point 17	Article 3, point 3
Article 2, point 18	Article 3, point 4
Article 2, point 19	Article 3, point 25
Article 15(1) and (2)	Article 2(1)
Article 15(3)	Article 2(3)
Article 15(4)	—
Article 15(5)	Article 2(2)
Article 16(1)	Article 10(1)
Article 16(2)	Article 16(5)
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Article 16(4)	—
Article 17(1)	Article 10(2)
Article 17(2)	Article 34(1), last sentence and Article 34(3), point (a)
Article 18(1)	Article 10(6)
Article 18(2), point (a)	Article 11(7), point (a)
Article 18(2), point (b)	—
Article 18(2), point (c)	Article 11(7), point (b)
Article 18(2), point (d)	—
Article 18(3)	Articles 10(5) and 14(1)
Article 18(4)	Article 14(2)
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Article 18(6)	Article 31(2), point (o)
Article 19(1), first subparagraph	Article 11(3)
Article 19(1), second subparagraph	Article 14(4), points (a), (b), (e) and (j)
Article 19(1), third subparagraph	Article 11(5)
Article 19(2)	Article 16(3), point (g)
Article 19(3)	Article 18(2)
Article 19(4)	Article 11(2)
Article 19(5)	Article 17

Regulation (EC) No 765/2008	This Regulation
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)
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Article 24(3)	—
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Article 25(2), point (b)	Article 31(2), points (g) and (m) and Article 33(1), points (i) and (k)
Article 25(3)	—
Article 26	—
Article 27(1), first sentence	Article 25(2)
Article 27(1), second sentence	Article 25(3)
Article 27(2)	Article 25(4)
Article 27(3), first subparagraph	Article 26(1)
Article 27(3), second subparagraph	Article 26(2)
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Article 27(5)	—
Article 28(1)	Article 27, first paragraph, point (a)
Article 28(2)	Article 27, first paragraph, point (b)
Article 29(1)	Article 28(1)
Article 29(2)	Article 28(2)
Article 29(3)	Article 28(3)
Article 29(4)	Article 28(4)
Article 29(5)	Article 25(5)
Article 32(1), point (d)	—
Article 32(1), point (e)	Article 36(2), point (e)

REGULATION (EU) 2019/1021 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 June 2019

on persistent organic pollutants

(recast)

(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 Article 192(1) thereof,

Having regard to the proposal from the European Commission,

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

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

After consulting the Committee of the Regions,

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

Whereas:

(1) Regulation (EC) No 850/2004 of the European Parliament and of the Council ([3]) has been substantially amended several times. Since it is necessary to make further amendments, that Regulation should be recast in the interests of clarity.

(2) The Union is seriously concerned by the continuous release of persistent organic pollutants ('POPs') into the environment. Those chemical substances are transported across international boundaries, far from their sources, and they persist in the environment, bioaccumulate through the food web, and pose a risk to human health and the environment. Therefore, further measures need to be taken in order to protect human health and the environment against those pollutants.

(3) In view of its responsibilities for the protection of the environment, the Union approved on 19 February 2004 the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants ([4]) ('the Protocol') and approved on 14 October 2004 the Stockholm Convention on Persistent Organic Pollutants ([5]) ('the Convention').

(4) In order to ensure coherent and effective implementation of the Union's obligations under the Protocol and the Convention, it is necessary to establish a common legal framework within which to take measures designed, in particular, to eliminate the manufacturing, placing on the market and use of intentionally manufactured POPs. Furthermore, POPs' characteristics should be taken into consideration in the framework of the relevant Union assessment and authorisation schemes.

([1]) OJ C 367, 10.10.2018, p. 93.
([2]) Position of the European Parliament of 18 April 2019 (not yet published in the Official Journal) and decision of the Council of 13 June 2019.
([3]) 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).
([4]) OJ L 81, 19.3.2004, p. 37.
([5]) OJ L 209, 31.7.2006, p. 3.

(5) When implementing the provisions of the Convention at Union level, it is necessary to ensure coordination and coherence with the provisions of the Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade, which was approved by the Union on 19 December 2002 ([6]), and with the provisions of the Basel Convention on the control of transboundary movements of hazardous wastes and their disposal, which was approved by the Union on 1 February 1993 ([7]) and of the Minamata Convention on Mercury, which was approved by the Union on 11 May 2017 ([8]). This coordination and coherence should also be maintained when participating in the implementation and further development of the Strategic Approach to International Chemicals Management (SAICM), adopted by the First International Conference on Chemicals Management in Dubai on 6 February 2006, and the Sound Management of Chemicals and Waste Beyond 2020 within the United Nations framework.

(6) Moreover, considering that the provisions of this Regulation are underpinned by the precautionary principle as set forth in the Treaty on the Functioning of the European Union (TFEU), and mindful of the precautionary approach to environmental protection as set forth in Principle 15 of the Rio Declaration on Environment and Development, and in view of the aim of the elimination, where feasible, of the release of POPs into the environment, it is appropriate in certain cases to provide for control measures stricter than those under the Protocol and the Convention.

(7) In the Union, the placing on the market and use of most of the POPs listed in the Protocol or the Convention have already been phased out as a result of the prohibitions laid down in, inter alia, Regulations (EC) No 1907/2006 ([9]), (EC) No 1107/2009 ([10]) and (EU) No 528/2012 ([11]) of the European Parliament and of the Council. However, in order to fulfil the Union's obligations under the Protocol and the Convention, and to minimise the release of POPs, it is necessary and appropriate also to prohibit the manufacturing of those substances and to restrict exemptions to a minimum so that exemptions only apply where a substance fulfils an essential function in a specific application.

(8) For reasons of clarity and consistency with other relevant Union legislative acts, certain definitions should be specified, and terminology should be aligned with that used in Regulation (EC) No 1907/2006 and Directive 2008/98/EC of the European Parliament and of the Council ([12]).

(9) Exports of substances covered by the Convention are regulated by Regulation (EU) No 649/2012 of the European Parliament and of the Council ([13]) and therefore need not be further addressed in this Regulation.

(10) Obsolete or carelessly managed stockpiles of POPs may seriously endanger the environment and human health through, for instance, contamination of soil and ground water. It is appropriate, therefore, to lay down stricter rules concerning the management of such stockpiles compared to those laid down in the Convention. Stockpiles of prohibited substances should be treated as waste, while stockpiles of substances the manufacturing or use of which is still allowed should be notified to the authorities and properly supervised. In particular, existing stockpiles which consist of or contain banned POPs should be managed as waste as soon as possible. If other substances are banned in the future, their stocks should also be destroyed without delay, and no new stockpiles should be built up.

(11) In line with the Protocol and the Convention, releases of POPs which are unintentional by-products of industrial processes should be identified and reduced as soon as possible, with the ultimate aim of elimination, where feasible. Appropriate national action plans, covering all sources and measures, including those provided for under existing Union legislation, should be developed, updated and implemented, as appropriate, as soon as possible, to reduce such releases continuously and cost-effectively. To this end, appropriate tools should be developed in the framework of the Convention.

([6]) OJ L 63, 6.3.2003, p. 29.
([7]) OJ L 39, 16.2.1993, p. 3.
([8]) OJ L 142, 2.6.2017, p. 4.
([9]) 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).
([10]) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).
([11]) 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).
([12]) Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).
([13]) Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p. 60).

(12) The Guidelines on Best Available Techniques and Provisional Guidance on Best Environmental Practices Relevant to Article 5 and Annex C of the Stockholm Convention on Persistent Organic Pollutants, which were adopted pursuant to the Stockholm Convention, should be used when considering proposals to construct new facilities or to significantly modify existing facilities using processes that release chemicals listed in Annex III to this Regulation.

(13) Appropriate programmes and mechanisms should be established or maintained, as appropriate, to provide adequate monitoring data on the presence of substances listed in Part A of Annex III in the environment. However, it is necessary to ensure that appropriate tools are available and can be used under economically and technically viable conditions.

(14) Under the Convention, the POP content in waste is to be destroyed or irreversibly transformed into substances that do not exhibit similar characteristics, unless other operations are environmentally preferable. In order for the Union to comply with its obligations under the Convention, it is necessary to lay down specific rules as regards those substances. To ensure a high level of protection, common concentration limits for the substances in waste should be established, monitored and enforced.

(15) Concerning polybrominated diphenyl ethers (PBDEs) listed in this Regulation, including decaBDE, the concentration limit for the sum of those substances in waste is set at 1 000 mg/kg. Considering that scientific and technical progress are rapidly evolving, the Commission should review that concentration limit and, where appropriate, adopt a legislative proposal to lower that value to 500 mg/kg. The Commission should act as quickly as possible and, in any event, not later than 16 July 2021.

(16) It is important to identify and separate waste consisting of, containing or contaminated by POPs at source in order to minimise the spread of those chemicals into other waste. Directive 2008/98/EC establishes Union rules on the management of hazardous waste, obliging Member States to take the necessary measures to require that establishments and undertakings which dispose of, recover, collect or transport hazardous waste, do not mix different categories of hazardous waste or mix hazardous waste with non-hazardous waste.

(17) In order to promote the traceability of waste containing POPs and ensure control, the provisions of the record keeping system established in accordance with Article 17 of Directive 2008/98/EC should apply also to such waste containing POPs which is not defined as hazardous waste according to Commission Decision 2014/955/EU ([14]).

(18) There is a need to ensure the effective coordination and management of technical and administrative aspects of this Regulation at Union level. The European Chemicals Agency ('the Agency'), established by Regulation (EC) No 1907/2006, has the competence and experience in implementing Union legislation on chemicals and international agreements on chemicals. The Member States and the Agency should therefore carry out tasks with regard to the administrative, technical and scientific aspects of the implementation of this Regulation and the exchange of information. The role of the Agency should include the preparation and examination of technical dossiers, including stakeholder consultations, and the drawing up of opinions that should be used by the Commission in considering whether to come forward with a proposal for listing a substance as a POP in the Convention or the Protocol. In addition, the Commission, the Member States and the Agency should cooperate in order to implement the Union's international obligations under the Convention effectively.

(19) The Convention provides that each Party is to draw up, update and endeavour to implement, as appropriate, a plan for the implementation of its obligations under the Convention. Member States should provide opportunities for public participation in drawing up, implementing and updating their implementation plans. Since the Union and the Member States share competence in that regard, implementation plans should be drawn up and updated both at national and Union level. Cooperation and exchange of information, including on sites contaminated by POPs, between the Commission, the Agency and the authorities of the Member States should be promoted.

(20) Substances listed in Part A of Annex I or Part A of Annex II to this Regulation should only be allowed to be manufactured and used as closed-system site-limited intermediates if an annotation to that effect is expressly entered in the relevant Annex and if the manufacturer demonstrates to the Member State concerned that the substance is only manufactured and used under strictly controlled conditions.

([14]) Commission Decision 2014/955/EU of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council (OJ L 370, 30.12.2014, p. 44).

(21) In accordance with the Convention and the Protocol, information on POPs should be provided to other Parties to those Agreements. The exchange of information with third countries not party to those Agreements should also be promoted.

(22) Since public awareness of the hazards that POPs pose to the health of present and future generations, as well as to the environment, particularly in developing countries, is often lacking, wide-scale information is needed to increase the level of caution and public understanding of the rationale for restrictions and bans. In accordance with the Convention, public awareness programmes on those substances as regards their health and environmental effects, especially for the most vulnerable groups, as well as training of workers, scientists, educators, technical and managerial personnel should be promoted and facilitated, as appropriate. The Union should ensure access to information, without prejudice to Regulations (EC) No 1049/2001 ([15]) and (EC) No 1367/2006 ([16]) of the European Parliament and of the Council, and to Directive 2003/4/EC of the European Parliament and of the Council ([17]).

(23) In order to promote the development of a comprehensive chemical exposure and toxicity knowledge base, in line with the General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' ('the 7th EAP') ([18]), the Commission has established the Information Platform for Chemical Monitoring. The use of that platform should be encouraged as a means for Member States to comply with their obligations to report chemical occurrence data and to simplify and reduce their reporting obligations.

(24) Upon request, and within available resources, the Commission, the Agency and the Member States should cooperate in providing appropriate and timely technical assistance designed especially to strengthen the capacity of developing countries and countries with economies in transition to implement the Convention. Technical assistance should include the development and implementation of suitable alternative products, methods and strategies, under the Convention, to ensure that POPs only continue to be used when locally safe, effective and affordable alternatives are not available to the country in question.

(25) There should be regular evaluation of the effectiveness of measures taken to reduce releases of POPs. To that end, Member States should report regularly, in standardised form, to the Agency, in particular as regards release inventories, notified stockpiles and the manufacturing and placing on the market of restricted substances.

(26) To address the need for information on implementation and compliance, an alternative system of collecting and making information available should be introduced, taking into account the results of the Commission Report on Actions to Streamline Environmental Reporting and its related Fitness Check. In particular, Member States should make all relevant data accessible. That should ensure that the administrative burden on all entities remains as limited as possible. It requires that active dissemination at national level be done in accordance with Directives 2003/4/EC and 2007/2/EC of the European Parliament and of the Council ([19]), to ensure the appropriate infrastructure for public access, reporting and data-sharing between public authorities. In that context, Member States and the Agency should base the specifications for spatial data on the implementing acts adopted under Directive 2007/2/EC.

(27) The Convention and the Protocol provide that Parties thereto may propose additional substances for international action and consequently additional substances may be listed under those Agreements. In such cases, this Regulation should be amended accordingly.

(28) In order to amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending this Regulation by permitting, where appropriate, the manufacture and use of a substance listed in Part A of Annex I or Part A of Annex II to this Regulation as a closed-system site-limited intermediate and amending the deadlines in an annotation entered in the relevant Annex for that purpose, of amending Annex III to this Regulation in order to move a substance from Part B to Part A thereof and of amending Annexes I, II and III to this Regulation in order to adapt them to any change to the list of substances set out in the Annexes to the Convention or the Protocol, as well as to

([15]) Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

([16]) Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13).

([17]) Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).

([18]) OJ L 354, 28.12.2013, p. 171.

([19]) Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1).

modify existing entries or provisions in Annexes I and II to this Regulation in order to adapt them to scientific and technical progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making ([20]). In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts should systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(29) When Annexes to this Regulation are amended to implement any listing of an additional, intentionally produced POP in the Protocol or in the Convention, the listing should be included in Annex II, instead of Annex I, only in exceptional cases and when duly justified.

(30) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt measures concerning waste management and the minimum information to be provided by Member States in monitoring the implementation of this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([21]).

(31) In order to ensure transparency, impartiality and consistency at the level of enforcement activities, Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive, since non-compliance can result in damage to human health and to the environment. To ensure consistent and effective enforcement of this Regulation, the Member States should coordinate relevant activities and exchange information in the Forum for Exchange of Information on Enforcement established under Regulation (EC) No 1907/2006. Information on infringements of the provisions of this Regulation should be made public, where appropriate.

(32) For the purposes of this Regulation other than matters relating to waste, the Commission should be assisted by the committee established by Regulation (EC) No 1907/2006, with a view to ensuring a consistent approach concerning chemicals legislation of the Union.

(33) For the purposes of this Regulation, on matters relating to waste, the Commission should be assisted by the committee established by Directive 2008/98/EC with a view to ensuring a consistent approach concerning waste legislation of the Union.

(34) Since the objective of this Regulation, namely to protect the environment and human health from POPs, cannot be sufficiently achieved by the Member States, owing to the transboundary effects of those pollutants, but can rather 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,

HAVE ADOPTED THIS REGULATION:

Article 1

Objective and subject matter

Taking into account, in particular, the precautionary principle, the objective of this Regulation is to protect human health and the environment from POPs by prohibiting, phasing out as soon as possible, or restricting the manufacturing, placing on the market and use of substances subject to the Stockholm Convention on Persistent Organic Pollutants, hereinafter 'the Convention', or the Protocol to the 1979 Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants, hereinafter 'the Protocol', by minimising, with a view to eliminating where feasible as soon as possible, releases of such substances, and by establishing provisions regarding waste consisting of, containing or contaminated by any of those substances.

Where appropriate, Member States may apply stricter requirements than those laid down in this Regulation, in accordance with the TFEU.

([20]) OJ L 123, 12.5.2016, p. 1.
([21]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Article 2

Definitions

For the purposes of this Regulation:

(1) 'placing on the market' means placing on the market as defined in point 12 of Article 3 of Regulation (EC) No 1907/2006;

(2) 'article' means article as defined in point 3 of Article 3 of Regulation (EC) No 1907/2006;

(3) 'substance' means substance as defined in point 1 of Article 3 of Regulation (EC) No 1907/2006;

(4) 'mixture' means mixture as defined in point 2 of Article 3 of Regulation (EC) No 1907/2006;

(5) 'manufacturing' means manufacturing as defined in point 8 of Article 3 of Regulation (EC) No 1907/2006;

(6) 'use' means use as defined in point 24 of Article 3 of Regulation (EC) No 1907/2006;

(7) 'import' means import as defined in point 10 of Article 3 of Regulation (EC) No 1907/2006;

(8) 'waste' means waste as defined in point 1 of Article 3 of Directive 2008/98/EC;

(9) 'disposal' means disposal as defined in point 19 of Article 3 of Directive 2008/98/EC;

(10) 'recovery' means recovery as defined in point 15 of Article 3 of Directive 2008/98/EC;

(11) 'closed-system site-limited intermediate' means a substance that is manufactured for, and consumed in or used for chemical processing in order to be transformed into another substance ('synthesis') and where the manufacture of the intermediate and the synthesis of one or more other substances from that intermediate take place on the same site, by one or more legal entities, under strictly controlled conditions in that it is rigorously contained by technical means during its whole life cycle;

(12) 'unintentional trace contaminant' means a level of a substance that is incidentally present in a minimal amount, below which the substance cannot be meaningfully used, and above the detection limit of existing detection methods to enable control and enforcement;

(13) 'stockpile' means substances, mixtures or articles accumulated by the holder that consist of or contain any substance listed in Annex I or II.

Article 3

Control of manufacturing, placing on the market and use, and the listing of substances

1. The manufacturing, placing on the market and use of substances listed in Annex I, whether on their own, in mixtures or in articles, shall be prohibited, subject to Article 4.

2. The manufacturing, placing on the market and use of substances listed in Annex II, whether on their own, in mixtures or in articles, shall be restricted, subject to Article 4.

3. Member States and the Commission shall, within the assessment and authorisation schemes for existing and new substances under the relevant Union legislation, take into consideration the criteria set out in paragraph 1 of Annex D to the Convention and take appropriate measures to control existing substances and prevent the manufacturing, placing on the market and use of new substances, which exhibit characteristics of POPs.

4. When preparing a proposal to the Council, pursuant to Article 218(9) TFEU, for the listing of a substance in accordance with the provisions of the Convention, the Commission shall be supported by the European Chemicals Agency ('the Agency'), established by Regulation (EC) No 1907/2006, as referred to in point (c) of Article 8(1). The competent authorities of Member States may forward proposals for listing to the Commission. In the further stages of the listing process, the Agency shall provide support to the Commission and the competent authorities of the Member States, as referred to in point (e) of Article 8(1).

5. The Commission and the Agency shall, in all stages of the process referred to in paragraphs 3 and 4, cooperate with and inform the competent authorities of the Member States.

6. Waste consisting of, containing or contaminated by any substance listed in Annex IV is regulated by Article 7.

Article 4

Exemptions from control measures

1. Article 3 shall not apply in the case of:

(a) a substance used for laboratory-scale research or as a reference standard;

(b) a substance present as an unintentional trace contaminant, as specified in the relevant entries of Annex I or II, in substances, mixtures or articles.

2. For a substance added to Annex I or II after 15 July 2019, Article 3 shall not apply for a six-month period if that substance is present in articles produced before or on the date that this Regulation becomes applicable to that substance.

Article 3 shall not apply in the case of a substance present in articles already in use before or on the date that this Regulation or Regulation (EC) No 850/2004 became applicable to that substance, whichever date came first.

Immediately upon becoming aware of articles as referred to in the first and second subparagraph, a Member State shall inform the Commission and the Agency accordingly.

Whenever the Commission is so informed or otherwise learns of such articles, it shall, where appropriate, notify the Secretariat of the Convention accordingly without further delay.

3. Where a substance is listed in Part A of Annex I or in Part A of Annex II, a Member State wishing to permit, until the deadline specified in the relevant Annex, the manufacturing and use of that substance as a closed-system site-limited intermediate shall notify accordingly the Secretariat of the Convention.

Such notification may be made only if the following conditions are satisfied:

(a) following the request of a Member State or on the Commission's own initiative, an annotation has been entered in the relevant Annex, by means of a delegated act adopted on the basis of the fourth subparagraph;

(b) the manufacturer demonstrates to the competent authority of the Member State in which the manufacturer is established that the manufacturing process will transform the substance into one or more other substances that do not exhibit the characteristics of a POP, ensuring that it is rigorously contained by technical means during its whole life cycle;

(c) the manufacturer demonstrates to the competent authority of the Member State in which the manufacturer is established that the substance is a closed-system site-limited intermediate and that it is not expected that either humans or the environment will be exposed to any significant quantities of the substance during its production and use;

(d) the manufacturer informs the Member State on the details of actual or estimated total manufacturing and use of the substance concerned and the nature of the closed-system site-limited process, specifying the amount of any non-transformed and unintentional trace contamination by any POP starting material in the final substance, mixture or article.

Within one month of submission of the notification to the Secretariat of the Convention, the Member State shall communicate the notification to the other Member States, to the Commission and the Agency, and shall give details of actual or estimated total manufacturing and use of the substance concerned and the nature of the closed-system site-limited process, specifying the amount of any non-transformed and unintentional trace contamination by any POP starting material in the final substance, mixture or article.

The Commission is empowered to adopt delegated acts in accordance with Article 18 in order to amend Annexes I and II by entering annotations expressly to the effect that manufacturing and use, as a closed-system site-limited intermediate, of a substance listed in Part A of the relevant Annex may be permitted, and to amend the deadlines in such annotations in cases where, following a repeat notification from the Member State concerned to the Secretariat of the Convention, express or tacit consent is issued under the Convention for the continued manufacturing and use of the substance for another period.

4. Waste consisting of, containing or contaminated by any substance listed in Annex IV is regulated by Article 7.

Article 5

Stockpiles

1. The holder of a stockpile, which consists of or contains any substance listed in Annex I or II, for which no use is permitted, shall manage that stockpile as waste and in accordance with Article 7.

2. The holder of a stockpile greater than 50 kg, consisting of or containing any substance listed in Annex I or II, and the use of which is permitted shall provide the competent authority of the Member State in which the stockpile is established with information concerning the nature and size of that stockpile. Such information shall be provided within 12 months of the date that this Regulation or Regulation (EC) No 850/2004 became applicable to that substance, whichever date came first for the holder, and of relevant amendments to Annex I or II and annually thereafter until the deadline specified in Annex I or II for restricted use.

The holder shall manage the stockpile in a safe, efficient and environmentally sound manner, in accordance with the thresholds and requirements laid down in Directive 2012/18/EU of the European Parliament and of the Council ([22]) and taking all adequate steps to ensure that the stockpile is managed in a manner that will protect human health and the environment.

3. Member States shall monitor the use and management of notified stockpiles.

Article 6

Release reduction, minimisation and elimination

1. Within two years of the date of entry into force of this Regulation or Regulation (EC) No 850/2004, whichever date came first, Member States shall draw up inventories for the substances listed in Annex III released into air, water and land in accordance with their obligations under the Convention and the Protocol and shall subsequently maintain such inventories.

2. Member States shall communicate their action plans on measures to identify, characterise and minimise, with a view to eliminating where feasible as soon as possible, the total releases of substances listed in Annex III as recorded in their inventories drawn up in accordance with their obligations under the Convention, to the Commission, the Agency and to the other Member States as part of their national implementation plans, pursuant to Article 9.

Such action plans shall include measures to promote the development of, and, where it is considered appropriate, shall require the use of substitute or modified substances, mixtures, articles and processes to prevent the formation and release of substances listed in Annex III.

3. Member States shall, when considering proposals to construct new facilities or to significantly modify existing facilities using processes that release chemicals listed in Annex III, give priority consideration to alternative processes, techniques or practices that have similar usefulness but which avoid the formation and release of substances listed in Annex III, without prejudice to Directive 2010/75/EU of the European Parliament and of the Council ([23]).

Article 7

Waste management

1. Producers and holders of waste shall undertake all reasonable efforts to avoid, where feasible, contamination of this waste with substances listed in Annex IV.

2. Notwithstanding Council Directive 96/59/EC ([24]), waste consisting of, containing or contaminated by any substance listed in Annex IV to this Regulation shall be disposed of or recovered, without undue delay and in accordance with Part 1 of Annex V to this Regulation, in such a way as to ensure that the POP content is destroyed or irreversibly transformed so that the remaining waste and releases do not exhibit the characteristics of POPs.

In carrying out such a disposal or recovery, any substance listed in Annex IV may be isolated from the waste, provided that this substance is subsequently disposed of in accordance with the first subparagraph.

3. Disposal or recovery operations that may lead to recovery, recycling, reclamation or re-use on their own of the substances listed in Annex IV shall be prohibited.

([22]) Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.7.2012, p. 1).

([23]) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

([24]) Council Directive 96/59/EC of 16 September 1996 on the disposal of polychlorinated biphenyls and polychlorinated terphenyls (PCB/PCT) (OJ L 243, 24.9.1996, p. 31).

4. By way of derogation from paragraph 2:

(a) waste containing or contaminated by any substance listed in Annex IV may be otherwise disposed of or recovered in accordance with the relevant Union legislation, provided that the content of the listed substances in the waste is below the concentration limits specified in Annex IV;

(b) a Member State or the competent authority designated by that Member State may, in exceptional cases, allow wastes listed in Part 2 of Annex V containing or contaminated by a substance listed in Annex IV up to concentration limits specified in Part 2 of Annex V to be otherwise dealt with in accordance with a method listed in Part 2 of Annex V, provided that the following conditions are fulfilled:

(i) the holder concerned has demonstrated to the satisfaction of the competent authority of the Member State concerned that decontamination of the waste in relation to substances listed in Annex IV was not feasible, and that destruction or irreversible transformation of the POP content, performed in accordance with best environmental practice or best available techniques, does not represent the environmentally preferable option and the competent authority has subsequently authorised the alternative operation;

(ii) the holder concerned has provided information on the POP content of the waste to the competent authority;

(iii) the operation is in accordance with relevant Union legislation and with the conditions laid down in relevant additional measures referred to in paragraph 5;

(iv) the Member State concerned has informed the other Member States, the Agency and the Commission of its authorisation and the justification for it.

5. The Commission may, where appropriate, and taking into consideration technical developments and relevant international guidelines and decisions and any authorisations granted by a Member State, or by the competent authority designated by that Member State in accordance with paragraph 4 and Annex V, adopt implementing acts concerning the implementation of this Article. In particular, the Commission may specify the format of the information to be submitted by Member States in accordance with point (b)(iv) of paragraph 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20(3).

6. Member States shall take the necessary measures to ensure the control and traceability, in accordance with Article 17 of Directive 2008/98/EC, of waste containing or contaminated by a substance listed in Annex IV to this Regulation.

Article 8

Tasks of the Agency and the Forum

1. The Agency shall, in addition to the tasks allocated to it under Articles 9, 10, 11, 13 and 17, carry out the following tasks:

(a) with the agreement of the Commission, provide the designated competent authorities of the Member States and the members of the Forum for Exchange of Information on Enforcement established by Regulation (EC) No 1907/2006 ('Forum'), as well as stakeholders as appropriate, with assistance and technical and scientific guidance in order to ensure the effective application of this Regulation;

(b) upon request, provide the Commission with technical and scientific input and assist it in order to ensure the effective implementation of this Regulation;

(c) provide technical and scientific support and input to the Commission as regards substances that may meet the criteria for listing in the Convention or the Protocol, taking into account, as appropriate, results from existing assessment schemes referred to in Article 3(3);

(d) publish on its website a notice that a proposal for the listing of a substance will be prepared by the Commission, invite all interested parties to submit comments within eight weeks, and publish those comments on its website;

(e) provide the Commission and the Member States with technical and scientific support in the preparation and review of the risk profile and the risk management evaluation of a substance considered under the Convention, invite all interested parties to submit comments or additional information, or both, within eight weeks and publish those comments on its website;

(f) upon request, provide the Commission with technical and scientific support in implementing and further developing the Convention, in particular with respect to the POPs Review Committee;

(g) compile, register, process and make available to the Commission and the competent authorities of the Member States all the information received or available pursuant to Article 4(2) and (3), point (b)(iv) of Article 7(4), Article 9(2) and Article 13(1). Where such information is non-confidential, the Agency shall make that information publicly available on its website and shall facilitate the exchange of that information with relevant information platforms such as those referred to in Article 13(2);

(h) establish and maintain sections on its website for all matters relating to the implementation of this Regulation.

2. The Forum shall be used to coordinate a network of the Member States' authorities responsible for enforcement of this Regulation.

The members of the Forum who are appointed by a Member State shall ensure that there is appropriate coordination between the tasks of the Forum and the work of their Member State competent authority.

The Forum shall involve the enforcement authorities of Member States responsible for waste when dealing with waste-related issues.

3. The Secretariat of the Agency shall carry out the tasks allocated to the Agency under this Regulation.

Article 9

Implementation plans

1. When preparing and updating their national implementation plans, Member States shall, in accordance with their national procedures, give the public early and effective opportunities to participate in this process.

2. As soon as a Member State has adopted its national implementation plan in accordance with its obligations under the Convention, it shall make it publicly available and communicate its publication to the Commission, the Agency and to the other Member States.

3. When Member States are preparing and updating their implementation plans, the Commission, supported by the Agency, and the Member States shall exchange information on the content, including information on measures taken at national level to identify and assess sites contaminated by POPs, as appropriate.

4. The Commission, supported by the Agency, shall maintain a plan for the implementation of Union obligations under the Convention and shall publish, review and update that plan, as appropriate.

Article 10

Monitoring

1. The Commission, supported by the Agency, and the Member States shall establish or maintain, as appropriate, in close cooperation, appropriate programmes and mechanisms, consistent with the state of the art, for the regular provision of comparable monitoring data on the presence of substances as listed in Part A of Annex III in the environment. When establishing or maintaining such programmes and mechanisms, due account shall be taken of developments under the Protocol and the Convention.

2. The Commission shall regularly assess the possible need for the mandatory monitoring of a substance listed in Part B of Annex III. In the light of such an assessment and any data made available to it by Member States, the Commission is empowered to adopt delegated acts in accordance with Article 18 to amend Annex III in order to move, where appropriate, a substance from Part B of Annex III to Part A thereof.

Article 11

Information exchange

1. The Commission, the Agency and the Member States shall facilitate and undertake the exchange within the Union and with third countries of information relevant to the reduction, minimisation or elimination, where feasible, of the manufacturing, use and release of POPs and to alternatives to those substances, specifying the risks and the economic and social costs related to such alternatives.

2. The Commission, the Agency and the Member States, as appropriate, shall promote and facilitate with regard to POPs:

(a) awareness programmes, including relating to their health and environmental effects and their alternatives and on the reduction or elimination of their manufacture, use and release, especially for:

(i) policy- and decision-makers;

(ii) particularly vulnerable groups;

(b) the provision of public information;

(c) training, including workers, scientists, educators and technical and managerial personnel.

3. Without prejudice to Regulations (EC) No 1049/2001, and (EC) No 1367/2006 and Directive 2003/4/EC, information on the health and safety of humans and the environment shall not be regarded as confidential. The Commission, the Agency and the Member States that exchange information with a third country shall protect any confidential information in accordance with Union law.

Article 12

Technical assistance

In accordance with Articles 12 and 13 of the Convention, the Commission and the Member States shall cooperate in providing appropriate and timely technical and financial assistance to developing countries and countries with economies in transition to assist them, upon request and within available resources and taking into account their particular needs, to develop and strengthen their capacity to fully implement their obligations under the Convention. Such support may also be channelled through regional centres, as identified under the Convention, non-governmental organisations or the Agency.

Article 13

Monitoring of implementation

1. Without prejudice to Directives 2003/4/EC and 2007/2/EC, Member States shall draw up and publish a report containing:

(a) information on the application of this Regulation, including information on enforcement activities, infringements and penalties;

(b) information compiled from the notifications received pursuant to Article 4(2) and (3), Article 5(2) and point (b)(iv) of Article 7(4);

(c) information compiled from the release inventories drawn up pursuant to Article 6(1);

(d) information on implementation in accordance with the national implementation plans drawn up pursuant to Article 9(2);

(e) information on the presence of substances listed in Part A of Annex III in the environment, as compiled pursuant to Article 10;

(f) annual monitoring and statistical data on the actual or estimated total manufacturing and placing on the market of any substance listed in Annex I or II, including relevant indicators, overview maps, reports.

Member States shall update the report annually as far as new data or information is available and otherwise at least every three years.

Members States shall give the Commission and the Agency access to the information contained in the reports.

2. Where a Member State shares the information referred to in point (e) of paragraph 1 with the Information Platform for Chemical Monitoring, this shall be indicated by that Member State in its report and the Member State shall be considered to have fulfilled its reporting obligations under that point.

Where the information referred to in point (e) of paragraph 1 is contained in the report of a Member State provided to the Agency, the Agency shall use the Information Platform for Chemical Monitoring for compiling, storing and sharing that information.

3. Regarding the substances listed in the Convention, the Commission, supported by the Agency, shall, at the intervals determined by the Conference of the Parties of the Convention, compile a report on the basis of the information provided by the Member States to the Agency in accordance with point (f) of paragraph 1 and communicate it to the Secretariat of the Convention.

4. The Agency shall compile and publish a Union overview report on the basis of the data referred to in paragraphs 1 and 2 that is published or notified by the Member States. The Union overview report shall include, as appropriate, indicators for outputs, results and impact of this Regulation, Union overview maps and Member State reports. The Union overview report shall be updated by the Agency at least once every six months or following receipt of a request from the Commission.

5. The Commission may adopt implementing acts concerning the minimum information to be provided in accordance with paragraph 1, including the definition of relevant indicators, overview maps and reports referred to in point (f) of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 20(3).

Article 14

Penalties

Member States shall lay down rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Where Member States have not already done so before the entry into force of this Regulation, they shall notify those rules and measures to the Commission on 16 July 2020 at the latest and shall notify it, without delay, of any subsequent amendment affecting them.

Article 15

Amendment of Annexes

1. The Commission is empowered to adopt delegated acts in accordance with Article 18 to amend the Annexes I, II and III to this Regulation in order to adapt them to changes to the list of substances set out in the Annexes to the Convention or the Protocol, on the basis that the Union has supported the change concerned by means of a Council decision adopted in accordance with Article 218(9) TFEU, or to modify existing entries or provisions in Annexes I and II to this Regulation in order to adapt them to scientific and technical progress.

Whenever the Commission amends Annex I, II or III to this Regulation, it shall adopt a separate delegated act in respect of each substance.

2. The Commission shall keep Annexes IV and V under constant review and shall, where appropriate, make legislative proposals to amend these Annexes in order to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to modify existing entries or provisions in the Annexes to this Regulation in order to adapt them to scientific and technical progress.

Article 16

The budget of the Agency

1. For the purposes of this Regulation, the revenues of the Agency shall consist of:

(a) a subsidy from the Union, entered in the general budget of the Union (Commission Section);

(b) any voluntary contribution from the Member States.

2. Revenues and expenditure for activities under this Regulation shall be combined with those relating to activities under Regulation (EU) No 649/2012 and shall be reflected in the same section in the Agency's budget. The revenues of the Agency referred to in paragraph 1 shall be used for carrying out its tasks under this Regulation.

Article 17

Formats and software for publication or notification of information

The Agency shall, in cooperation with the Member States, specify formats and software for the publication or notification of data by Member States pursuant to this Regulation and shall make them available free of charge on its website. In relation to spatial data sets and spatial data services, Member States and the Agency shall design the formats in accordance with the requirements of Directive 2007/2/EC. Member States and other parties subject to this Regulation shall use those formats and software in their data management or data exchange with the Agency.

Article 18

Exercise of the delegation

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

2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15(1) shall be conferred on the Commission for a period of five years from 15 July 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 4(3), 10(2) and 15(1) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

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

6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15(1) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 19

Competent authorities

Each Member State shall designate a competent authority or authorities responsible for the administrative tasks and enforcement required by this Regulation. It shall inform the Commission of such designation at the latest three months after the entry into force of this Regulation, unless it has already done so before the entry into force of this Regulation, and shall also inform the Commission of any change of designated competent authority.

Article 20

Committee procedure

1. Except in the case referred to in paragraph 2, the Commission shall be assisted by the Committee established by Article 133 of Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. For matters relating to waste, the Commission shall be assisted by the Committee established by Article 39 of Directive 2008/98/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 21

Repeal

Regulation (EC) No 850/2004 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex VII.

Article 22

Entry into force

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

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

Done at Brussels, 20 June 2019.

For the European Parliament	*For the Council*
The President	*The President*
A. TAJANI	G. CIAMBA

ANNEX I

Part A

Substances listed in the Convention and in the Protocol as well as substances listed only in the Convention

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
Tetrabromodiphenyl ether $C_{12}H_6Br_4O$	40088-47-9 and others	254-787-2 and others	1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of Tetrabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) where it is present in substances. 2. For the purposes of the entries on tetra-, penta-, hexa-, hepta- and decaBDE, point (b) of Article 4(1) shall apply to the sum of the concentration of those substances up to 500 mg/kg where they are present in mixtures or articles, subject to review and assessment by the Commission by 16 July 2021. This review shall assess, inter alia, all relevant impacts with regard to health and the environment. 3. By way of derogation, the manufacturing, placing on the market and use of the following shall be allowed: electrical and electronic equipment within the scope of Directive 2011/65/EC of the European Parliament and of the Council ([1]). 4. Use of articles already in use in the Union before 25 August 2010 containing Tetrabromodiphenyl ether shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.
Pentabromodiphenyl ether $C_{12}H_5Br_5O$	32534-81-9 and others	251-084-2 and others	1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of pentabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) where it is present in substances. 2. For the purposes of the entries on tetra-, penta-, hexa-, hepta- and decaBDE, point (b) of Article 4(1) shall apply to the sum of the concentration of those substances up to 500 mg/kg where they are present in mixtures or articles, subject to review and assessment by the Commission by 16 July 2021. This review shall assess, inter alia, all relevant impacts with regard to health and the environment. 3. By way of derogation, the manufacturing, placing on the market and use of the following shall be allowed: electrical and electronic equipment within the scope of Directive 2011/65/EC. 4. Use of articles already in use in the Union before 25 August 2010 containing Pentabromodiphenyl ether shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.
Hexabromodiphenyl ether $C_{12}H_4Br_6O$	36483-60-0 and others	253-058-6 and others	1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of hexabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) where it is present in substances.

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
			2. For the purposes of the entries on tetra-, penta-, hexa-, hepta- and decaBDE, point (b) of Article 4(1) shall apply to the sum of the concentration of those substances up to 500 mg/kg where they are present in mixtures or articles, subject to review and assessment by the Commission by 16 July 2021. This review shall assess, inter alia, all relevant impacts with regard to health and the environment. 3. By way of derogation, the manufacturing, placing on the market and use of the following shall be allowed: electrical and electronic equipment within the scope of Directive 2011/65/EC. 4. Use of articles already in use in the Union before 25 August 2010 containing Hexabromodiphenyl ether shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.
Heptabromodiphenyl ether $C_{12}H_3Br_7O$	68928-80-3 and others	273-031-2 and others	1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of heptabromodiphenyl ether equal to or below 10 mg/kg (0,001 % by weight) where it is present in substances. 2. For the purposes of the entries on tetra-, penta-, hexa-, hepta- and decaBDE, point (b) of Article 4(1) shall apply to the sum of the concentration of those substances up to 500 mg/kg where they are present in mixtures or articles, subject to review and assessment by the Commission by 16 July 2021. This review shall assess, inter alia, all relevant impacts with regard to health and the environment. 3. By way of derogation, the manufacturing, placing on the market and use of the following shall be allowed: electrical and electronic equipment within the scope of Directive 2011/65/EC. 4. Use of articles already in use in the Union before 25 August 2010 containing Heptabromodiphenyl ether shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.
Bis(pentabromophenyl) ether (decabromodiphenyl ether; decaBDE)	1163-19-5	214-604-9	1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of decaBDE equal to or below 10 mg/kg (0,001 % by weight) where it is present in substances. 2. For the purposes of the entries on tetra-, penta-, hexa-, hepta- and decaBDE, point (b) of Article 4(1) shall apply to the sum of the concentrations of those substances up to 500 mg/kg where they are present in mixtures or articles, subject to review and assessment by the Commission by 16 July 2021. This review shall assess, inter alia, all relevant impacts with regard to health and the environment. 3. By way of derogation, the manufacturing, placing on the market and use of decaBDE shall be allowed for the following purposes, provided that Member States report to the Commission by December 2019 in accordance with the Convention: (a) in the manufacturing of an aircraft, for which type approval has been applied for before 2 March 2019 and has been received before December 2022, until 18 December 2023, or, in cases where the continuing need is justified, until 2 March 2027;

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
			(b) in the manufacturing of spare parts for either of the following: (i) an aircraft, for which type approval has been applied for before 2 March 2019 and has been received before December 2022, produced before 18 December 2023, or, in cases where the continuing need is justified, produced before 2 March 2027, until the end of service life of that aircraft; (ii) motor vehicles within the scope of Directive 2007/46/EC of the European Parliament and of the Council [2], produced before 15 July 2019, either until 2036 or the end of service life of those motor vehicles, whichever date comes earlier; (c) electric and electronic equipment within the scope of Directive 2011/65/EC. 4. The specific exemptions for spare parts for use in motor vehicles referred to in point 2(b)(ii) shall apply for the manufacturing and use of commercial decaBDE falling into one or more of the following categories: (a) powertrain and under-hood applications such as battery mass wires, battery interconnection wires, mobile air condition (MAC) pipes, powertrains, exhaust manifold bushings, under-hood insulation, wiring and harness under-hood (engine wiling, etc.), speed sensors, hoses, fan modules and knock sensors; (b) fuel system applications such as fuel hoses, fuel tanks and fuel tanks under body; (c) pyrotechnical devices and applications affected by pyrotechnical devices such as airbag ignition cables, seat covers/fabrics, only if airbag relevant and airbags (front and side). 5. Use of articles already in use before 15 July 2019 in the Union containing decaBDE shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles. 6. Without prejudice to the application of other Union provisions on the classification, packaging and labelling of substances and mixtures, articles in which decaBDE is used shall be identifiable by labelling or other means throughout its life cycle. 7. The placing on the market and use of articles containing decaBDE imported for the purposes of the specific exemptions in point 2 shall be allowed until the expiry of those exemptions. Point 6 shall apply as if such articles were produced pursuant to the exemption in point 2. Such articles already in use by the date of expiry of the relevant exemption may continue to be used. 8. For the purposes of this entry 'aircraft' means the following: (a) a civil aircraft produced in accordance with a type certificate issued under Regulation (EC) No 216/2008 of the European Parliament and of the Council [3] or with a design approval issued under the national regulations of a contracting state of ICAO, or for which a certificate of airworthiness has been issued by an ICAO Contracting State under Annex 8 to the Convention on International Civil Aviation; (b) a military aircraft.

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
Perfluorooctane sulfonic acid and its derivatives (PFOS) $C_8F_{17}SO_2X$ (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers)	1763-23-1 2795-39-3 29457-72-5 29081-56-9 70225-14-8 56773-42-3 251099-16-8 4151-50-2 31506-32-8 1691-99-2 24448-09-7 307-35-7 and others	217-179-8 220-527-1 249-644-6 249-415-0 274-460-8 260-375-3 223-980-3 250-665-8 216-887-4 246-262-1 206-200-6 and others	1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOS equal to or below 10 mg/kg (0,001 % by weight) where it is present in substances or in mixtures. 2. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOS in semi-finished products or articles, or parts thereof, if the concentration of PFOS is lower than 0,1 % by weight calculated with reference to the mass of structurally or micro-structurally distinct parts that contain PFOS or, for textiles or other coated materials, if the amount of PFOS is lower than 1 µg/m² of the coated material. 3. Use of articles already in use in the Union before 25 August 2010 containing PFOS shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles. 4. If the quantity released into the environment is minimised, manufacturing and placing on the market is allowed for the following specific uses provided that Member States report to the Commission every four years on progress made to eliminate PFOS: mist suppressants for non-decorative hard chromium (VI) plating in closed loop systems. Where such a derogation concerns production or use in an installation within the scope of Directive 2008/1/EC of the European Parliament and of the Council [4], the relevant best available techniques for the prevention and minimisation of emissions of PFOS described in the information published by the Commission pursuant to Article 17(2), second subparagraph, of Directive 2008/1/EC shall apply. As soon as new information on details of uses and safer alternative substances or technologies becomes available, the Commission shall review the derogation in the second subparagraph so that: (a) the uses of PFOS will be phased out as soon as the use of safer alternatives is technically and economically feasible; (b) a derogation can only be continued for essential uses for which safer alternatives do not exist and where the efforts undertaken to find safer alternatives have been reported on; (c) releases of PFOS into the environment have been minimised by applying best available techniques. 5. Once standards are adopted by the European Committee for Standardisation (CEN) they shall be used as the analytical test methods for demonstrating the conformity of substances, mixtures and articles to points 1 and 2. Any other analytical method for which the user can prove equivalent performance could be used as an alternative to the CEN standards.
DDT (1,1,1-trichloro-2,2-bis (4-chlorophenyl)ethane)	50-29-3	200-024-3	—
Chlordane	57-74-9	200-349-0	—
Hexachlorocyclohexanes, including lindane	58-89-9	200-401-2	—

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
	319-84-6	206-270-8	
	319-85-7	206-271-3	
	608-73-1	210-168-9	
Dieldrin	60-57-1	200-484-5	—
Endrin	72-20-8	200-775-7	—
Heptachlor	76-44-8	200-962-3	—
Endosulfan	115-29-7 959-98-8 33213-65-9	204-079-4	1. Placing on the market and use of articles already in use before or on 10 July 2012 containing endosulfan shall be allowed. 2. Article 4(2), third and fourth subparagraphs shall apply to articles referred to in point 1.
Hexachlorobenzene	118-74-1	204-273-9	—
Chlordecone	143-50-0	205-601-3	—
Aldrin	309-00-2	206-215-8	—
Pentachlorobenzene	608-93-5	210-172-0	—
Polychlorinated Biphenyls (PCB)	1336-36-3 and others	215-648-1 and others	Without prejudice to Directive 96/59/EC, articles already in use at the time of the entry into force of this Regulation are allowed to be used. Member States shall identify and remove from use equipment (e.g. transformers, capacitors or other receptacles containing liquid stocks) containing more than 0,005 % PCBs and volumes greater than 0,05 dm^3, as soon as possible but no later than 31 December 2025.
Mirex	2385-85-5	219-196-6	—
Toxaphene	8001-35-2	232-283-3	—
Hexabromobiphenyl	36355-01-8	252-994-2	—
1 Hexabromocyclododecane 'Hexabromocyclododecane' means: hexabromocyclododecane, 1,2,5,6,9,10-hexabromocyclododecane and its main diastereoisomers: alpha-hexabromocyclododecane; beta-hexabromocyclododecane; and gamma-hexabromocyclododecane	25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8	247-148-4, 221-695-9	1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of hexabromocyclododecane equal to or below 100 mg/kg (0,01 % by weight) where it is present in substances, mixtures, articles or as constituents of the flame-retarded articles, subject to review by the Commission by 22 March 2019.

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification
			2. Expanded polystyrene articles containing hexabromocyclododecane already in use in buildings before 21 February 2018 in accordance with Commission Regulation (EU) 2016/293 ([5]) and Commission Implementing Decision No 2016/C 12/06 ([6]), and extruded polystyrene articles containing hexabromocyclododecane already in use in buildings before 23 June 2016 may continue to be used. Article 4(2), third and fourth subparagraphs shall apply to such articles. 3. Without prejudice to the application of other Union provisions on the classification, packaging and labelling of substances and mixtures, expanded polystyrene placed on the market after 23 March 2016 in which hexabromocyclododecane was used shall be identifiable by labelling or other means throughout its life cycle.
Hexachlorobutadiene	87-68-3	201-765-5	1. Placing on the market and use of articles already in use before or on 10 July 2012 containing hexachlorobutadiene shall be allowed. 2. Article 4(2), third and fourth subparagraphs shall apply to articles referred to in point 1.
Pentachlorophenol and its salts and esters	87-86-5 and others	201-778-6 and others	
Polychlorinated naphthalenes ([7])	70776-03-3 and others	274-864-4 and others	1. Placing on the market and use of articles already in use before or on 10 July 2012 containing polychlorinated naphthalenes shall be allowed. 2. Article 4(2), third and fourth subparagraphs shall apply to articles referred to in point 1.
Alkanes C_{10}-C_{13}, chloro (short-chain chlorinated paraffins) (SCCPs)	85535-84-8 and others	287-476-5	1. By way of derogation, the manufacturing, placing on the market and use of substances or mixtures containing SCCPs in concentrations lower than 1 % by weight or articles containing SCCPs in concentrations lower than 0,15 % by weight shall be allowed. 2. Use shall be allowed in respect of: (a) conveyor belts in the mining industry and dam sealants containing SCCPs already in use before or on 4 December 2015; and (b) articles containing SCCPs other than those referred to in point (a) already in use before or on 10 July 2012. 3. The third and fourth subparagraphs of Article 4(2) shall apply to the articles referred to in point 2.

([1]) 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).

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

([3]) Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1).

([4]) Directive 2008/1/EC of the European Parliament and of the Council of 15 January 2008 concerning integrated pollution prevention and control (OJ L 24, 29.1.2008, p. 8).

([5]) Commission Regulation (EU) 2016/293 of 1 March 2016 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annex I (OJ L 55, 2.3.2016, p. 4).

([6]) OJ C 10, 13.1.2016, p. 3.

([7]) Polychlorinated naphthalenes means chemical compounds based on the naphthalene ring system, where one or more hydrogen atoms have been replaced by chlorine atoms.

Part B

Substances listed only in the Protocol

Substance	CAS No	EC No	Specific exemption on intermediate use or other specification

ANNEX II

LIST OF SUBSTANCES SUBJECT TO RESTRICTIONS

Part A

Substances listed in the Convention and in the Protocol

Substance	CAS No	EC No	Conditions of restriction

Part B

Substances listed only in the Protocol

Substance	CAS No	EC No	Conditions of restriction

ANNEX III

LIST OF SUBSTANCES SUBJECT TO RELEASE REDUCTION PROVISIONS

PART A

Substance (CAS No)

Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)

Polychlorinated biphenyls (PCB)

PART B

Hexachlorobenzene (HCB) (CAS No 118-74-1)

Polycyclic aromatic hydrocarbons (PAHs) ([1])

Pentachlorobenzene (CAS No 608-93-5)

Hexachlorobutadiene (CAS No 87-68-3)

Polychlorinated naphthalenes (CAS No 70776-03-3 and others)

([1]) For the purpose of emission inventories, the following four compound indicators shall be used: benzo(a)pyrene, benzo(b) fluoranthene, benzo(k)fluoranthene and indeno(1,2,3-cd)pyrene.

ANNEX IV

List of substances subject to waste management provisions set out in Article 7

Substance	CAS No	EC No	Concentration limit referred to in Article 7(4)(a)
Endosulfan	115-29-7 959-98-8 33213-65-9	204-079-4	50 mg/kg
Hexachlorobutadiene	87-68-3	201-765-5	100 mg/kg
Polychlorinated naphthalenes (1)			10 mg/kg
Alkanes C_{10}-C_{13}, chloro (short-chain chlorinated paraffins) (SCCPs)	85535-84-8	287-476-5	10 000 mg/kg
Tetrabromodiphenyl ether $C_{12}H_6Br_4O$	40088-47-9 and others	254-787-2 and others	Sum of the concentrations of tetrabromodiphenyl ether, pentabromodiphenyl ether, hexabromodiphenyl ether, heptabromodiphenyl ether and decabromodiphenyl ether: 1 000 mg/kg. The Commission shall review that concentration limit and shall, where appropriate and in accordance with the Treaties, adopt a legislative proposal to lower that value to 500 mg/kg. The Commission shall carry out such review as soon as possible and, in any event, not later than 16 July 2021.
Pentabromodiphenyl ether $C_{12}H_5Br_5O$	32534-81-9 and others	251-084-2 and others	
Hexabromodiphenyl ether $C_{12}H_4Br_6O$	36483-60-0 and others	253-058-6 and others	
Heptabromodiphenyl ether $C_{12}H_3Br_7O$	68928-80-3 and others	273-031-2 and others	
Decabromodiphenyl ether $C_{12}Br_{10}O$	1163-19-5 and others	214-604-9 and others	
Perfluorooctane sulfonic acid and its derivatives (PFOS) $C_8F_{17}SO_2X$ (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers)	1763-23-1 2795-39-3 29457-72-5 29081-56-9 70225-14-8 56773-42-3 251099-16-8 4151-50-2 31506-32-8 1691-99-2 24448-09-7 307-35-7 and others	217-179-8 220-527-1 249-644-6 249-415-0 274-460-8 260-375-3 223-980-3 250-665-8 216-887-4 246-262-1 206-200-6 and others	50 mg/kg
Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)			15 µg/kg (2)
DDT (1,1,1-trichloro-2,2-bis (4-chlorophenyl)ethane)	50-29-3	200-024-3	50 mg/kg
Chlordane	57-74-9	200-349-0	50 mg/kg

Substance	CAS No	EC No	Concentration limit referred to in Article 7(4)(a)
Hexachlorocyclohexanes, including lindane	58-89-9 319-84-6 319-85-7 608-73-1	210-168-9 200-401-2 206-270-8 206-271-3	50 mg/kg
Dieldrin	60-57-1	200-484-5	50 mg/kg
Endrin	72-20-8	200-775-7	50 mg/kg
Heptachlor	76-44-8	200-962-3	50 mg/kg
Hexachlorobenzene	118-74-1	204-273-9	50 mg/kg
Chlordecone	143-50-0	205-601-3	50 mg/kg
Aldrin	309-00-2	206-215-8	50 mg/kg
Pentachlorobenzene	608-93-5	210-172-0	50 mg/kg
Polychlorinated Biphenyls (PCB)	1336-36-3 and others	215-648-1	50 mg/kg ([3])
Mirex	2385-85-5	219-196-6	50 mg/kg
Toxaphene	8001-35-2	232-283-3	50 mg/kg
Hexabromobiphenyl	36355-01-8	252-994-2	50 mg/kg
Hexabromocyclododecane ([4])	25637-99-4, 3194-55-6, 134237-50-6, 134237-51-7, 134237-52-8	247-148-4 221-695-9	1 000 mg/kg, subject to review by the Commission by 20 April 2019

([1]) Polychlorinated naphthalenes means chemical compounds based on the naphthalene ring system, where one or more hydrogen atoms have been replaced by chlorine atoms.

([2]) The limit is calculated as PCDD and PCDF according to the following toxic equivalency factors (TEFs):

PCDD	TEF
2,3,7,8-TeCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0,1
1,2,3,6,7,8-HxCDD	0,1
1,2,3,7,8,9-HxCDD	0,1
1,2,3,4,6,7,8-HpCDD	0,01
OCDD	0,0003

PCDF	TEF
2,3,7,8-TeCDF	0,1
1,2,3,7,8-PeCDF	0,03
2,3,4,7,8-PeCDF	0,3
1,2,3,4,7,8-HxCDF	0,1

PCDD	TEF
1,2,3,6,7,8-HxCDF	0,1
1,2,3,7,8,9-HxCDF	0,1
2,3,4,6,7,8-HxCDF	0,1
1,2,3,4,6,7,8-HpCDF	0,01
1,2,3,4,7,8,9-HpCDF	0,01
OCDF	0,0003

([3]) The calculation method laid down in European standards EN 12766-1 and EN 12766-2 shall apply.

([4]) 'Hexabromocyclododecane' means hexabromocyclododecane, 1,2,5,6,9,10-hexabromocyclododecane and its main diastereoisomers: alpha-hexabromocyclododecane, beta-hexabromocyclododecane and gamma-hexabromocyclododecane.

ANNEX V

WASTE MANAGEMENT

Part 1

Disposal and recovery under Article 7(2)

The following disposal and recovery operations, as provided for in Annexes I and II of Directive 2008/98/EC, are permitted for the purposes of Article 7(2), when applied in such a way as to ensure that the persistent organic pollutant content is destroyed or irreversibly transformed

D9	Physico-chemical treatment.
D10	Incineration on land.
R1	Use principally as a fuel or other means to generate energy, excluding waste containing PCBs.
R4	Recycling/reclamation of metals and metal compounds, under the following conditions: The operations are restricted to residues from iron- and steel-making processes such as dusts or sludges from gas treatment or mill scale or zinc-containing filter dusts from steelworks, dusts from gas cleaning systems of copper smelters and similar wastes and lead-containing leaching residues of the non-ferrous metal production. Waste containing PCBs is excluded. The operations are restricted to processes for the recovery of iron and iron alloys (blast furnace, shaft furnace and hearth furnace) and non-ferrous metals (Waelz rotary kiln process, bath melting processes using vertical or horizontal furnaces), provided the facilities meet as minimum requirements the emission limit values for PCDDs and PCDFs laid down in accordance with Directive 2010/75/EU of the European Parliament and of the Council ([1]), whether or not the processes are subject to that Directive and without prejudice to the other provisions of the Directive.

([1]) Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

Pre-treatment operation prior to destruction or irreversible transformation pursuant to this Part of this Annex may be performed, provided that a substance listed in Annex IV that is isolated from the waste during the pre-treatment is subsequently disposed of in accordance with this Part of this Annex. Where only part of a product or waste, such as waste equipment, contains or is contaminated with persistent organic pollutants, it shall be separated and then disposed of in accordance with the requirements of this Regulation. In addition, repackaging and temporary storage operations may be performed prior to such pre-treatment or prior to destruction or irreversible transformation pursuant to this part of this Annex.

Part 2

Wastes and operations to which Article 7(4)(b) applies

The following operations are permitted for the purposes of Article 7(4)(b) in respect of the wastes specified, defined by the six-digit code as classified in Commission Decision 2000/532/EC ([1]).

Pre-treatment operations prior to permanent storage pursuant to this part of this Annex may be performed, provided that a substance listed in Annex IV that is isolated from the waste during the pre-treatment is subsequently disposed of in accordance with Part 1 of this Annex. In addition, repackaging and temporary storage operations may be performed prior to such pre-treatment or prior to permanent storage pursuant to this part of this Annex.

([1]) Commission Decision 2000/532/EC of 3 May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste (OJ L 226, 6.9.2000, p. 3).

Wastes as classified in Decision 2000/532/EC		Maximum concentration limits of substances listed in Annex IV [1]	Operation
10	WASTES FROM THERMAL PROCESSES	Alkanes C_{10}-C_{13}, chloro (short-chain chlorinated paraffins) (SCCPs): 10 000 mg/kg; Aldrin: 5 000 mg/kg; Chlordane: 5 000 mg/kg; Chlordecone: 5 000 mg/kg; DDT (1,1,1-trichloro-2,2-bis (4-chlorophenyl) ethane): 5 000 mg/kg; Dieldrin: 5 000 mg/kg; Endosulfan: 5 000 mg/kg; Endrin: 5 000 mg/kg; Heptachlor: 5 000 mg/kg; Hexabromobiphenyl: 5 000 mg/kg; Hexabromocyclododecane [3]: 1 000 mg/kg; Hexachlorobenzene: 5 000 mg/kg; Hexachlorobutadiene: 1 000 mg/kg; Hexachlorocyclohexanes, including lindane: 5 000 mg/kg; Mirex: 5 000 mg/kg; Pentachlorobenzene: 5 000 mg/kg; Perfluorooctane sulfonic acid and its derivatives (PFOS) ($C_8F_{17}SO_2X$) (X = OH, Metal salt (O-M+), halide, amide, and other derivatives including polymers): 50 mg/kg; Polychlorinated Biphenyls (PCB) [6]: 50 mg/kg; Polychlorinated dibenzo-p-dioxins and dibenzofurans: 5 mg/kg; Polychlorinated naphthalenes (*): 1 000 mg/kg; Sum of the concentrations of tetrabromodiphenyl ether $C_{12}H_6Br_4O$), pentabromodiphenyl ether ($C_{12}H_5Br_5O$), hexabromodiphenyl ether ($C_{12}H_4Br_6O$)and heptabromodiphenyl ether ($C_{12}H_3Br_7O$): 10 000 mg/kg; Toxaphene: 5 000 mg/kg.	Permanent storage shall be allowed only when all the following conditions are met: (1) The storage takes place in one of the following locations: — safe, deep, underground, hard rock formations, — salt mines, — a landfill site for hazardous waste, provided that the waste is solidified or partly stabilised where technically feasible as required for classification of the waste in subchapter 19 03 of Decision 2000/532/EC. (2) The provisions of Council Directive 1999/31/EC [4] and Council Decision 2003/33/EC [5] were respected. (3) It has been demonstrated that the selected operation is environmentally preferable.
10 01	Wastes from power stations and other combustion plants (except 19)		
10 01 14 * [2]	Bottom ash, slag and boiler dust from co-incineration containing hazardous substances		
10 01 16 *	Fly ash from co-incineration containing hazardous substances		
10 02	Wastes from the iron and steel industry		
10 02 07 *	Solid wastes from gas treatment containing hazardous substances		
10 03	Wastes from aluminium thermal metallurgy		
10 03 04 *	Primary production slags		
10 03 08 *	Salt slags from secondary production		
10 03 09 *	Black drosses from secondary production		
10 03 19 *	Flue-gas dust containing hazardous substances		
10 03 21 *	Other particulates and dust (including ball-mill dust) containing hazardous substances		
10 03 29 *	Wastes from treatment of salt slags and black drosses containing hazardous substances		
10 04	Wastes from lead thermal metallurgy		
10 04 01 *	Slags from primary and secondary production		
10 04 02 *	Dross and skimmings from primary and secondary production		
10 04 04 *	Flue-gas dust		

Wastes as classified in Decision 2000/532/EC		Maximum concentration limits of substances listed in Annex IV [1]	Operation
10 04 05 *	Other particulates and dust		
10 04 06 *	Solid wastes from gas treatment		
10 05	Wastes from zinc thermal metallurgy		
10 05 03 *	Flue-gas dust		
10 05 05 *	Solid waste from gas treatment		
10 06	Wastes from copper thermal metallurgy		
10 06 03 *	Flue-gas dust		
10 06 06 *	Solid wastes from gas treatment		
10 08	Wastes from other non-ferrous thermal metallurgy		
10 08 08 *	Salt slag from primary and secondary production		
10 08 15 *	Flue-gas dust containing hazardous substances		
10 09	Wastes from casting of ferrous pieces		
10 09 09 *	Flue-gas dust containing hazardous substances		
16	WASTES NOT OTHERWISE SPECIFIED IN THE LIST		
16 11	Waste linings and refractories		
16 11 01 *	Carbon-based linings and refractories from metallurgical processes containing hazardous substances		
16 11 03 *	Other linings and refractories from metallurgical processes containing hazardous substances		
17	CONSTRUCTION AND DEMOLITION WASTES (INCLUDING EXCAVATED SOIL FROM CONTAMINATED SITES)		
17 01	Concrete, bricks, tiles and ceramics		

Wastes as classified in Decision 2000/532/EC		Maximum concentration limits of substances listed in Annex IV (1)	Operation
17 01 06 *	Mixtures of, or separate fractions of concrete, bricks, tiles and ceramics containing hazardous substances		
17 05	Soil (including excavated soil from contaminated sites), stones and dredging spoil		
17 05 03 *	Soil and stones containing hazardous substances		
17 09	Other construction and demolition wastes		
17 09 02 *	Construction and demolition wastes containing PCB, excluding PCB containing equipment		
17 09 03 *	Other construction and demolition wastes (including mixed wastes) containing hazardous substances		
19	WASTES FROM WASTE MANAGEMENT FACILITIES, OFF-SITE WASTE WATER TREATMENT PLANTS AND THE PREPARATION OF WATER INTENDED FOR HUMAN CONSUMPTION AND WATER FROM INDUSTRIAL USE		
19 01	Wastes from incineration or pyrolysis of waste		
19 01 07 *	Solid wastes from gas treatment		
19 01 11 *	Bottom ash and slag containing hazardous substances		
19 01 13 *	Fly ash containing hazardous substances		
19 01 15 *	Boiler dust containing hazardous substances		
19 04	Vitrified waste and waste from vitrification		
19 04 02 *	Fly ash and other flue-gas treatment wastes		
19 04 03 *	Non-vitrified solid phase		

(1) These limits apply exclusively to a landfill site for hazardous waste and do not apply to permanent underground storage facilities for hazardous waste, including salt mines.

(2) Any waste marked with an asterisk '*' is considered as hazardous waste pursuant to Directive 2008/98/EC and is subject to the provisions of that Directive.

(3) 'Hexabromocyclododecane' means hexabromocyclododecane, 1,2,5,6,9,10-hexabromocyclododecane and its main diastereoisomers: alpha- hexabromocyclododecane, beta- hexabromocyclododecane and gamma- hexabromocyclododecane.

(4) Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ L 182, 16.7.1999, p. 1).

(5) Council Decision 2003/33/EC of 19 December 2002 establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC (OJ L 11, 16.1.2003, p. 27).

(6) The calculation method laid down in European standards EN 12766-1 and EN 12766-2 shall apply.

The maximum concentration limit of polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD and PCDF) shall be calculated according to the following toxic equivalency factors (TEFs):

PCDD	TEF
2,3,7,8-TeCDD	1
1,2,3,7,8-PeCDD	1
1,2,3,4,7,8-HxCDD	0,1
1,2,3,6,7,8-HxCDD	0,1
1,2,3,7,8,9-HxCDD	0,1
1,2,3,4,6,7,8-HpCDD	0,01
OCDD	0,0003
PCDF	TEF
2,3,7,8-TeCDF	0,1
1,2,3,7,8-PeCDF	0,03
2,3,4,7,8-PeCDF	0,3
1,2,3,4,7,8-HxCDF	0,1
1,2,3,6,7,8-HxCDF	0,1
1,2,3,7,8,9-HxCDF	0,1
2,3,4,6,7,8-HxCDF	0,1
1,2,3,4,6,7,8-HpCDF	0,01
1,2,3,4,7,8,9-HpCDF	0,01
OCDF	0,0003

ANNEX VI

Repealed Regulation with list of the successive amendments thereto

Regulation (EC) No 850/2004 of the European Parliament and of the Council (OJ L 158, 30.4.2004, p. 7)	
Council Regulation (EC) No 1195/2006 (OJ L 217, 8.8.2006, p. 1)	
Council Regulation (EC) No 172/2007 (OJ L 55, 23.2.2007, p. 1)	
Commission Regulation (EC) No 323/2007 (OJ L 85, 27.3.2007, p. 3)	
Regulation (EC) No 219/2009 of the European Parliament and of the Council (OJ L 87, 31.3.2009, p. 109)	Only point 3.7 of the Annex
Commission Regulation (EC) No 304/2009 (OJ L 96, 15.4.2009, p. 33)	
Commission Regulation (EU) No 756/2010 (OJ L 223, 25.8.2010, p. 20)	
Commission Regulation (EU) No 757/2010 (OJ L 223, 25.8.2010, p. 29)	
Commission Regulation (EU) No 519/2012 (OJ L 159, 20.6.2012, p. 1)	
Commission Regulation (EU) No 1342/2014 (OJ L 363, 18.12.2014, p. 67)	
Commission Regulation (EU) 2015/2030 (OJ L 298, 14.11.2015, p. 1)	
Commission Regulation (EU) 2016/293 (OJ L 55, 2.3.2016, p. 4)	
Commission Regulation (EU) 2016/460 (OJ L 80, 31.3.2016, p. 17)	

ANNEX VII

CORRELATION TABLE

Regulation (EC) No 850/2004	This Regulation
Article 1(1)	Article 1
Article 2, introductory wording	Article 2, introductory wording
Article 2, points (a) to (d)	Article 2, points (1) to (4)
—	Article 2, points (5) to (7)
Article 2, point (e)	Article 2, point (8)
Article 2, point (f)	Article 2, point (9)
Article 2, point (g)	Article 2, point (10)
—	Article 2, points (11) to (13)
Article 3	Article 3(1) to (3)
—	Article 3(4) and (5)
Article 1(2)	Article 3(6)
Article 4(1) to (3)	Article 4(1) to (3)
—	Article 4(3), point (d)
Article 1(2)	Article 4(4)
Article 5	Article 5
Article 6	Article 6
Article 7(1) to (4)	Article 7(1) to (4)
Article 7(6)	Article 7(5)
—	Article 7(6)
Article 7(7)	—
—	Article 8
Article 8	Article 9
Article 9	Article 10
Article 10	Article 11
Article 11	Article 12
Article 12(1)	Article 13(1), point (a)
Article 12(3), point (a)	Article 13(1), point (b)
Article 12(3), point (b)	Article 13(1), point (c)
—	Article 13(1), point (d)
Article 12(3), point (c)	Article 13(1), point (e)
Article 12(2)	Article 13(1), point (f)
—	Article 13(2)
Article 12(4)	—
Article 12(5)	Article 13(3)
Article 12(6)	—
—	Article 13(4) and (5)
Article 13	Article 14
Article 14	Article 15(1)

Regulation (EC) No 850/2004	This Regulation
Article 7(5)	Article 15(2)
—	Article 16
—	Article 17
—	Article 18
Article 15	Article 19
Articles 16 and 17	Article 20
Article 18	—
—	Article 21
Article 19	Article 22
Annexes I to V	Annexes I to V
—	Annex VI
—	Annex VII

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