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WORKING PAPER

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WORKING DOCUMENT

From:	Presidency
To:	Working Party on Technical Harmonisation (Goods package)
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on market surveillance of products and amending Council Directive 2004/42/EC and Regulation (EC) No 765/2008 of the European Parliament and of the Council - draft I (clean version)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on market surveillance of products and amending Council Directive 2004/42/EC and Regulation (EC) No 765/2008 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Acting in accordance with the ordinary legislative procedure,

Whereas:

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

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

(3) The framework established by this Regulation should complement and strengthen existing provisions in Union harmonisation legislation relating to the provision of compliance of products and the framework for cooperation with economic operators, the market surveillance of products and controls on products entering the Union. However, in accordance with the principle of *lex specialis*, this Regulation should apply only in so far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of Union harmonisation legislation. The corresponding provisions of this Regulation should not therefore apply in the areas covered by such specific provisions, for instance those set out in Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products, Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices, including the use of EUDAMED and Regulation (EU) 2018/858 of the European Parliament and of the Council on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles.

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

(5) Provisions on market surveillance of this Regulation should cover products that are subject to the Union harmonisation legislation listed in Annex I. The legislation listed in Annex I should cover all Union harmonisation legislation concerning manufactured products other than food, feed, medicinal products for human and

veterinary use, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction. This will ensure a uniform framework for market surveillance of those products at Union level. If new Union harmonisation legislation is adopted in the future, it will be for that legislation to provide whether this Regulation is also to apply to that legislation.

(6) Articles 15 to 29 of Regulation (EC) No 765/2008 dealing with market surveillance will be replaced by this regulation. This includes also the provisions on controls entering the Union market in Articles 27, 28 and 29, which apply not only to products as outlined above, but to all Union legislation in so far as other Union legislation does not contain specific provisions relating to the organisation of controls on products entering the Union market. It is therefore necessary to extend the scope of Articles 26, 27, 28 and 30 of this Regulation on products entering the Union market to all Union legislation as well.

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

(8) Practical experience of market surveillance has shown that increasingly complex supply chains sometimes involve economic operators whose novel form means that they do not fit easily into the traditional legal framework. Such is the case, in particular, with fulfilment service providers, which perform many of the same functions as importers but which might not always correspond to the traditional definition of importer in Union law. In order to ensure that market surveillance authorities can carry out their responsibilities effectively and to avoid a gap in the enforcement system, it is appropriate to include fulfilment service providers within the list of economic operators against whom enforcement measures may be taken by market surveillance authorities. By including such fulfilment centres within the scope of the present 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 operator acts both as a distributor as regards certain products but as a fulfilment service provider as regards other products.

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

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

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

(12) Modern supply chains encompass a wide variety of economic operators who should all be subject to enforcement of Union harmonisation legislation, while taking due consideration of their respective role in the supply chain, and the extent to which they contribute to the making available of products on the Union market. Therefore, it is necessary to apply this Regulation to economic operators that are directly concerned by Union harmonisation legislation as listed in Annex I.

(13) The development of e-commerce is also due to a great extent to the proliferation of information society service providers, normally through platforms and for remuneration, which offer intermediary services by storing third party content, but without exercising any control over such content, thus not acting on behalf of an economic operator. Removal of content regarding non-compliant products or where it is not feasible blocking access to non-compliant products offered through their services should be without prejudice to the rules laid down in Directive 2000/31/EC of the European Parliament and of the Council.

(14) A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this purpose, strengthened enforcement of Union harmonisation legislation on products is necessary.

(15) Good cooperation between manufacturers and the market surveillance authorities is a key element allowing immediate intervention and corrective action in relation to the product. It is important that there should be a contact person established in the Union so that market surveillance authorities have someone to whom questions can

be addressed regarding a product's compliance with Union harmonisation legislation and who can be required to take corrective action in case a non-compliance cannot be brought to an end otherwise. The person responsible for compliance should be the manufacturer, the importer, any other natural or legal person established in the Union subject to obligations in relation to the manufacture of products or placing on the market, an authorised representative or a fulfilment service provider established in the Union for consignments handled by it when no other economic operator is established in the Union. The role of a person responsible for compliance established in the Union is essential for providing market surveillance authorities with an interlocutor established in the Union, and for performing specific tasks in a timely manner to ensure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, workers and businesses within the Union.

(16) There is Union harmonisation legislation in the scope of this regulation using specific terms for economic operators, among them: the operators as defined in Regulation (EC) No 273/2004, the producer of an article and the downstream user as defined in each case in Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008, the installer as defined in Directive 2014/33/EU, the supplier as defined in Regulation (EC) No 1222/2009, or the dealer as defined in Regulation (EU) 2017/1369. It should be clarified that also these economic operators have responsibilities as economic operators.

(17) Obligations of this Regulation requiring an economic operator to be established in the Union should only apply to areas where the Union legislator has already identified the need for an economic operator as a liaison point with the market surveillance authorities. This need is no longer properly addressed due to new supply chains. Therefore, this Regulation should remedy this.

(18) However, the provisions need only apply where a risk-based approach indicates that this would be appropriate, having regard to the principle of proportionality, taking into account high level of protection of end-users in the Union. In this respect, consideration should 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. Such is the case e.g. for Directive 2014/33 ('lifts'), Directive 2016/424 ('cableways'), Directive 2013/53 ('recreational craft') and Directive 2014/28 ('civil explosives').

(19) Moreover, those provisions need not apply where the specific requirements set out in certain legal instruments on products achieve the same result in effect, namely Regulation (EC) No 1223/2009 Regulation 648/2004 ('detergents'), Regulation (EC) No 1223/2009 ('cosmetics'), Regulation 167/2013 ('agricultural and forestry vehicles'), Regulation 168/1013 ('motorcycles'), Directive 2014/90 ('marine equipment'), Regulation 2016/1628 ('non-road mobile machinery'), Regulation (EU) 2017/745 ('medical devices'), Regulation 2017/746 ('in-vitro diagnostics'), Regulation 2017/1369 ('energy labelling') and Regulation 2018/858 ('motor vehicles').

(20) The information related to economic operator responsible for compliance should be indicated with the product and online in order to facilitate checks throughout the supply chain and online. The indication online also enables end-users to distinguish between law-abiding and rogue traders and to enhance their trust into e-commerce.

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

(22) Economic operators should have easy access to high quality, comprehensive information. The single digital gateway established under Regulation xxxx/2019 provides for a single point of access, independently whether Member States decide to integrate the information into their Product Contact Point established under Regulation yyyy/2018 on mutual recognition, or select a different solution, in line with the principle of subsidiarity.

Guidance on the technical standards, the design, or pre-market approvals of a specific product should not be an obligation of Member States under this article.

(23) Member States should designate their own market surveillance authorities. This Regulation should not prevent Member States from choosing the competent national authorities to carry out the market surveillance tasks. In order to facilitate administrative assistance and cooperation, Member States should also designate a single liaison office. Liaison offices should provide a single contact point for national and other Member States' authorities as well as for the Commission regarding all matters of market surveillance. In this function, they should represent at least a coordinated position of the market surveillance authorities and the authorities in charge of the control on products entering the Union market.

(24) Member States should be required to ensure that adequate financial resources are always available in order to staff and equip the market surveillance authorities appropriately. An efficient market

surveillance activity is demanding in terms of resources, and stable resources should be provided, at a level appropriate to the enforcement needs at any given moment. Member States should have the possibility to supplement public financing by reclaiming the costs incurred when performing market surveillance activities in relation to products that were found to be non-compliant.

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

(26) 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.

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

(28) 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.

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

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

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

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

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

(34) The implementation and exercise of powers in the application of this Regulation should also comply with other Union and national law (e.g. Directive

2000/31/EC), including with applicable procedural safeguards and principles of the fundamental rights. The implementation and exercise of powers should also be proportionate and adequate in view of the nature and the overall actual or potential harm of the infringement. Competent authorities should take all facts and circumstances of the case into account and should choose the most appropriate measures, which are essential to address the infringement covered by this Regulation. Those measures should be proportionate, effective and dissuasive. Member States should remain free to set out conditions and limits for the exercise of the powers and fulfil duties in national law. Where, for example, in accordance with national law, prior authorization 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 authorization has been obtained. Where for example, in accordance with national law, there are limits for using specified kind of evidence, as a right to refuse to give evidence as a witness if the witness is the party's relative, or prohibition of hearing an ordained person who is bound by the secret of the confession, market surveillance authority should refrain from actions that would be contrary to goals of these limits.

(35) Market surveillance authorities act in the interest of economic operators, end-users, and of the general public, to ensure that public interests established by Union harmonisation legislation on products are consistently preserved and protected through appropriate enforcement measures, and that compliance with such legislation is ensured across the supply chain through appropriate checks.

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

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

(38) Information exchanged between market surveillance authorities, and the use of evidence and investigation findings should follow the principle of confidentiality subject to the requirement of protecting the interests of end-users. Information should be handled according to applicable national law, in order to ensure that investigations are not compromised and that the reputation of the economic operator is not prejudiced.

(39) 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 and Regulation (EC) No 45/2001 of the European Parliament and of the Council, as the case may be.

(40) In case that there is a longer lasting or permanent lack of testing capacity, resulting in high prices, long waiting times and complicated procedures, the Commission should set up a programme to facilitate the extension of scope and capacity of existing or the creation of new testing capabilities. It also should be avoided, that the testing of some kinds of technology are only in the hands of one or very view labs. The programme has to be based on a survey; This should be preceded by a mapping of the existing available testing capacities for the different sectors compared to the needs for joint actions and national controls by market surveillance authorities. Details are set up by implementing acts, to ensure the reliability and consistency of testing across the Union. The Commission may also set up a proper monitoring.

(41) Mechanisms for mutual assistance should be established, as it is imperative for the Union market for goods that the market surveillance authorities of the Member States cooperate with each other effectively. Professional and commercial secrecy should not establish a reason to refuse acquiring or exchanging legally required documentation, like the declaration of conformity, or the technical documentation.

(42) 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.

(43) 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 customs territory of the Union, enjoy a complete overview of trade flows across the external borders, and should therefore be required to carry out adequate controls on a risk assessment basis, to contribute to a safer market place. A uniform enforcement of Union harmonisation legislation on products can only be achieved through systematic cooperation and exchange of

information between market surveillance and authorities in charge of the control on products entering the customs territory of the Union. These authorities should receive well in advance from the market surveillance authorities all the necessary information concerning non-compliant products or information on economic operators where a higher risk of non- compliance has been identified. In turn, authorities in charge of the control on products entering the customs territory of the Union should inform the market surveillance authorities in a timely manner of the release of products for free circulation, and the results of controls, where such information is relevant for the enforcement of Union harmonisation legislation on products. Furthermore, where the Commission becomes aware of a serious risk posed by an imported product, it should inform the Member States about those risks in order to ensure coordinated and more effective compliance and enforcement controls at the first points of entry to the Union.

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

(45) 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 for automatic data transfer. Additional burden for customs authorities should be limited and the interfaces should be highly automated and easily to use.

(46) It is necessary to establish a Union Product Compliance Network, hosted by the Commission, aimed at coordinating and facilitating the implementation of joint enforcement activities by Member States, such as joint investigations. This administrative support structure should allow the pooling of resources and maintain a communication and information system between Member States and the Commission, thereby helping to strengthen enforcement of Union harmonisation legislation on products and deter infringements. The establishment and involving of ADCOs (Administrative Cooperation Groups, established by Member States to discuss sector-specific issues) in the Network is to be understood in a general sense, so that also groups can be included that do not bear the name “ADCO”. These groups, on their own initiative, should also invite representatives of relevant stakeholders and experts if it seems useful. The Commission has in this respect the tasks to provide the necessary administrative and financial support.

(47) In that context, it is necessary to maintain and further develop the existing Information and Communication System for Market Surveillance (ICSMS). For the purpose of collecting information relating to the enforcement of Union harmonisation legislation on products, ICSMS should be upgraded and be accessible to the Commission, single liaison offices, market surveillance and customs authorities. Furthermore, an electronic interface should be developed to allow effective exchange of information between national systems of customs and market surveillance authorities. 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 the period of time according to Article 22(2) is not met. When sectoral legislation already foresees electronic systems for cooperation and data exchange, as is the case for example for medical devices by the EUDAMED system, those systems should be kept in use when appropriate.

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

(49) The use of ICSMS for interactions between customs and market surveillance authorities should provide for transparency of cooperation and also facilitate reporting and later statistical evaluations. Nevertheless, where national systems up to this purpose are already in implementation or operational, individual solutions should be applied, which could include as an example a delayed use of ICSMS until electronic interfaces between ICSMS and the national systems are available.

(50) 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 injuries they learn about in the course of their investigations, thus facilitating later statistical evaluations.

(51) The Commission should be able to exchange market surveillance related information with regulatory authorities of third countries or international organisations, with a view to ensuring compliance prior to their export of products to the Union market. Such agreement should be based on implementing acts adopted according to the committee procedure.

(52) 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, after having consulted Member States, be able to enter into negotiations with third countries and ultimately approve country specific systems. After having completed an approved pre-export control, products may, 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. Member States should be able to support or reject the details of a proposed pre-export control system through use of the examination procedure.

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

(54) 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.

(55) 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.

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

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

(58) 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 respecting those rights and principles. In particular, this Regulation seeks to ensure full respect for consumer protection, the freedom to conduct a business, the freedom of expression and information, the right to property and the protection of personal data.

Chapter I
General provisions

Article 1
Subject matter

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

and any other public interests protected by that legislation, are made available on the Union market.

2. It also lays down rules and procedures for the economic operator responsible for compliance of products. It establishes a framework for cooperation with economic operators in relation to such products.

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

Article 2
Scope

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

2. Articles 23, 24, 25 and 26 (Chapter VII - Products entering the Union market) shall apply to products covered by Union legislation in so far as other Union legislation does not contain specific provisions relating to the organisation of controls on products entering the Union market.

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

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

Article 3
Definitions

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

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

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

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

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

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

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

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

(8) 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark, as well as any natural or legal person defined as 'manufacturer' in Union legislation on marketing of products;

(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 legal or natural person offering the service of warehousing, picking, packaging or shipping without having ownership of the products involved. Services provided according to Article 1(1) of Directive 97/67/EC (Community postal services), Article 2(2) of Regulation (EU) 2018/644 (cross-border parcel delivery services), any other postal services or freight transport services are not considered fulfilment services;

(12) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

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

(14) 'information society service provider' means a provider of a service within the meaning of Article 1(1)(b) of Directive 2015/1535/EU;

(15) 'online marketplace' means a provider on an intermediary service that allows economic operators, on the one hand, and end-users, on the other hand, to conclude transactions via online

sales either on website or on an economic operator's website that uses computing services provided by the online marketplace;

(16) '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;

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

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

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

(20) '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. This 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;

(21) 'product presenting a serious risk' means a product presenting a risk, for which the combination of the probability of occurrence of a hazard causing harm and the degree of severity of the harm is considered serious. This based on a risk assessment, including cases where the effects are not immediate, and thus requiring rapid intervention by the market surveillance authorities;

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

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

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

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

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

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

Chapter II
Compliance

Article 4
Economic operator responsible for compliance

1. A product in the scope of Union harmonisation legislation may be made available on the market only if there is an economic operator established in the Union who is responsible for compliance with the applicable legislation in respect to this product.

2. For the purpose of paragraph 1, the economic operator responsible for compliance means any of:

   (a) the manufacturer established in the Union;

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

   (c) any other natural or legal person established in the Union subject to obligations in relation to the manufacture of products or placing on the market;

   (d) an authorised representative established in the Union;

   (e) a fulfilment service provider established in the Union for consignments handled by it when no other economic operator is established in the Union.

3. Products offered for sale online or through other means of distance sales shall be deemed to be made available on the market if the offer is targeted at end-users in the Union. An offer for sale shall be considered targeted at end-users in the Union, if dispatch of the product is offered to an address in the Union.

4. Without prejudice to any obligations and responsibilities of economic operators under the applicable Union harmonisation legislation, the economic operator responsible for compliance shall perform the following tasks as a minimum:

   (a) if the Union harmonisation legislation applicable to the product provides for an EU declaration of conformity and technical documentation, verifying that EU declaration of conformity and technical documentation have been drawn up and

keeping the declaration of conformity and technical documentation at the disposal of market surveillance authorities for the period required by that legislation;

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

(c) cooperating with the market surveillance authorities, including further to a reasoned request taking immediate corrective action to remedy any case of non-compliance with the requirements set out in Union harmonisation legislation applicable to the product in question, or, if that is not possible, mitigate the risks posed by that product at their own initiative or when required to do so by the market surveillance authorities;

5. The name, registered trade name or registered trade mark and the contact details, including the postal address, of the economic operator responsible for compliance with respect to the product shall be indicated on the product or on its packaging, the parcel or an accompanying document.

6. Economic operators offering a product for sale online shall indicate with their offer information as described in paragraph 4**a**, of the economic operator responsible for compliance with respect to the product. In this regard, online marketplaces shall facilitate the display of abovementioned information for the products sold through them.

7. This Article shall only apply in relation to products that are subject to regulations (EU) 305/2011 (‘construction products’), (EU) 2016/425 (EU) (‘personal protective equipment’), 2016/426 (‘gas appliancies’) and directives 2000/14/EC (‘outdoor noise’), 2006/42/EC (‘machinery directive’), 2009/48/EU (‘toy safety’), 2009/125/EC (‘ecodesign’), 2010/35/EU (‘transportable pressure equipment’), 2011/65 (‘RoHS’), 2013/29/EU (‘pyrotechnics’), 2014/29/EU (‘simple pressure vessels’), 2014/30 (‘electromagnetic compatibility’), 2014/31/EU (‘non-automatic weighing instruments’), 2014/32/EU (‘measuring instruments’), 2014/34/EU (‘ATEX’), 2014/35/EU (‘low voltage directive’), 2014/53/EU (‘radio equipment’), 2014/68/EU (‘pressure equipment’).

Article 5
Authorised representative

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

2. The mandate shall be valid only when accepted in writing by the authorised representative and shall be signed by both parties.

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

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

Article 6
Obligation of cooperation

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

2. In line with Directive 2000/31/EC information society service providers shall cooperate with the market surveillance authorities, at their request, to facilitate any action taken to eliminate or, if that is not possible, mitigate the risks posed by a product that is or was offered for sale online through their services.

Chapter III
Assistance to and cooperation with economic operators

Article 7
Information to economic operators

1. The Commission shall be responsible for making available relevant information on Union harmonisation legislation to economic operators. For this purpose, the Commission shall establish a system accessible in accordance with Article 4 (2) of Regulation xxxx/2019 (Single digital gateway regulation). This system shall enable the economic operator to determine the harmonisation legislation applicable to his product, and its requirements.

2. In addition, Member States shall have procedures in place for providing economic operators at their request with specific information in respect to the national transposition of Union harmonisation legislation applicable to a product in accordance with Article 4(1) of Regulation xxxx/2019. This information shall be provided generally within 15 working days and free of charge.

Article 8

Joint awareness raising and information campaigns

Market surveillance authorities may, in compliance with national legislation, agree with other relevant authorities, organisations representing economic operators or end-users on carrying out joint activities aimed at promoting compliance, raising awareness and providing advice and guidance in relation to the Union harmonisation legislation with respect to categories of products, in particular the ones that are often found to be presenting a serious risk, including the products sold online.

Chapter IV
Organisation, activities and obligations of market surveillance authorities

Article 9

General requirements

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

2. Market surveillance shall ensure that products covered by Union harmonisation legislation which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Union harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly.

Article 10

Designation of market surveillance authorities and the single liaison office

1. Each Member State shall designate one or more market surveillance authorities in its territory. It shall inform the Commission and the other Member States of the market surveillance authorities designated by it and the areas of competence of each of those authorities, using the information and communication system referred to in Article 32.

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

3. 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 23(1) and for the national strategies as set out in Article 12. It shall also assist in the cooperation between market surveillance authorities in different Member States as set out in Chapter VI.

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

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

Article 11

Activities of market surveillance authorities and use of findings

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

   (a) the effective surveillance of the market within their territory with respect to 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) when the economic operator fails to take corrective action, the taking of appropriate measures.

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

3. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory controls based on an adequate sample, taking into account the national market surveillance strategy referred to in Article 12.

4. In deciding what checks to perform and on what scale, market surveillance authorities shall follow a risk-based approach taking into account in particular the possible hazards and non-compliances associated with the product and when available, its occurrence on the market, activities and operations under the control of the economic operator, complaints and other information.

5. Where economic operators present test reports or certificates attesting conformity of their products with Union harmonisation legislation issued by an

accredited conformity assessment body, market surveillance authorities shall take due account of such reports or certificates.

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

7. Market surveillance authorities shall actively participate in administrative coordination groups according to Article 28(2) to ensure communication and coordination with their counterparts in other Member States.

8. Market surveillance authorities shall establish adequate procedures in connection with products subject to the Union harmonisation legislation as follows:

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

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

9. Products deemed to be non-compliant on the basis of a decision of a market surveillance authority in one Member State, shall be presumed to be non-compliant by market surveillance authorities in another Member State, unless justification to the contrary is provided or a Member State has raised objections considered justified by the Commission in accordance with the applicable Union safeguard procedure.

Article 12
National market surveillance strategies

1. Each Member State shall draw up an overarching national market surveillance strategy, as a minimum, every 4 years, at first after 3 years after coming into force of this regulation. The strategy shall promote a consistent, comprehensive and integrated approach to market surveillance and enforcement of Union harmonisation legislation within the territory of the Member State. When drawing up the strategy all Union harmonisation legislation and stages of the product supply chain, including imports and digital supply chains, shall be considered.

2. The national market surveillance strategy shall include, as a minimum, the following elements, when this information does not compromise market surveillance activities:

   (a) the available information of the occurrence of non-compliant products, in particular taking into account the controls referred to in Articles 11(3) and 23(3), and, where applicable, market trends that may affect non-compliance rates in the categories of product;

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

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

3. Member States shall communicate their national market surveillance strategy through the system referred to in Article 32.

Chapter V
Market surveillance powers and measures

Article 13
Powers and duties of market surveillance authorities

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

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

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

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

   (b) where appropriate, upon by recourse to other public authorities, in accordance with the division of powers and the institutional

and administrative organisation of the Member State in question;

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

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

(a) powers to start investigations on their own initiative in order to identify non-compliances and bring them to an end;

(b) powers to carry out, without prior announcement, on-site inspections and physical controls;

(c) powers to acquire product samples, including under a cover identity, where the evidence cannot be obtained by other means;

(d) powers to enter any premises, land or means of transport that the economic operator in question uses for purposes related to his trade, business, craft or profession, in order to detect non-compliance and obtain evidence;

(e) powers to require economic operators to provide any information on compliance, physical, marketing and economic aspects in any form or format and irrespective of its storage medium or the place where it is stored, and to take or obtain copies of this information;

(f) powers to take appropriate measures for mitigating risks or when compliance cannot be established, including powers to prohibit or restrict the making available on the market or to order withdrawal or recall;

(g) powers, where there are no other effective means available to prevent a serious risk:

(h) to require operators of online interfaces to remove content from the online interface referring to the related products and/or to order the explicit display of a related warning to end-users when they access the online interface;

(i) where a request according to (i) is not observed, to require information society service providers to restrict access to the online interface,

including by requesting a third party to implement such measures;

(j) powers to impose penalties according to Art. 61.

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 14

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. Those costs may include the costs of carrying out testing, the costs of taking measures in accordance with Article 26(1) and (2) and the costs of their activities relating to products that are found to be non-compliant and subject to corrective action prior to their release for free circulation or their placing on the market.

Article 15

Market surveillance measures

1. Where market surveillance authorities find that a product is non-compliant and/or presents a risk, they shall without delay require the relevant economic operator to take appropriate and proportionate action to address, as applicable, the non-compliance and/or the risk within a period they specify.

2. For the purpose of paragraph 1 action may include inter alia:

(a) bringing the product into compliance and/or ensuring that the product no longer presents a risk;

(b) preventing the product from being placed on the market;

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

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

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

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

(g) alerting the persons at risk immediately and in an appropriate form, including by publication of special warnings in the language or languages determined by the

Member State in which the product is made available on the market.

3. Corrective actions referred to in points (e), (f) and (g) may only be required in cases where a product is liable to present a risk only in certain conditions or only to certain persons and where such risk is not addressed by requirements of Union harmonisation legislation.

4. Where products are withdrawn, recalled, prohibited or restricted, and where the non-compliance is not restricted to its national territory, market surveillance authorities shall ensure that the Commission and the other Member States are informed accordingly through the system referred to in Article 32. This information also fulfils the notification requirements for safeguard procedures of Union harmonisation legislation.

5. If a national measure is considered justified according to Article 11(9) or the applicable safeguard procedure, the competent market surveillance authorities in the other Member States shall take the measures necessary in respect to the non-compliant product and where applicable the economic operator or information society service provider, and shall enter the related information in the system referred to in Article 32.

Article 16

Use of information, professional and commercial secrecy

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

Article 17

Judicial protection and due process

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

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

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

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

Article 18

Products presenting a serious risk

1. Where a product presents a serious risk, market surveillance authorities shall require the relevant economic operator to take appropriate actions to ensure that such products are recalled, withdrawn, or that their being made available on the market is prohibited. Market surveillance authorities shall inform the Commission of such measures without delay, in accordance with Article 19.

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

Article 19

Union Rapid Alert System (RAPEX)

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

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

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

taken and any voluntary measures taken by economic operators.

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

5. The Commission shall provide and maintain a data interface between the RAPEX system to the system referred to in Article 32 so that the need for double data entry is reliably avoided.

Article 20
Testing facility support

1. Objective of the testing facility support is ensuring sufficient laboratory capacity, as well as reliability and consistency of testing, for the purposes of market surveillance within the Union.

2. When the Commission determines on its own initiative or on request of the Network, that testing capacity for specific harmonisation legislation or product categories is missing or not sufficient, it shall set up a programme for the establishment of new testing facilities or to encourage existing facilities to increase their scope or capacity. All testing facilities under this programme shall be accredited in accordance with the requirements of Chapter II of Regulation (EC) No 765/2008.

3. The establishment of new testing facilities or the increase of the scope or capacity of existing facilities and request of tests by market surveillance authorities may be financed by the Union in conformance with the Article 24(2).

4. The Commission shall adopt implementing acts on testing facility support programmes. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 40(3).

Chapter VI
Cross-border mutual assistance

Article 21
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 an authority has undertaken all appropriate efforts to obtain information itself, and nevertheless cannot conclude its investigations, it may put forward a motivated request to the authority of another Member State where access to this information can be enforced.

3. The applicant authority remains responsible for the case it has initiated, unless the requested authority expressively agrees to take over responsibility.

4. In well justified cases, a requested authority may refuse to comply with a request for information under paragraph 1, when own duties would be substantially impaired, or when the applicant authority does not agree that the information is subject to the rules on confidentiality and on professional and commercial secrecy as laid down in Article 16.

Article 22
Procedure for mutual assistance requests

1. The applicant authority shall carry out itself all investigations reasonable possible before launching a request for assistance.

2. The requested authority shall without delay, and in any event within 4 weeks unless otherwise agreed, give assistance on an adequate scale by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measures, and by participating in investigations initiated by the applicant authority.

3. Requests for mutual assistance and all communication linked to them shall be made using electronic standard forms by means of the system referred to in Article 32.

4. Communication shall take place either directly between the involved authorities or through the single liaison office.

5. The languages to be used for requests for mutual assistance and for all communication linked to them shall be agreed upon by the competent authorities concerned.

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

7. The system referred to in Article 32 shall provide structured information on mutual assistance cases to the single liaison offices involved. Utilizing this information, single liaison offices shall give any support necessary to facilitate assistance.

Chapter VII
Products entering the Union market

Article 23
Controls on products entering the Union market

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

   Each Member State shall inform the Commission and the other Member States of the authorities designated under the first subparagraph and of their areas of competence through the system referred to in Article 32.

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

3. Products subject to Union legislation that are to be placed under the customs procedure 'release for free circulation' shall be subject to controls performed by the authorities designated under paragraph 1. They shall perform those controls on the basis of a risk analysis in accordance with articles 46 and 47 of Regulation (EU) No 952/2013 and on the basis of risk-based approach as referred to in Article 11(4).

4. Information may, if appropriate in accordance with national legislation, be exchanged between:

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

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

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

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

6. By 31 March each year, Member States shall submit to the Commission statistical data by means of the system referred to in Article 32 covering controls during the previous calendar year with respect to products subject to Union legislation performed by the authorities designated under paragraph 1 . The statistical data shall cover the number of interventions in the field of controls on such products,with regard to product safety and compliance.

   The Commission shall draw up a report each year by 30 June, containing the information submitted by the Member States for the previous calendar year. The report shall be published in the system referred to in Article 32.

7. Where the Commission becomes aware of a serious risk posed by products subject to Union legislation that are imported from a third country, it shall inform the Member States.

8. The Commission shall specify further by means of implementing acts the details of the data to be submitted under paragraph 6. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 40(2).

Article 24
Suspension of release for free circulation

1. Authorities designated under Article 23(1) shall suspend the release of a product for free circulation, if in the course of controls pursuant to Article 23, paragraph 3, it is established that:

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

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

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

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

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

2. Authorities designated under Article 23(1) shall immediately notify the market surveillance authorities of any suspension of release referred to in paragraph 1.

3. Where the market surveillance authorities have reason to believe that a product does not comply

with the Union harmonisation legislation applicable to it or poses a serious risk, they shall require the authorities designated under Article 23(1) to suspend the process for its release for free circulation.

4. Notifications according to paragraph 2 and requests according to paragraph 3 shall take place by means of the system referred to in Article 32 including utilisation of electronic interfaces between this system and systems used by customs.

Article 25
Release of products

Where the release of a product for free circulation has been suspended in accordance with Article 24, that product shall be released for free circulation when all the other requirements and formalities relating to such a release have been fulfilled and if any of the following conditions is satisfied:

(a) the non-compliance established according to Art. 24(1) has been rectified through changes allowed for under the applicable customs procedure;

(b) within five working days of the suspension, the authorities designated under Article 23(1) have not been requested by the market surveillance authorities to maintain the suspension;

(c) the authorities designated under Article 23(1) have been informed by the market surveillance authorities of its approval for release for free circulation.

The release for free circulation shall not be deemed as proof of conformity with Union legislation.

Article 26
Refusal to release

1. Where the market surveillance authorities conclude that a product presents a serious risk, they shall take measures to prohibit the placing of the product on the market and shall require the authorities designated under Article 23(1) not to release it for free circulation. They shall also require these authorities to include the following notice on the commercial invoice accompanying the product and on any other relevant accompanying document, including in the customs data-processing system, as appropriate:

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

   Market surveillance authorities shall immediately enter that information into the system referred to in Article 32.

2. Where market surveillance authorities conclude that a product may not be placed on the market as it does not comply with the Union harmonisation legislation applicable to it, they shall take measures to prohibit the placing of the product on the market and shall require the authorities designated under Article 23(1) not to release it for free circulation. They shall also require these authorities to include the following notice on the commercial invoice accompanying the product and on any other relevant accompanying document, including in the customs data-processing system, as appropriate:

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

   Market surveillance authorities shall immediately enter that information into the system referred to in Article 32.

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

4. Member States' authorities may destroy or otherwise render inoperable a product which presents a risk to the health and safety of end-users where it is deemed, by the authority in question, necessary and proportionate to do so. The cost of such measure shall be borne by the natural or legal person declaring the product for free circulation.

Chapter VIII
Coordinated enforcement and international cooperation

Article 27
Union Product Compliance Network

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

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

Article 28
Composition and operation of the Network

1. The network shall be composed of representatives from each Member State, including a representative of the single liaison offices according to Art. 11, and an optional national expert, the chairs of administrative cooperation

groups of market surveillance authorities (ADCOs), and representatives from the Commission.

2. Administrative cooperation groups of market surveillance authorities (ADCOs), set up by the Member States for the implementation of Union harmonisation legislation are composed of representatives of the national market surveillance authorities.

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

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

5. The Network may invite experts and other third parties to attend meetings or provide written contributions.

6. The Network may establish standing or temporary sub-groups.

7. The Network shall establish its rules of procedure.

Article 29

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 evaluations of products including risk assessment, test methods and results, recent scientific developments and other aspects relevant to control activities;

(c) to provide coordination of ADCOs and their activities;

(d) to provide input to the Commission, in particular by identifying the needs of specific testing facility support according to Art. 20;

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

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

(g) to facilitate the organisation of training programmes and exchanges of national officials;

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

(i) to discuss questions arising from cross-border mutual assistance mechanism;

(j) to contribute to the development of guidance to ensure the effective and uniform implementation of this Regulation;

(k) to propose the financing of activities foreseen in Article 34;

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

(m) to provide advice and assist the Commission with issues related to the further development of RAPEX and the information system referred to in Article 32;

(n) to define processing of collected data as referred to in Article 32;

(o) to prepare system approvals for the execution by a third country related to pre-export product controls as referred to in Article 33 to ensure that these products comply with applicable Union harmonisation legislation;

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

(q) to take up any other issues in activities under the purview of the Network aimed at contributing to the effective functioning of market surveillance within the Union.

Article 30

Role and tasks of administrative coordination groups

1. In carrying out the tasks set out in paragraph 3, ADCOs shall address specific matters of market surveillance and sector-specific issues.

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

3. ADCOs shall have the following tasks:

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

(b) to promote informal contacts and develop mutual confidence between national market surveillance authorities;

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

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

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

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

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

Article 31

Role and tasks of the Commission

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

2. 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 nationality and contact information;

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

(d) to support the functioning of Product Contact Points having duties assigned by Member States according to Article 7(2);

(e) to determine the need for additional testing capacity in accordance with Article 20 and to propose taylored solutions for this purpose;

(f) to apply the instruments of international cooperation referred to in Article 33 (1) and (2);

(g) to provide support for the establishment of separate or joint ADCOs for the instruments of Union harmonisation legislation;

(h) to develop and maintain the system referred to in Article 32, including the interface with the EU Single Window referred to in paragraph 5 of that Article, as well as the interface with national market surveillance databases, and provide information to the general public by means of that system;

(i) to provide for the processing of collected data referred to in Article 32 in collaboration with the Network;

(j) 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, research work, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work;

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

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

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

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

(o) 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 32

Information and communication system

1. The Commission shall further develop and maintain an information and communication system for the collection and storage of information, in a structured form, on issues relating to the enforcement of Union legislation,

with the aim of improving the sharing of data between Member States and providing a comprehensive overview of market surveillance activities, results and trends. The Commission, market surveillance authorities, single liaison offices, and authorities designated in accordance with Article 23 (1) shall have access to that system.

2. The Commission shall further develop and maintain an IT interface to national systems.

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

   (a) the identity of the market surveillance authorities in their Member State and areas of competence of those authorities pursuant to Article 10(1);

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

   (c) the national market surveillance strategy drawn up by their Member State under Article 12 and the results from the review and assessment of the market surveillance strategy drawn up by their Member State.

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

   in relation to products made available on the market for which an in-depth check of compliance has been carried out without prejudice to Article 12 of Directive 2001/95/EC and Article 19 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 24, in their territory, information concerning:

   (a) restrictive measures taken by that market surveillance authority;

   (b) reports of testing carried out by them;

   (c) corrective action taken by economic operators concerned;

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

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

   (f) when available, failures by authorized representatives to comply with Article 5(2) and (3);

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

5. Where market surveillance authorities consider it useful, they may enter any additional information related to the checks they perform and results of testing carried out by 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 relating to products placed under the customs procedure 'release for free circulation' related to the enforcement of Union harmonisation legislation and transmit it to the information and communication system.

7. The Commission, shall develop an electronic interface to enable the transmission of such data. This interface shall be in place [four years] from the date of adoption of the implementing acts.

8. The Commission shall adopt implementing acts specifying the details of implementation arrangements for paragraphs 1 to 5, in particular on the data processing that will be applied in accordance with Article 1 and defining the data to be transmitted in accordance with paragraph 5. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 40(2).

Article 33

International cooperation

1. In order to improve the efficiency of market surveillance in the Union, the Commission may exchange market surveillance related information, including information contained in the information exchange system provided for in Article 12 of Directive 2001/95/EC, with regulatory authorities of third countries or international organisations where a framework for cooperation and information exchange of selected information has been established in accordance with paragraph 1a.

   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 corrective actions;

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

2. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 40(3) in order to establish each framework for cooperation and information exchange.

3. The Commission may approve a specific system of product-related pre-export control carried out by a third country on products immediately prior

to their export into the Union in order to verify that those products satisfy the requirements of the Union harmonisation legislation applicable to them. The approval may be granted in respect of one or more products, in respect of one or more categories of product or in respect of products or categories of product manufactured by certain manufacturers.

4. The Commission shall produce and maintain a list of those products or categories of products refered to in Paragraph 3 of which approval has been granted 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 demonstrate that products exported to the Union from that third country satisfy the requirements set out in Union harmonisation legislation.

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

   Authorities designated under Article 23(1) may however carry out controls on those products or categories of product entering the Union market, including in order to ensure that the pre-export controls carried out by the third country are effective to determine compliance with Union harmonisation legislation.

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

8. The competent authority, referred to in paragraph 6, 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 4 reveal significant non-compliance, the market surveillance authorities shall notify immediately the Commission through the system referred to in Article 32 and adapt the level of controls on such products.

10. The Commission shall adopt implementing acts to approve each specific system of product-related pre-export controls, referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 40(3).

11. The Commission shall by means of an implementing act withdraw an approval granted under paragraph 3 where it is revealed that the products entering the Union market do not comply with Union harmonisation legislation in a significant number of instances. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 40(3). The Commission shall inform the affected third country of the outcome of the decision of the committee accordingly.

12. The system of product-related pre-export control shall be evaluated in accordance with Article 39(4) in this Regulation.

Chapter IX
Financial provisions

Article 34
Financing activities

1. The Union shall finance performance of the tasks of the Network referred to in Article 33a.

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

   (a) the functioning of the Product Contact Points having duties according to Article 7(2) assigned by Member States;

   (b) the provision of testing facility support referred to in Article 20;

   (c) the development of instruments of international cooperation referred to in Article 33;

   (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 12;

   (g) Member States' and Union market surveillance campaigns and similar activities, including means, IT tools and training;

   (h) the performance of preliminary or ancillary work in connection with the implementation of market surveillance

activities linked to the application of Union harmonisation legislation such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits, research work, training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work;

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

3. The financing of the electronic interface referred to in Article 32(7) shall be shared between the Union and the Member States. The Union shall be responsible for financing the central module and the development allowing that the system referred to in Article 32 can receive automatic flows of electronic data from national customs systems according to Article 32(7). Member States shall be responsible for financing the developments allowing the connection of their national systems to the interface.

4. The Union shall finance the interface according to Article 32(2) allowing the exchange of data with national market surveillance systems.

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

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

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

Article 35

Protection of the Union's financial interests of the Union

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

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

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

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

Chapter X
Final provisions

Article 36

Amendments to Directive 2004/42/EC

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

Article 37

Amendments to Regulation (EC) No 765/2008

1. The words in the title "and market surveillance relating to the marketing of products", Article 1(2), 1(3), 2(1), (2), (14), (15), (17) to (19),

Articles 15 to 29 and Article 32(1e) of Regulation (EC) No 765/2008 are deleted.

2. References to the repealed articles shall be construed as references to the respective articles of this Regulation and shall be read in accordance with the correlation table in Annex II.

Article 38
Penalties

1. The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and of Union harmonisation legislation listed in Annex II that impose obligations on economic operators and shall take all measures necessary to ensure that they are implemented according to national legislation.
2. The penalties provided for shall be effective, proportionate and dissuasive.
3. The Member States shall notify those provisions to the Commission by 31 March 2022 and shall notify it without delay of any subsequent amendment affecting them.

Article 39
Evaluation

1. By 31 December 2026 and every five years thereafter, the Commission shall carry out an evaluation of this Regulation against the objectives it pursues and present a report on the main findings to the European Parliament, to the Council and to the European Economic and Social Committee.
2. The report shall assess whether this Regulation achieved its objectives, in particular with regard to reducing the number of non-compliant products on the Union market, ensuring effective and efficient enforcement of Union harmonisation legislation within the Union, improving cooperation between competent authorities and strengthening the controls on products entering the Union market, whilst taking into account the impact on business and in particular on small and medium-sized enterprises. In addition, the evaluation should also assess the effectiveness of the market surveillance activities that receive Union financing in the light of the requirements of Union policies and legislation.
3. The first report shall evaluate the scope and the costs and benefits of the provisions of Article 4.
4. By the latest [four years] after the first approval of a system for product-related pre-export control according to Article 33(3), the Commission shall carry out an evaluation of its effects and cost efficiency. The report shall especially assess whether the product-related pre-export control was useful for market surveillance authorities and improved their preconditions to carry out controls on products from third countries.

Article 40
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.
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 41
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 2 years after entering into force.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX I

Union harmonisation legislation

1. Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (OJ L 326, 29.12.1969, p. 599);
2. Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (OJ L 042 , 23.02.1970, p. 16-20);
3. Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14–20);
4. Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 147, 9.6.1975, p. 40–47);
5. Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products (OJ L 46, 21.2.1976, p. 1–11);
6. Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40–50);
7. Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ L 167, 22.6.1992, p. 17–28*)*;
8. Directive 94/11/EC of the European Parliament and of the Council of 23 March 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to labelling of the materials used in the main components of footwear for sale to the consumer (OJ L 100, 19.4.1994, p. 37–41);
9. European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (OJ L 365, 31.12.1994, p. 10–23);
10. Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels and amending Council Directive 93/12/EEC (OJ L 350, 28.12.1998, p. 58–68);
11. Directive 2000/14/EC of the European Parliament and of the Council of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors (OJ L 162, 3.7.2000, p. 1–78);
12. Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles (OJ L 269, 21.10.2000, p. 34–43);
13. Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1–194);
14. Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents (OJ L 104, 8.4.2004, p. 1–35);
15. Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC (OJ L 158, 30.4.2004, p. 7–49);
16. Directive 2004/42/CE of the European Parliament and of the Council of 21 April 2004 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products and amending Directive 1999/13/EC (OJ L 143, 30.4.2004, p. 87–96);
17. Directive 2005/64/EC of the European Parliament and of the Council of 26 October 2005 on the type-approval of motor vehicles with regard to their reusability, recyclability and recoverability and amending Council Directive 70/156/EEC (OJ L 310, 25.11.2005, p. 10–27);
18. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery (OJ L 157, 9.6.2006, p. 24–86);
19. Directive 2006/40/EC of the European Parliament and of the Council of 17 May 2006 relating to emissions from air conditioning systems in motor vehicles and amending Council Directive 70/156/EEC (OJ L 161, 14.6.2006, p. 12–18);

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

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

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

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

24. Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (OJ L 151, 14.6.2018, p.1–218);

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. 1–1355);

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. 1–31);

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. 32–46);

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. 7–24);

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. 1–37);

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. 1–13);

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. 1–24);

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. 10–35);

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. 1–30);

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. 46–58);

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. 59–209);

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. 1–19);

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

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. 5–43);
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. 88–110);
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. 1–64);
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. 1–123);
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– 71);
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. 1–51);
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. 52–128);
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. 27–65);
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. 90–131);
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. 1–44);
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. 45–78);
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. 79–106);
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. 107–148);
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. 149–250);
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. 251–308);
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. 309–356);
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. 357–374);
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. 1–38);
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. 62–106);

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. 164–259);

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. 146–185);

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. 195–230);

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. 131–195);

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. 1–50);

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. 51–98);

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. 99–147);

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. 53–117);

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. 1–175);

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. 176–332);

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

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. 1–23).

ANNEX II

Union harmonisation legislation without provisions on penalties

1. Council Directive 69/493/EEC of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (OJ L 326, 29.12.1969, p. 599);
2. Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (OJ L 042 , 23.02.1970, p. 16-20);
3. Council Directive 75/107/EEC of 19 December 1974 on the approximation of the laws of the Member States relating to bottles used as measuring containers (OJ L 42, 15.2.1975, p. 14–20);
4. Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (OJ L 147, 9.6.1975, p. 40–47);
5. Council Directive 76/211/EEC of 20 January 1976 on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain pre-packaged products (OJ L 46, 21.2.1976, p. 1–11);
6. Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ L 167, 22.6.1992, p. 17–28);
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. 37–41);
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. 10–23);
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. 1–78);
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. 34–43);
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. 10–27);
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. 12–18);
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. 17–20);
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. 46–58);
15. Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment (OJ L 165, 30.6.2010, p. 1–18);
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. 5–43);
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. 1–64);
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. 146–185);

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. 131–195);

ANNEX III

Correlation table

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