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PROPOSAL

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date of receipt:	20 December 2017
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products and amending Regulations (EU) No 305/2011, (EU) No 528/2012, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2017/1369 of the European Parliament and of the Council, and Directives 2004/42/EC, 2009/48/EC, 2010/35/EU, 2013/29/EU, 2013/53/EU, 2014/28/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

{SWD(2017) 466 final} - {SWD(2017) 467 final} - {SWD(2017) 468 final} -
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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Reasons for and objectives of the proposal

Achieving a deeper and fairer single market, that builds on its strengths and fully exploits its potential in all its dimensions, is one of the key political priorities of the European Commission's main political priorities.[1] Following up and implementing the 2015 Communication on Upgrading the Single Market: more opportunities for people and business, is one of the main objectives of the 2017 Commission work programme.[2]

Within the single market, free movement of goods is the most developed of all four fundamental freedoms. It generates around 25 % of EU GDP and 75 % of trade in goods between EU Member States. The EU accounts for around one sixth of the world's trade in goods. Trade in goods between EU Member States was valued at EUR 3 063 billion in 2015.[3] However, there is still work to do to ensure a deep and fair European single market.

The increasing number of illegal and non-compliant products on the market distorts competition and puts consumers at risk. Many economic operators disregard the rules either through lack of knowledge or intentionally to gain a competitive advantage. Greater deterrents are needed, yet market surveillance authorities are often underfunded and constrained by national boundaries. Businesses are often active both within the EU and worldwide, and modern supply chains are evolving rapidly. In e-commerce in particular, market surveillance authorities have great difficulty tracing non-compliant products imported into the Union and identifying the responsible entity within their jurisdiction.

In its 2017 work programme[4], the Commission announced an initiative to strengthen product compliance and enforcement Union harmonisation legislation on products, as part of the 'Goods Package'. The initiative is to address the increasing amount of non-compliant products on the Union market while offering incentives to boost regulatory compliance and ensuring fair and equal treatment that will benefit of businesses and citizens.

The initiative is mainly aimed at providing the right incentives to businesses, intensifying compliance checks and promoting closer cross-border cooperation among enforcement authorities. It will:

- consolidate the existing framework for market surveillance activities;
- encourage joint actions by market surveillance authorities from several Member States;
- improve the exchange of information and promote the coordination of market surveillance programmes;
- create a strengthened framework for controls on products entering the Union market and for improved cooperation between market surveillance authorities and customs authorities.

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1 Jean-Claude Juncker, 'A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change', Political Guidelines for the next European Commission, Opening Statement in the European Parliament Plenary Session, 15 July 2014: http://ec.europa.eu/about/juncker-commission/priorities/index_en.htm.

2 COM(2016) 710 final: http://ec.europa.eu/atwork/key-documents/index_en.htm

3 Source Eurostat.

4 COM(2016) 710 final: http://ec.europa.eu/atwork/key-documents/index_en.htm

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1.2. Consistency with existing policy provisions in the policy area

(a) Regulation (EC) No 765/2008 of the European Parliament and of the Council[5] and Decision No 768/2008/EC of the European Parliament and of the Council[6]

Regulation (EC) No 765/2008 provides the current framework for the market surveillance of products and is complementary to Decision No 768/2008/EC. The Decision establishes reference provisions for Union legislation to harmonise marketing conditions for products, in particular the obligations for businesses in the supply chain.

It is proposed that Articles 15 to 29 of the Regulation (EC) No 765/2008 will no longer apply to the legislation listed in the Annex to this legislative proposal.

The reference provisions established under Decision No 768/2008/EC will continue to provide the general framework for the obligations of manufacturers, authorised representatives, importers and distributors.

(b) Proposal for a Regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council[7]

This proposal is consistent with the proposal for a Regulation on market surveillance of products which was adopted by the Commission in February 2013 [COM(2013)75] as part of the 'Consumer Product Safety and Market Surveillance Package'. The overarching objective of COM(2013)75 was to simplify fundamentally the Union market surveillance framework in the field of non-food products through the reduction of the number of pieces of legislation containing market surveillance rules, and to produce a one-tier system in which all of those rules are brought together in a single instrument. In particular, COM(2013)75 was conceived to revise and streamline the rules on market surveillance of the General Product Safety Directive 2001/95/EC, Regulation (EC) 765/2008 and many sector-specific pieces of Union harmonisation legislation into a single legal instrument that would apply horizontally across all sectors.

The European Parliament adopted its position at first reading on the proposal on 15 April 2014. However, the legislative discussions stalled in 2015. If the legislative discussions on COM(2013)75 were to resume, an analysis of the Union harmonisation legislation that applies at that moment, taking into account the developments since 2013, and the present proposal, could feed into the progress made by the co-legislators on the proposal, in accordance with the Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making.

The present proposal contains 'lex generalis provisions' in order to avoid any possible risk of overlapping or contradictory provisions with the 'market surveillance proposal' COM(2013)75.

(c) Union harmonisation legislation on products

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

6 Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

7 COM(2013) 75 final: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2013:0075:FIN

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Union harmonisation legislation on products sets out common requirements on how a product has to be manufactured, including rules on its product, size and composition. Its aim is not only to eliminate barriers to the free movement of goods in the single market, but also to ensure that only safe and compliant products are sold in the EU. In this way, honest traders will benefit from a level playing field, thus protecting consumers and professional users and promoting a competitive single market.

Union harmonisation legislation on products as listed in the Annex to this proposed Regulation provides the specific framework for marketing each category of products it covers, and thus the obligations of each business in the supply chain.

Smooth cooperation and good contacts between manufacturers and market surveillance authorities are key to ensuring that products comply with the Union harmonisation legislation. Under this initiative, a product can only be made available on the market if a person responsible for compliance information is established in the Union and can be a direct interlocutor for market surveillance authorities. This person could be the manufacturer, the importer or any other economic operator mandated by the manufacturer.

(d) Directive 2001/95/EC on General Product Safety[8]

The Directive ensures that products placed on the Union market are safe, in particular by targeting products that pose a serious risk and where a Member State's authorities intend to deny or prohibit its marketing or use to mitigate the risk to consumer health and safety.

(e) Regulation (EU) No 952/2013 of the European Parliament and of the Council (Union Customs Code)[9]

Cooperation between market surveillance authorities and customs authorities is crucial to effectively enforce Union harmonisation legislation on products. This is because the most important filter for non-compliant products is at the EU's external borders, where the authorities have a complete overview of trade flows.

Furthermore, rules on safety and compliance controls need to be enforced in a more uniform manner. This can only be achieved through systematic cooperation between market surveillance authorities and authorities in charge of checking products at the EU's external borders.

Effective and efficient cooperation is also important when more than one authority in the Member States is responsible for checking that imported goods comply with product safety rules. Those authorities have to cooperate, in particular by sharing relevant information.

1.3. Consistency with other Union policies

The Commission recognised the essential role of enforcement networks and set out to encourage and help Member States improve their capacity to enforce Union law and to make sure that administrative authorities and inspectorates are adequately equipped to perform their tasks[10].

In order to strengthen enforcement of Union harmonisation legislation on products, the Commission took into account similar recent work to improve enforcement in other areas. One such area was food and feed, where Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on

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

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

10 Commission Communication "EU Law: Better Results through Better Application", 13.12.2016, Pages 5-6.

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animal health and welfare, plant health and plant protection products[11] will improve Member States' ability to prevent, eliminate or reduce health risks to humans, animals and plants. The Commission also put forward a proposal to reform the Consumer Protection Cooperation Regulation[12] on the powers of enforcement authorities and the manner in which they can cooperate.

The Commission also proposed new rules to further empower Member States' competition authorities and ensure they have all the tools they need to enforce EU antitrust rules more effectively[13]. Stronger enforcement powers are also a key issue in other recent legislative initiatives[14] and data protection laws[15] and recent legislation on fertilisers[16].

Increasing product imports yet declining resources for customs mean that the Customs Union's governance needs to be better geared to current and future challenges. The provisions of this proposal take into account the advocated coordination and inter-agency cooperation mechanisms, and improved risk assessments, including at the level of the Customs Union, to make controls more efficient and effective[17].

Regarding global trade, the Commission reaffirmed its policy based on openness and cooperation. However, to combat situations where rules exist but are not respected, the EU would need to have the instruments at its disposal to restore a level playing field and act decisively against countries or companies that engage in unfair practices. Strong enforcement of Union rules would also ensure that penalties are imposed on all companies present or active in Union which break the rules. This will be done in cooperation with Member State authorities and strengthened Union customs risk management in order to facilitate and accelerate legitimate EU trade, while ensuring the safety and security of citizens by stopping fake or dangerous goods permeating EU borders[18].

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

2.1. Legal basis

The proposal is based on Articles 33, 114 and 207 of the Treaty on the Functioning of the European Union.

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11 Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), OJ L 95, 7.4.2017, p. 1-142.

12 COM(2016)283 — Proposal for a Regulation of the European Parliament and of the Council on cooperation between national authorities responsible for the enforcement of consumer protection laws.

13 COM(2017)142 — Proposal for a Directive of the European Parliament and of the Council to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market.

14 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 (Medical Devices); Regulation (EU); 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); COM(2016)31 final - Proposal for a Regulation 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.

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

16 COM(2016)157, SWD(2016)64 and 65.

17 Developing the EU Customs Union and its governance, COM(2016)813 final, 21.12.2016.

18 Point 3.3, Commission Reflection paper on harnessing globalisation, 10 May 2017: https://ec.europa.eu/commission/publications/reflection-paper-harnessing-globalisation_en

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2.2. Subsidiarity

Market surveillance activities, and in particular enforcement of Union harmonisation legislation on products, fall within the competence of Member States' national authorities. This will not change. However, in order to be effective, the market surveillance effort must be uniform across the Union. If market surveillance is 'softer' in some parts of the EU, weak spots are created which threaten the public interest, create unfair trading conditions and encourage 'forum shopping'.

The risk to the various public interests that Union harmonisation legislation tries to protect should be considered also as regards products imported into the Union. There must therefore be effective market surveillance along the entire length of the Union's external borders.

It is therefore necessary to strengthen the enforcement of Union harmonisation legislation on products, preserve the public interests defended in this context, in particular health protection, and to ensure a level playing field for businesses established within and outside the EU. Market surveillance authorities should receive a set of powers allowing them to effectively enforce the Union harmonisation legislation on products. Their cooperation across borders and with customs authorities should be increased. Controls at the external borders of the Union should also be strengthened. Consequently, market surveillance instruments and mechanisms must be established to make possible and facilitate these endeavours, in particular by establishing an Union Product Compliance Network whose main task will be coordinating enforcement across the Union. Financing and reporting also all need to be addressed at Union level.

2.3. Proportionality

The proposal does not affect the Member States' competences in enforcement. However, some Member States may need to adapt their national procedural laws to ensure that their market surveillance authorities can effectively use their enforcement powers in the cross-border context, to cooperate and address product non-compliance within the EU.

The measures set out in this proposal do not extent beyond what is necessary to solve the problems identified and to achieve its objectives. The proposal provides for a common set of powers for all competent authorities in the Member States which should help strengthen enforcement and compliance with Union harmonisation rules on products. The level of harmonisation chosen is necessary to ensure smooth cooperation and exchanges of evidence among competent authorities. Furthermore, it is necessary to remedy the current situation where certain product requirements laid down in Union harmonisation legislation are not enforced consistently and coherently in the single market because the market surveillance authorities in some Member States lack the powers needed to investigate and put an end to non-compliance.

The proposal will improve enforcement cooperation without imposing a disproportionate or excessive burden on Member States' authorities. Therefore, the proposal does not exceed what is necessary to attain its objectives.

2.4. Choice of the instrument

The only suitable instrument to achieve the objective of improving enforcement of and compliance with Union harmonisation legislation on products is a Regulation. A Directive would not achieve the objectives as jurisdictional boundaries and potential jurisdictional conflicts would persist following its transposition.

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3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

3.1. Ex-post evaluations/fitness checks of existing legislation

As part of the 2017 Commission work programme, an evaluation of the current legal framework for market surveillance, notably of provisions of Article 15 to 29 of Regulation (EC) No 765/2008 was undertaken.[19] The evaluation covered the period from 2010 (date of application of the Regulation) to 2015.

Effectiveness

The evaluation of Regulation (EC) No 765/2008 indicated that it has been only partly effective in achieving its specific and strategic objectives. This is mainly because coordination and cooperation have still not reached a satisfactory level. Tools such as the Union Rapid Alert System for dangerous non-food products (RAPEX) and the Information and Communication System on Market Surveillance (ICSMS) are in place to ensure cross-border market surveillance cooperation, but they are not sufficiently used by Member States. As a result, market surveillance authorities rarely restrict the marketing of a product if their counterpart in another Member State notifies them of measures related to the product. There seems to be limited scope for market surveillance and customs authorities to make use of findings (including test reports) made by peer authorities in another Member State and, therefore, to avoid duplicating efforts. Furthermore, Regulation (EC) No 765/2008 is not yet uniformly applied, due to the significant differences in how Member States implement it. This concerns the organisation of market surveillance at national level, the availability of financial, human and technical resources, the strategies of market surveillance, the powers of inspection and of sanctions and the systems of monitoring and reporting. Last but not least, border controls on imported products seem insufficient. The main difficulties caused by market surveillance authorities not having jurisdiction outside of their Member State, particularly in the context of online sales.

Therefore, it is safe to assess that Regulation (EC) No 765/2008 does not fully meet its strategic objectives of strengthening the protection of public interests and of ensuring fair trading conditions for economic operators by reducing the number of non-compliant products on the single market. The data available suggest that non-compliant products continue to be placed on the market, and are possibly increasing.

Efficiency

Most of the costs of the market surveillance are borne by Member States and their market surveillance authorities, and vary considerably from one Member State to another. This is because different national organisational models require different levels of both human and financial resources, but also results from the different approaches of market surveillance authorities when reporting data on financial resources used and the activities performed.

Economic operators' information costs due to Regulation (EC) No 765/2008 are perceived as insignificant. However, businesses point to the negative impact that across-the-board inconsistencies in Member States' approach to market surveillance have on them, stressing that the current enforcement mechanism is not able to create equal conditions for businesses.

[19] SWD(2017)469 - Commission services staff working document on the evaluation of the market surveillance provisions of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

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In terms of benefits, Regulation (EC) No 765/2008 did not improve safety for consumers and other end-users as expected. The persistence of and increase in non-compliant products show that it did not create fair trading conditions for businesses either.

Coherence

The evaluation pointed to problems of consistency with the General Product Safety Directive 2001/95/EC (GPSD), whose definitions are not always aligned with those of the Regulation. This proposal clarifies the boundaries between the GPSD and Regulation (EC) No 765/2008. The coherence of Regulation (EC) No 765/2008 with sectoral directives is sufficiently safeguarded by the *lex specialis* provision. Nonetheless, in certain cases, discrepancies and gaps in the definitions and terminology provided in the different pieces of legislation diminish the overall clarity of the framework for market surveillance, without hindering the implementation of Regulation (EC) No 765/2008.

Relevance

The evaluation highlighted some difficulties in understanding the scope of Regulation (EC) No 765/2008. While its definitions are generally clear and appropriate, they are not complete and up-to-date, especially as regards online sales. Regulation (EC) No 765/2008 is relevant when considering current stakeholders' needs such as cooperation and exchange of information, and border controls, but it becomes less relevant when looking at needs related to current market dynamics (increasing online trade, budgetary constraints at national level), that requires a fast reaction.

Only a revised framework for market surveillance could help reach the expected level of protection of public interests and of ensure fair trading conditions for market operators.

EU added value

Member States are responsible for enforcing Union harmonisation legislation and taking effective action against products that pose a risk. A single market without internal borders poses challenges for public authorities in enforcing this legislation since they are constrained by jurisdictional boundaries. Furthermore, weaknesses in the market surveillance organisation in a single Member State create weak links in the chain.

To ensure consistent enforcement and to efficiently tackle non-compliance spanning over several Member States, it is necessary to coordinate activities across the Union. The evaluation indicated that the benefits of having a single piece of European legislation on harmonising market surveillance instead of several different pieces of national legislation are widely recognised.

The EU added value of Regulation (EC) No 765/2008 mainly stems from provisions envisaging common information systems that will favour administrative cooperation and enhance cooperation between market surveillance authorities and authorities in charge of checking products at the EU's external borders.

Full EU added value is still hindered by the currently sub-optimal cross-border exchange of information and cooperation, by inconsistent implementation of the market surveillance framework at national level, and by a lack of resources.

3.2. Stakeholder consultations

The **market surveillance authorities** were consulted during several meetings of the Expert Group on the Internal Market for Products held on 1 February 2016, 21 October 2016 and 31 March 2017. The last meeting focused on the legislative proposal and its main objectives and especially on how to enhance cooperation between the Member States, create a uniform and

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sufficient level of market surveillance and have stronger border controls on products imported into the Union market.

A **stakeholder conference** open to industry, consumers, authorities, etc. was organised by the Commission on **17 June 2016**. The aim was to identify the main issues related to the compliance of products in the single market, how to better enforce harmonisation legislation, and to identify possible ways forward.

A **public consultation in all EU official languages** was published on a consultation website hosted on *Europa.* The consultation ran from 1 July to 31 October 2016. Its objective was to gather evidence and views on the actions to enhance enforcement and compliance in the single market for Goods. The European Enterprise Network encouraged and supported small and medium-sized enterprises in the consultation. 239 replies were received from businesses (127), public authorities (80), and citizens (32).

The consultation results show action is needed to increase product compliance in the single market because non-compliance negatively affects consumers and other end-users, but also sales and/or market shares of businesses that do comply with legal obligations. Furthermore, respondents suggested that the best way to reduce non-compliance is a mix of information, support and enforcement by the public authorities. As regards non-compliant products traded by businesses located in a non-EU country, the results of the consultation point to the need for customs and market surveillance authorities to better coordinate controls on products entering the Union market. It also noted the need to oblige businesses established in non-EU countries to designate a person located in the Union to be responsible for compliance information.

3.3. Collection and use of expertise

The Commission or external contractors carried out several surveys, consultations and studies between 2012 and 2016. Member States were also consulted on how effectively market surveillance functions across the Union.

An external evaluation on the application of Regulation (EC) No 765/2008 was carried out between July 2016 and May 2017.

The results have been taken into account in this legislative proposal with the view to improve the enforcement of Union harmonisation legislation on products.

3.4. Regulatory fitness and simplification

The evaluation carried out on the current legal framework for market surveillance (see section 3.1. above) concluded that most of the enforcement costs stemming from current market surveillance rules are borne by public authorities, while costs on businesses only relate to information obligations (responding to requests from authorities, information on non-compliances detected) and are therefore regarded as insignificant by them. The enhanced enforcement coordination and priority setting supported by the Union Product Compliance Network and peer reviewed enforcement strategies would results in a better level-playing field, reducing some of the negative impacts of across-the-board enforcement inconsistencies that businesses face.

The main potential for simplification and burden reduction lie nonetheless with authorities. The impact assessment underlying this proposal examined for each objective possible simplifications and/or administrative burden reduction, such as better use of IT tools used for simpler and quicker exchange information on planned controls, more effective mutual assistance requests, transferability of enforcement evidence and decisions to avoid duplication of work by authorities, a common set of investigative and enforcement powers, and easier

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access to compliance information for market surveillance authorities through the availability of a person responsible for compliance information.

3.5. Impact assessment

An impact assessment report prepared by the Commission covers all aspects related to the legislative proposal[20].

The policy options envisaged range from maintaining the status quo, to more ambitious measures and EU coordination and action, as follows:

(1) baseline;

(2) improving existing tools and cooperation mechanisms;

(3) option (2) plus increased deterrence effect to enforcement tools and stepped up EU coordination; and

(4) further added-on centralised EU level enforcement in certain cases.

The preferred option is option (3), including in particular:

(a) extending Product Contact Points' advisory role to businesses and ad-hoc public-private partnerships;

(b) creating digital systems through which manufacturers or importers would make compliance information available to both consumers and market surveillance authorities, the obligation of manufacturers to designate a person responsible for compliance information established in the Union and setting up a common European portal for voluntary measures;

(c) establishing rules on how to publicise decisions to restrict the marketing of products, fine-tune authorities' powers (notably in relation to online sales imports from non-EU countries), recovering the costs of controls on products found to be non-compliant; and

(d) stricter obligations for mutual assistance and legal presumption that products found to be noncompliant in one Member State are non-compliant throughout the EU.

Furthermore, Member States' enforcement strategies setting out national control activities and capacity building requires an Union Product Compliance Network. This network would provide administrative support structure to peer review Member States' performance and coordinate and help implement Member States' joint enforcement activities.

The impact assessment received an initial negative opinion, on 7 April 2017, and subsequently a positive opinion with reservations from the Regulatory Scrutiny Board on 8 June 2017. The recommendations contained in the opinions have been incorporated into the report[21]. The amended report includes more extensive descriptions of the current market surveillance framework, the relation to the 2013 'Consumer Product Safety and Market Surveillance Package' and the evaluation results. The presentation of the problems, objectives and options were reworked and supporting evidence and cost estimates added. In relation to the Union Product Compliance Network, the report sets out the expected outputs and cost in different scenarios and discusses the impacts and feasibility of governance options to host the Union Product Compliance Network either in an existing agency or by the Commission. Considering the complexity of amending founding regulations of an existing agency, this

20 SWD (2017) 466, Commission services staff working document Impact assessment accompanying the proposal for a Regulation of the European Parliament and of the Council on Enforcement of Union harmonisation legislation

21 The summary sheet and the positive opinion of the Regulatory Scrutiny Board are available at [link to be inserted].

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proposal tasks the Commission with the supporting secretariat of the Network. In relation to the obligation of manufacturers to designate a person responsible for compliance information established in the Union, the impact assessment report describes the main trade and business models affected, in particular distance sales from outside the EU. The report clarifies the mandate of the person responsible for compliance information. It also estimates the cost related to compliance information facilitation and discusses the impacts on 3rd country traders and the fair market conditions for businesses operating in the Union.

3.6. Fundamental rights

The impact of various options examined took into account the impact on concerned fundamental rights. The legislative proposal respects fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union. It is to be interpreted and applied with respect to those rights and principles. Market surveillance authorities would exercise the powers set out in this Regulation, on the basis of proportionality and necessity, and subject to national procedural safeguards.

This legislative proposal strikes a careful balance between the interests protected by fundamental rights health and safety, consumer protection, environmental protection the freedom to conduct business and freedom of information.

4. BUDGETARY IMPLICATIONS

The proposal requires human and administrative resources, as well as operational appropriations, as highlighted in the financial statement.

5. OTHER ELEMENTS

5.1. Implementation plans and monitoring, evaluation and reporting arrangements

The Commission will review the implementation of this Regulation 5 years after the date on which it starts to apply, and will submit an evaluation report to the European Parliament and the Council. The report will assess whether the Regulation achieved its objectives, in particular with regard to reducing the number of non-compliant products, ensuring effective and efficient enforcement of Union harmonisation legislation, improving cooperation between competent authorities and strengthening the controls on products entering the Union market, taking into account its impact on business and in particular on small and medium-sized enterprises.

5.2. Entry into application

The proposal would delay the entry into application of the Regulation until 1 January 2020 to allow Member States, market surveillance authorities, and the European Commission through the Union Product Compliance Network to make the necessary practical arrangements and legislative changes.

5.3. Detailed explanation of the specific provisions of the proposal

The proposal consists of 11 chapters comprising 64 articles and one Annex.

Chapter I – General provisions

This Chapter defines the scope and the main terms used in the Regulation. It updates the definitions used in Regulation (EC) No 765/2008, in particular to take into account the diversity of actors in the supply chain and the need to make them all subject to enforcement of the Union harmonisation legislation on products. The proposed definition of ‘economic operator’ encompasses all actors directly concerned by this legislation.

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Chapter II – Compliance information

This Chapter introduces the concept of a 'person responsible for compliance information established within the Union' as a necessary condition for making the products available on the market. The main objectives are to enforce of Union harmonisation legislation on products by ensuring good contacts between manufacturers or their designated representatives and the market surveillance authorities, and to create fair trading conditions on the Union market.

The person responsible for compliance information can be the manufacturer, the importer or any other economic operator designated by the manufacturer.

The tasks of the person responsible for compliance information are essentially to provide information on the product to market surveillance authorities and to cooperate with the authorities.

Chapter III – Assistance to and cooperation with economic operators

This Chapter defines how to designate competent authorities and single liaison offices for this Regulation and clarifies the roles of the single liaison offices. It calls on the Member States to ensure smooth cooperation among the members of the enforcement network in their territory. It requires Member States to ensure that other national authorities support the work of the competent authorities, in particular in cases where criminal measures are needed to stop the infringement.

Chapter IV – Organisation and general principles of market surveillance

The Regulation sets out the Member States' obligations as regards organisation of market surveillance within their territory. It also lays down the procedures they must establish to follow up complaints or issues relating to risks; monitor accidents and harm to the health of end-users; verify corrective actions taken by economic operators; and follow up scientific and technical knowledge of safety issues.

The Regulation defines how Member States should designate market surveillance authorities and single liaison offices. It also lays down principles for the activities of market surveillance authorities, namely that surveillance must be effective, measures be proportional to compliance, that the authorities must take a risk-based approach against the background of defined factors, and act with transparency, independence and impartiality.

The Regulation also requires Member States to issue regular national market surveillance strategies and lists what they must include.

Chapter V – Market surveillance powers and measures

The Regulation provides for a set of powers for market surveillance authorities, defined with the view to ensure effective enforcement of Union harmonisation legislation on products is enforced effectively across borders. These powers include the power to access data and documents related to an instance of non-compliance, to require economic operators and public entities to provide all information related to an instance of non-compliance; to carry out on sit inspections; to make test purchases and carry out mystery shopping; to adopt temporary measures; to initiate investigations or procedures aimed at ceasing non-compliance; to prohibit the supply of products, or withdraw and recall and destroy them; to impose penalties and order the recovery of profits obtained as a result of non-compliance; and to publish decisions, including the identity of the concerned economic operator.

When exercising these powers, Member States retain the possibility to decide whether the competent authorities will exercise the minimum powers directly under their own authority or

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whether these powers will be exercised by application to courts, in accordance with national law.

The Regulation also defines market surveillance measures and establishes the procedures and principles to be observed. As regards products which present a serious risk requiring rapid intervention, the Chapter links with Directive 2001/95/EC and the Union Rapid Alert System established under that Directive.

The Regulation also introduces the possibility of designating Union testing facilities and specifies their tasks.

In addition to the principle of financing market surveillance, this Chapter provides for market surveillance authorities to recover their costs by charging economic operators administrative fees for non-compliance.

Chapter VI – Cooperation and procedure for mutual assistance

Mutual assistance may take two forms:

- requests for information, which enable market surveillance authorities in one Member State to obtain information and evidence from another; and
- requests for enforcement measures which enable market surveillance authorities to request their counterparts in another Member State to take enforcement measures.

The Regulation sets out the procedure for mutual assistance requests. These requests must be sent to the single liaison offices in the Member States of both the requesting and the requested authorities, using standard forms by means of an information and communication system. The Regulation also provides for that evidence obtained and investigation findings in one Member State may be used in another Member State.

The underlying principle that is that products deemed to be non-compliant on the basis of a decision taken by market surveillance authorities in one Member State are presumed to be non-compliant by market surveillance authorities in another Member State, unless the concerned economic operator can provide evidence to the contrary. The aim of the instruments of mutual assistance is to address instances of non-compliance of a product in cross-border context, and to allow measures to end the non-compliance or the ban the product in all Member States. The Regulation will also help evidence and investigation findings obtained through the use of minimum powers of market surveillance authorities can be used across the borders.

Under the Regulation, the requested authority must reply to a mutual assistance request within the time limit set the implementing measures.

The Regulation ensures the protection of professional and commercial secrets by providing that information communicated to market surveillance authorities will only be used to ensure compliance with Union harmonisation legislation.

Chapter VII – Products entering the Union market

The Regulation provides for a strengthened framework for controls on products entering the Union market. It starts from the assumption that the most effective way to ensure that unsafe or non-compliant products are not placed on the Union market is to carry out adequate checks before they are released for free circulation. Customs authorities execute controls based on risk analysis.

It also strengthens the exchange of information between market surveillance authorities and customs authorities, in particular through procedures for releasing products, suspending and

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refusing of release for free circulation. Market surveillance authorities can be asked to provide information on products and economic operators where a higher risk of non-compliance is detected. Customs authorities are required to inform the market surveillance authorities in timely manner on the placing of products under release for free circulation and the results of controls if that information is relevant for enforcing of Union harmonisation legislation.

The release for free circulation may be suspended if:

- the product is not accompanied by the required documentation, is not marked or labelled as required, does not bear the CE marking or other marking required under the Union harmonisation legislation;
- no person responsible for compliance information established within the Union can be identified; or
- there is cause to believe that the product is not placed on the market in accordance with requirements set out by Union harmonisation legislation.

The Regulation also provides for the favourable treatment of products declared for free circulation by authorised economic operators with special status under Regulation (EU) No 952/2013. It also lays down conditions for suspending this favourable treatment if non-compliance is detected during the controls. Procedural rules for exchanging information on authorised economic operators, between market surveillance authorities and customs authorities, will be established in implementing measures.

Chapter VIII – Coordinated enforcement and international cooperation

The Regulation establishes a Union Product Compliance Network ('Network'), within the Commission. The Network is composed of a board, administrative coordination groups and a secretariat; its tasks are detailed in the Regulation.

The role of the Network will be to coordinate enforcement tasks, thereby boosting market surveillance cooperation at EU level. Furthermore, the Network will be in charge of maintaining an information and communication system for collecting and storing information on the enforcement of Union harmonisation legislation on products. The system is available to the Commission and market surveillance authorities in the Member States and will have a public interface in order to comply with the obligation to inform the general public and ensure transparency.

The Regulation sets out the framework for international cooperation with third countries or international organisations to ensure Union harmonisation legislation on products is enforced. It also provides for a system for product related pre-export controls carried out by a third country on products, before they are exported to the Union. The details of the implementation of this system will be established by implementing acts.

Chapter IX – Financial provisions

The Regulation provides for the financing by the Commission of activities in all matters falling under the general market surveillance policy for the Union.

The Regulation includes for general clauses on protecting the financial interests of the Union.

Chapter X – Final provisions

The Regulation provides that Union harmonisation legislation listed its Annex will not be governed by Articles 15 to 29 of Regulation (EC) No 765/2008.

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23 legal instruments set out in the Annex to this Regulation have to be amended, by deleting references to Article 15 to 29 of Regulation (EC) No 765/2008. The Regulation also amends Directive 2004/42/EC of the European Parliament and of the Council[22].

Chapter XI – Penalties, evaluation, committee procedure and entry into force and application

While recognising that establishing penalties is a national competence, this Regulation sets out guiding principle for penalties.

The Regulation also lays down for standard provisions on evaluating of the application of this Regulation and on the committee procedure for adopting of implementing acts.

Annex

The Annex lists the Union harmonisation legal instruments for products, thus determining the scope of the application of the Regulation.

22 Directive 2004/42/EC of the European Parliament and of the Council 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 (OJ L 143, 30. 4.2004, p. 87).

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2017/0353 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

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

Having regard to the opinion of the European Economic and Social Committee[23],

Acting in accordance with the ordinary legislative procedure,

Whereas:

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

(2) Strengthening the Single Market for goods through further enhancing efforts to keep non-compliant products from being placed on the Union market was identified as a priority in the Communication from the Commission 'Upgrading the Single Market: more opportunities for people and businesses'[24]. 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.

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23 OJ C , , p. .

24 COM(2015) 550 final of 28 October 2015.

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

(4) Directive 2001/95/EC of the European Parliament and of the Council[25] 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[26] should be complemented to make them more effective.

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

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

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

(8) The framework established by this Regulation should complement and strengthen existing provisions in Union harmonisation legislation relating to the provision of compliance information about products and the framework for cooperation with economic operators, the market surveillance of products and controls on those products entering the Union. However, in accordance with the principle of *lex specialis*, this Regulation should apply only in so far as there are no specific provisions with the same objective, nature or effect in other existing or future rules of Union harmonisation legislation. The corresponding provisions of this Regulation should not therefore apply in the areas covered by such specific provisions, for instance those set out in Regulation (EC) No 273/2004 of the European Parliament and

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

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

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of the Council on drug precursors[27], Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products[28], Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices[29] and Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices[30].

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

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

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

(12) Modern supply chains encompass a wide variety of economic operators who should all be subject to enforcement of Union harmonisation legislation, while taking due consideration of their respective role in the supply chain, and the extent to which they contribute to the making available of products on the Union market. Therefore, it is necessary to apply this Regulation to economic operators that are directly concerned by Regulation (EC) No 273/2004 of the European Parliament and of the Council[31], Regulation (EC) No 1907/2006 of the European Parliament and of the Council[32], Regulation (EC) No 1272/2008 of the European Parliament and of the Council[33], Regulation (EC) No 1222/2009 of the European Parliament and of the Council[34], Regulation (EC) No 1223/2009, Regulation (EU) 2016/424 of the European

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

28 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).

29 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).

30 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).

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

32 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).

33 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).

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).

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Parliament and of the Council[35], Regulation (EU) 2016/425 of the European Parliament and of the Council[36], Regulation (EU) 2016/426 of the European Parliament and of the Council[37] and Regulation (EU) 2017/1369 of the European Parliament and of the Council[38], Regulation (EU) 2017/745 and Regulation (EU) 2017/746, and in Directive 2006/42/EC of the European Parliament and of the Council[39], Directive 2006/66/EC of the European Parliament and of the Council[40], Directive 2009/48/EC of the European Parliament and of the Council[41], Directive 2010/35/EU of the European Parliament and of the Council[42], Directive 2013/29/EU of the European Parliament and of the Council[43], Directive 2013/53/EU of the European Parliament and of the Council[44], Directive 2014/28/EU of the European Parliament and of the Council[45], Directive 2014/29/EU of the European Parliament and of the Council[46], Directive 2014/30/EU of the European Parliament and of the Council[47], Directive 2014/31/EU of the European Parliament and of the Council[48], Directive 2014/32/EU of the European Parliament and of the Council[49], Directive 2014/33/EU of the European Parliament and of the Council[50], Directive 2014/34/EU of the European Parliament and of the Council[51], Directive 2014/35/EU of the European Parliament and of the Council[52], Directive 2014/68/EU of the European

35 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).

36 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).

37 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).

38 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).

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

40 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).

41 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).

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

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

44 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).

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

46 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).

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

48 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).

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

50 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).

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

52 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).

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Parliament and of the Council[53], and Directive 2014/90/EU of the European Parliament and of the Council[54].

(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[55]. In particular, no general obligation should be imposed on service providers to monitor the information which they transmit or store, nor should a general obligation be imposed upon them to actively seek facts or circumstances indicating illegal activity. Furthermore, hosting service providers should not be held liable as long as they do not have actual knowledge of illegal activity or information and are not aware of the facts or circumstances from which the illegal activity or information is apparent.

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

(15) Member States should provide assistance to economic operators either through information on the applicable Union harmonisation legislation by the Product Contact Points established under Regulation (EU) [*Reference to new Regulation on mutual recognition to be inserted*][56], or through guidance on the applicable Union harmonisation legislation by the market surveillance authority within the framework of compliance partnership arrangements. Market surveillance authorities should able to

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53 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).

54 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).

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

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

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build on the existing cooperation with stakeholders and be permitted to conclude memoranda of understanding with stakeholders, with a view to promoting compliance or identifying non-compliance with regard to categories of product within a given geographical area.

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

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

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

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

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

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

(22) Market surveillance authorities should have access to all necessary evidence, data and information relating to the subject matter of an investigation in order to determine

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

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

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

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

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

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

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

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

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

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

(32) Where for the purposes of this Regulation it is necessary to process personal data, this should be carried out in accordance with Union law on the protection of personal data. Any processing of personal data under this Regulation is subject to Regulation (EU) 2016/679 of the European Parliament and of the Council[57] and Regulation (EC) No 45/2001 of the European Parliament and of the Council[58], as the case may be.

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

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

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

(36) The financing of market surveillance activities through fees collected from economic operators should take place in full transparency, so as to enable citizens and businesses

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

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

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to understand the method and data used to establish fees and to be informed on the use of revenue from fees.

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

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

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

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

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

(42) The Commission should carry out an evaluation of this Regulation against the objectives it pursues. Pursuant to point 22 of the Interinstitutional Agreement of 13 April 2016 on Better Law Making[59], the evaluation, based on efficiency, effectiveness,

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

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relevance, coherence and value added, should provide the basis for impact assessments of options for further action.

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

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

(45) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission in relation to the procedures for designating Union testing facilities, to the procedure for requests for information and requests for enforcement measures, to statistical data covering controls performed by customs authorities with respect to products subject to Union harmonisation legislation, to the data to be exchanged and the procedure to be followed for the exchange of information between customs authorities and market surveillance authorities on the status of authorised economic operators, to details of implementation arrangements for the information and communication system and data relating to the placing of products under the customs procedure 'release for free circulation' transmitted by customs authorities, and to the implementation of the system of product-related pre-export controls, including a model for the certificates of compliance or verification to be used. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[60].

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

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

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

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HAVE ADOPTED THIS REGULATION:

Chapter I

General provisions

Article 1

Subject matter

This Regulation lays down rules and procedures for the provision of compliance information about certain products that are the subject of Union acts harmonising the conditions for the marketing of those products. It establishes a framework for cooperation with economic operators in relation to such products.

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

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

Article 2

Scope

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

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

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

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

Article 3

Definitions

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

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

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

(3) 'market surveillance' means the activities carried out and measures taken by market surveillance authorities to ensure that products comply with the requirements under

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Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

(4) ‘market surveillance authority’ means an authority designated by a Member State under Article 11 as a market surveillance authority in the territory of that Member State;

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

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

(7) ‘non-compliance’ means any failure to comply with any of the requirements under the Union harmonisation legislation applicable to the product in question;

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

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

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

(11) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regards to the manufacturer’s obligations under the relevant Union harmonisation legislation;

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

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

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

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

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

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

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

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

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

(13) ‘corrective action’ means any action taken by an economic operator to bring any non-compliance to an end, including action to restrict the making available of products on the market or to destroy a product on the market;

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

(15) ‘serious risk’ means any serious risk, including a serious risk where the effects are not immediate, requiring rapid intervention by the market surveillance authorities;

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

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

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

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

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

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

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

Chapter II

Compliance information

Article 4

Person responsible for compliance information

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

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

      (i) an importer;

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

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

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

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

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

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

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

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

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

6. For the purposes of paragraph 1:

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

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

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

Article 5

Declaration of conformity

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

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Chapter III

Assistance to and cooperation with economic operators

Article 6

Information to economic operators

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

Article 7

Compliance partnership arrangements

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

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

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

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

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

Article 8

Memoranda of understanding with stakeholders

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

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

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

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

Article 9

Publication of voluntary measures

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

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

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

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

Chapter IV

Organisation and general principles of market surveillance

Article 10

Obligations of market surveillance authorities as regards organisation

1. Market surveillance authorities shall establish appropriate communication and coordination mechanisms with other market surveillance authorities.

2. Market surveillance authorities shall establish the following procedures in connection with products subject to the Union harmonisation legislation set out in the Annex:

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

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

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

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

Article 11

Market surveillance authorities and single liaison offices

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

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

3. The single liaison office of a Member State shall be responsible for coordinating the enforcement and market surveillance activities of the market surveillance authorities designated by that Member State.

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

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

Article 12

Activities of market surveillance authorities

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

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

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

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

(a) the identified risks associated with:

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

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

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

(c) any further information that might indicate non-compliance in relation to a particular product.

3. Market surveillance authorities shall ensure that a product is withdrawn or recalled from the market or that the making available of the product on the market is prohibited or restricted if, when it is being used either in accordance with its intended purpose or under conditions that can be reasonably foreseen and it is properly installed and maintained, either of the following conditions would be met:

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

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

Where the products are withdrawn, recalled, prohibited or restricted, the market surveillance authority shall ensure that the Commission through the Network established under Article 31, the other Member States and end-users are informed accordingly.

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

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

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

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

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

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

Article 13

National market surveillance strategies

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

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

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

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

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

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

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

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

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

Chapter V

Market surveillance powers and measures

Article 14

Powers and duties of market surveillance authorities

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

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

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

(b) by recourse to other public authorities;

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

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

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

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

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

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

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

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

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

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

(f) the power to take samples of products free of charge in order to detect non-compliance and obtain evidence;

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

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

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

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

(k) the power to prohibit the making available of products on the market or to withdraw, recall or destroy products, where economic operators fail to provide

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the information requested by the market surveillance authority to verify the compliance of those products and while the failure persists;

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

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

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

4. Market surveillance authorities shall publish any commitments given to them by economic operators, details of any corrective action taken by economic operators in their territory, and details of any temporary measures taken by the relevant market surveillance authority pursuant to this Regulation.

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

Article 15

Market surveillance measures

1. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory controls on the basis of a representative sample.

In deciding what checks to perform and on what scale, market surveillance authorities shall take into account, in particular, established principles of risk assessment and complaints.

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.

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

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

3. Where the market surveillance authorities of one Member State decide to withdraw a product manufactured in another Member State, they shall inform the economic operator concerned without delay.

Article 16

Use of information, professional and commercial secrecy

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

Article 17

Restrictive measures

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

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

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

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

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

Article 18

Products presenting a serious risk

1. Market surveillance authorities shall take measures to recall or withdraw products which present a serious risk or to prohibit the making available of them on the market. They shall inform the Commission of such measures without delay, in accordance with Article 19.

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

Article 19

Exchange of information — Union Rapid Alert System

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

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

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

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

Article 20

Union testing facilities

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

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

   (a) they must have suitably qualified staff with adequate training in the analytical techniques used in their area of competence and an adequate knowledge of standards and practices;

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

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

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

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

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

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

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

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

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

(d) develop new techniques and methods of analysis;

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

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

Article 21

Financing and recovery of costs by market surveillance authorities

1. Member States shall ensure that market surveillance authorities within their territory are provided with the necessary financial resources for the proper performance of their tasks.

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

Chapter VI

Cooperation and procedure for mutual assistance

Article 22

Requests for information

1. At the request of an applicant authority, the requested authority shall supply any information that the requested authority deems relevant to establish whether a product is non-compliant and to ensure that the non-compliance can be brought to an end.

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

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

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

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

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

Article 23

Requests for enforcement measures

1. At the request of an applicant authority, the requested authority shall without delay take all necessary enforcement measures using the powers conferred on it under this Regulation in order to bring an instance of non-compliance to an end.

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

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

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

   (a) whether temporary measures have been imposed;

   (b) whether the non-compliance has ceased;

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

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

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

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

Article 24

Procedure for mutual assistance requests

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

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

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

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

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

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

Article 25

Use of evidence and investigation findings

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

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

3. Products deemed to be non-compliant on the basis of a decision of a market surveillance authority in one Member State, shall be presumed to be non-compliant by market surveillance authorities in another Member State, unless economic operators can provide evidence to the contrary.

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

Chapter VII

Products entering the Union market

Article 26

Controls on products entering the Union market

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

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

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

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

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

5. Risk-related information shall be exchanged between:

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

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

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

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

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

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

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

(c) the results of controls on such products;

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

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

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

9. The Commission shall specify further by means of implementing acts the details of the data to be submitted by Member States under paragraph 7. Those implementing

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acts shall be adopted in accordance with the examination procedure referred to in Article 63.

Article 27

Suspension of release for free circulation

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

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

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

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

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

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

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

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

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

Article 28

Release of products

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

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

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

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

Article 29

Cooperation with authorised economic operators

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

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

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

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

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

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

Article 30

Refusal to release

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

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

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

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

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

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

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

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

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

Chapter VIII

Coordinated enforcement and international cooperation

Article 31

Union Product Compliance Network

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

Article 32

Composition of the Union Product Compliance Network

1. The Network shall be composed of a Union Product Compliance Board ('EUPC Board'), administrative coordination groups and a secretariat.

2. The EUPC Board shall consist of one representative from each of the single liaison offices referred to in Article 11, and two representatives from the Commission, and their respective alternates.

3. The Commission shall establish separate or joint administrative coordination groups for all the instruments of Union harmonisation legislation listed in the Annex to this Regulation. Each administrative coordination group shall be composed of representatives of the competent national market surveillance authorities and, if appropriate, representatives of the single liaison offices, and representatives of the relevant business associations and of consumer associations.

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4. The secretariat shall be composed of Commission staff.

5. The Commission may attend the meetings of the administrative coordination groups.

Article 33

Coordinated enforcement tasks

1. The Commission shall have the following tasks:

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

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

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

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

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

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

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

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

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

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

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

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

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

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application of this Regulation, including by setting standards for minimum penalties.

2. The EUPC Board shall have the following tasks:

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 34

Information and communication system

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

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

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

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

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

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

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

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

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

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

(i) any non-compliance;

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

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

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

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

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

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

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

(ix) failures by manufacturers to comply with Article 4(4).

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

(i) any non-compliance;

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

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

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

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

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

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

4. Where relevant for the enforcement of Union harmonisation legislation and for the purposes of minimising risk and combating fraud, customs authorities shall extract

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from national customs systems and transmit to the information and communication system data relating to the placing of products under the customs procedure 'release for free circulation' and the results of controls related to product safety.

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

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

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

Article 35

International cooperation

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

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

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

   (b) coordinated product recalls or other similar actions;

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

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

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

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

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

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

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

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

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

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

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

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

Chapter IX

Financial provisions

Article 36

Financing activities

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

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

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

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

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

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

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

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

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

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

4. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council[61], either directly, or by delegating budget implementation tasks to the entities listed in Article 58(1)(c) of that Regulation.

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

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

Article 37

Protection of the Union's financial interests of the Union

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

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

3. The European Anti-fraud Office (OLAF) may carry out investigations, including on-the-spot controls and inspections, in accordance with the procedures laid down in

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

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Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[62] and Council Regulation (Euratom, EC) No 2185/96[63] 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 38

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

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

Article 39

Amendments to Directive 2004/42/EC

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

Article 40

Amendments to Directive 2009/48/EC

Directive 2009/48/EC is amended as follows:

(1) Article 40 is deleted;

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

(3) Article 44 is deleted.

Article 41

Amendments to Directive 2010/35/EU

Directive 2010/35/EU is amended as follows:

(1) Article 16 is deleted;

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

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

63 OJ L292, 14.11.1996, p.2.

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Article 42

Amendments to Regulation (EU) No 305/2011

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

Article 43

Amendments to Regulation (EU) No 528/2012

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

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

Article 44

Amendments to Directive 2013/29/EU

Directive 2013/29/EU is amended as follows:

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

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

Article 45

Amendments to Directive 2013/53/EU

Directive 2013/53/EU is amended as follows:

(1) Article 43 is deleted;

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

Article 46

Amendments to Directive 2014/28/EU

Directive 2014/28/EU is amended as follows:

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

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

Article 47

Amendments to Directive 2014/29/EU

Directive 2014/29/EU is amended as follows:

(1) Article 34 is deleted;

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

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Article 48

Amendments to Directive 2014/30/EU

Directive 2014/30/EU is amended as follows:

(1) Article 37 is deleted;

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

Article 49

Amendments to Directive 2014/31/EU

Directive 2014/31/EU is amended as follows:

(1) Article 36 is deleted;

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

Article 50

Amendments to Directive 2014/32/EU

Directive 2014/32/EU is amended as follows:

(1) Article 41 is deleted;

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

Article 51

Amendments to Directive 2014/33/EU

Directive 2014/33/EU is amended as follows:

(1) Article 37 is deleted;

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

Article 52

Amendments to Directive 2014/34/EU

Directive 2014/34/EU is amended as follows:

(1) Article 34 is deleted;

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

Article 53

Amendments to Directive 2014/35/EU

Directive 2014/35/EU is amended as follows:

(1) Article 18 is deleted;

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

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Article 54

Amendments to Directive 2014/53/EU

Directive 2014/53/EU is amended as follows:

(1) Article 39 is deleted;

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

Article 55

Amendments to Directive 2014/68/EU

Directive 2014/68/EU is amended as follows:

(1) Article 39 is deleted;

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

Article 56

Amendments to Directive 2014/90/EU

Directive 2014/90/EU is amended as follows:

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

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

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

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

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

Article 57

Amendments to Regulation (EU) 2016/424

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

(1) Article 39 is deleted;

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

Article 58

Amendments to Regulation (EU) 2016/425

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

(1) Article 37 is deleted;

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

Article 59

Amendments to Regulation (EU) 2016/426

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

(1) Article 36 is deleted;

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

Article 60

Amendments to Regulation (EU) 2017/1369

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

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

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

Chapter XI

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

Article 61

Penalties

1. The Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation that impose obligations on economic operators and to infringements of provisions of any Union harmonisation legislation on products covered by this Regulation that impose obligations on economic operators where that legislation does not provide for penalties, and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive.

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

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

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

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

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

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

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

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

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

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

Article 62

Evaluation

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

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

Article 63

Committee procedure

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

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

Article 64

Entry into force and application

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

It shall apply from [*1 January 2020*].

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

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LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

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1.2. Policy area(s) concerned in the ABM/ABB structure

1.3. Nature of the proposal/initiative

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LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and the Council laying down rules and procedures for compliance with and enforcement of Union harmonisation legislation on products

1.2. Policy area(s) concerned in the ABM/ABB structure[64]

02 03 Internal Market for goods and services

1.3. Nature of the proposal/initiative

☐ The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[65]

☒ The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objective(s)

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

In the Single Market Strategy, Upgrading the Single Market: more opportunities for people and business (COM(2015)555/2) the Commission announced an initiative to strengthen market surveillance of products to combat the increasing number of illegal and non-compliant products on the market which distort competition and put consumers at risk. This proposal aims to strengthen product compliance by providing the right incentives to economic operators, intensifying compliance checks and promoting closer cross-border cooperation among enforcement authorities, including through cooperation with customs authorities.

This proposal is part of the "Goods Package" and should be set in the context of the fourth priority policy area to be tackled under President Juncker's Agenda for Jobs, Growth, Fairness and Democratic Change, i.e. a deeper and fairer internal market with a strengthened industrial base.

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective No

1. Reinforcing market surveillance cooperation procedures among enforcement authorities, reducing fragmentation and inefficiencies;
2. Increasing operational capacity, improving efficiency and availability of resources for cross-border controls and coordination of enforcement;
3. Strengthening the enforcement toolbox, allowing market surveillance authorities to use more deterrent, effective and future-proof tools;

64 ABM: activity-based management; ABB: activity-based budgeting.

65 As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

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4. Promoting compliance with EU legislation on non-food products, improving accessibility of compliance information and assistance to businesses.

The objectives cover market surveillance within the EU and at the external borders and encompass digital as well as traditional supply chains

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The proposal is expected to strengthen the market surveillance framework, leading to reduced numbers of non-compliant products in the Single Market.

Member State market surveillance authorities will be able to more frequently re-use evidence and replicate restrictive measures from other member states allowing cost-savings and efficiency gains.

The Union Product Compliance Network will assist market surveillance authorities to conduct more coordinated cross-border control campaigns, based on better prioritised joint actions and improved intelligence. This will allow a better integration of EU Single Market Dimension in national controls and more visible EU wide action.

The consistency of enforcement on products traded in the Union and on imports will improve due to the coordination of enforcement by the Network. In turn businesses that trade cross-border will benefit from a more level-playing field, legal certainty and predictability.

Consumers and businesses will have easier access to information and businesses will benefit from assistance to help them comply with Union product legislation.

1.4.4. Indicators of results and impact

Specify the indicators for monitoring implementation of the proposal/initiative.

- Compliance rates by Member State/sectors and for e-commerce and imports (improvements in availability and quality of information in Member State enforcement strategies, progress in reduction of compliance gaps)
- Number of coordination controls campaigns and results (detected infringements corrective measures)
- Usage of mutual assistance mechanisms by market surveillance authorities (number, types, timelines, outcomes) and number of measures taken by other authorities 'replicated' in each Member State
- Awareness/understanding of product rules by businesses
- Number of voluntary measures registered in the common web-portal on voluntary measures

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

The assessment of the market surveillance framework identified important shortcomings that are driven by four main factors, namely (1) fragmentation and limited coordination of market surveillance in the EU, (2) resources constraints for market surveillance authorities, (3) low deterrence of the current enforcement tools, notably with respect to imports from third countries and e-commerce and (4)

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important information gaps (i.e. lack of awareness of rules by businesses and little transparency as regards product compliance). To address these problems, the proposal foresees

- a mechanism for effective mutual assistance requests between market surveillance authorities of different Member States and transferability of enforcement evidence and decisions;

- an administrative support structure to coordinate and implement joint enforcement activities (Union Product Compliance Network), Member State enforcement strategies, performance indicators and peer reviews;

- common investigative and enforcement powers for market surveillance authorities and the obligation of manufacturers to designate a person responsible for compliance information in the EU;

- more systematic publication of restrictive measures taken by market surveillance authorities and recovery of control costs in case of non-compliant products;

- an extension of the advice role to businesses of Product Contact Points, a web-portal on voluntary measures taken by businesses on dangerous products, and digital publication of compliance information by manufacturers and importers.

1.5.2. Added value of EU involvement

The enforcement of Union harmonisation legislation within the single market creates major challenges for public authorities whose action is constrained by their jurisdictional boundaries, while many undertakings implement their business models in several Member States or at the EU level. To increase the level of compliance on the market, every Member State depends on the market surveillance of its neighbours. Consequently, weaknesses in the organisation of market surveillance in one single Member State can seriously undermine the efforts taken by other Member States to keep non-compliant products from the market; this creates a weak link in the chain.

Therefore to ensure consistent enforcement of Union harmonisation legislation across the EU and to tackle efficiently non-compliance spanning over several Member States, it is necessary to coordinate public enforcement activities. The issue being addressed has therefore cross-border aspects which cannot be sufficiently achieved by the Member States' individual actions because they cannot ensure cooperation and coordination by acting alone and need to be achieved at the Union level.

1.5.3. Lessons learned from similar experiences in the past

The assessment of the existing market surveillance framework and in particular Regulation (EC) n° 765/2008 concluded that it is not fully effective in relation to its strategic objectives of strengthening the protection of public interests and of ensuring a level playing field among economic operators through the reduction of the number of non-compliant products on the Internal Market. Data available actually points to the persistence and possibly to the increase of non-compliant products. As a consequence the existing market surveillance framework does not realise the expected improved safety for consumers/ users and level playing field for businesses. The main weaknesses identified were insufficient coordination and cooperation among market surveillance authorities and Member States, insufficient uniformity and rigorousness of market surveillance and border controls on imported products.

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Limited resources are available for market surveillance and vary significantly among Member States with a direct impact on the controls market surveillance can undertake. Across-the-board inconsistencies in the approach taken on market surveillance by different Member States on businesses may reduce businesses' willingness to comply with the rules and discriminate businesses that abide by the rules against those who do not.

The definitions in Regulation (EC) n° 765/2008 are generally clear and appropriate, however they are not complete and up-to-date, especially when considering the need to cover also online sales.

Overall the evaluation found that the benefits of having a single piece of European legislation on harmonising market surveillance instead of having several different pieces of national legislation were widely recognised. However the potential for the Regulation to achieve a full EU added value is still hindered by the sub-optimal level of cross-border exchange of information and cooperation, and by the lack of a uniform implementation of the market surveillance framework at the national level.

1.5.4. Compatibility and possible synergy with other appropriate instruments

The proposal is one of the initiatives under the European Commission's Single Market Strategy.

The proposal ensures a better alignment with the provisions of the EU Customs Code which entered into force in 2013. The proposal takes into account the new concepts advocated in the Code as regards coordination and inter-agency cooperation mechanisms, facilitations for trusted traders with good track-record and enhanced risk assessments including at the level of the Customs Union to make controls more efficient and effective.

The proposal is fully consistent and compatible with the existing EU policies and recent proposals to strengthen enforcement in other policy areas, such as Food and Feed controls, Consumer Protection Cooperation and Competition.

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1.6. Duration and financial impact

☐ Proposal/initiative of **limited duration**

☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

☐ Financial impact from YYYY to YYYY

☒ Proposal/initiative of **unlimited duration**

Implementation with a start-up period from 2020 to 2022, followed by full-scale operation.

1.7. Management mode(s) planned[66]

☒ **Direct management** by the Commission

☒ by its departments, including by its staff in the Union delegations;

☐ by the executive agencies

☐ **Shared management** with the Member States

☐ **Indirect management** by entrusting budget implementation tasks to:

☐ third countries or the bodies they have designated;

☐ international organisations and their agencies (to be specified);

☐the EIB and the European Investment Fund;

☐ bodies referred to in Articles 208 and 209 of the Financial Regulation;

☐ public law bodies;

☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

If more than one management mode is indicated, please provide details in the 'Comments' section.

Comments

66 Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

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2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

The IT-tool that connects market surveillance authorities and the Commission will be strengthened by this proposal (Article 34, Information and Communication System). By using the IT-tool the monitoring of operational activity could take place on an ongoing basis in an efficient manner. The monitoring through the IT-tool will be completed by the work of the Union Product Compliance Network set up by this Regulation and the provision by Member States of more reliable and more comprehensive information on compliance rates and enforcement activity as part of their national enforcement strategies. The Union Product Compliance Network will set up and monitor overall performance indicators and perform peer reviews.

2.2. Management and control system

2.2.1. Risk(s) identified

Operational risks regards the IT-tool: risk that the IT-system fail to effectively support the cooperation of market surveillance authorities and the Union Product Compliance Network.

2.2.2. Information concerning the internal control system set up

Effective IT-governance processes, which actively involve the systems' users.

2.2.3. Estimate of the costs and benefits of the controls and assessment of the expected level of risk of error

The costs of controls are negligible compared to the appropriations for the development of the IT tool itself

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures.

The measures implemented by the Commission will be subject to the ex-ante and ex-post controls in accordance with the Financial Regulation. Contracts and agreements financing the implementation of this Regulation will expressly entitle the Commission, including OLAF and the Court of Auditors to conduct audits, on the spot checks and inspections.

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3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Chapter 02.03 Internal market of goods and services	Diff./Non-diff.[67]	from EFTA countries[68]	from candidate countries[69]	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
1a	02.03.01 Internal market of goods and services	Diff.	YES	NO	NO	NO

67 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

68 EFTA: European Free Trade Association.

69 Candidate countries and, where applicable, potential candidates from the Western Balkans.

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3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

The expenditure in this financial statement is limited to the current multi-annual financial framework, up to 2020 included. Given the budgetary constraints in the current Multiannual Financial Framework, allocations would have to be covered at least partially by redeployments during the annual budgetary procedure. Indicative estimates of the longer term financial impacts of the measures in this proposal are set out in the impact assessment.

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	1A Competitiveness for Growth and Jobs

DG GROW			Year **2020**[70]	Year -	Year -		
• Operational appropriations							
02.03.01 Internal market of goods and services - Union Product Compliance Network	Commitments	(1)	4.450				
	Payments	(2)	2.910				
02.03.01 Internal market of goods and services - Other measures Compliance and Enforcement initiative (pilot strategies, benchmark study)	Commitments	(1a)	4.000				
	Payments	(2a)	1.700				
Appropriations of an administrative nature financed from the envelope of specific programmes[71]							

[70] Year N is the year in which implementation of the proposal/initiative starts.

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Number of budget line		(3)					
TOTAL appropriations for DG GROW	Commitments	=1+1a +3	8.450				
	Payments	=2+2a +3	4.610				

TOTAL			Year **2020**[72]	Year -	Year -		
• TOTAL operational appropriations	Commitments	(4)	8.450				
	Payments	(5)	4.610				
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)					
TOTAL appropriations under HEADING 1A of the multiannual financial framework	Commitments	=4+ 6	8.450				

Heading of multiannual financial framework	**5**	'Administrative expenditure'

EUR million (to three decimal places)

	Year **2020**	Year -	Year -		

[71] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

[72] Year N is the year in which implementation of the proposal/initiative starts.

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DG: GROW						
Human resources		*0.787*				
Secretariat Union Product Compliance Network		*3.246*				
• Human resources (total)		4.033				
• Other administrative expenditure		0.093				
TOTAL DG GROW	4.126	6.752				

TOTAL appropriations under HEADING 5 of the multiannual financial framework	(Total commitments = Total payments)	4.126				

EUR million (to three decimal places)

		Year **2020**[73]	Year -	Year -		
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	12.576				
	Payments	8.736				

[73] Year N is the year in which implementation of the proposal/initiative starts.

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3.2.2. *Estimated impact on operational appropriations*

☐ The proposal/initiative does not require the use of operational appropriations

☒ The proposal/initiative requires the use of operational appropriations:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **2020**		Year -		Year -							
	OUTPUTS													
	Type 74	Average cost	No	Cost	No	Cost	No	Cost						
SPECIFIC OBJECTIVE No 1 75	. Reinforcing market surveillance cooperation procedures among enforcement authorities, reducing fragmentation and inefficiencies													
SPECIFIC OBJECTIVE No 2 76	. Increasing operational capacity, improving efficiency and availability of resources for cross-border controls and coordination of enforcement													
Pilot national enforcement strategies *(n°co-funded pilot strategies/year)*			3	3.000										
Peer review/performance indicators *(baseline study)*			1	1.000										
Union Product Compliance Network *(headline indicator: n° of joint control campaigns)**			15	4.450										
SPECIFIC OBJECTIVE No 3 77	. Strengthening the enforcement toolbox, allowing market surveillance authorities to use more deterrent, effective and future-proof tools													

74 Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

75 As described in point 1.4.2. 'Specific objective(s)…'

76 As described in point 1.4.2. 'Specific objective(s)…'

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SPECIFIC OBJECTIVE No 4[78]	. Promoting compliance with EU legislation on non-food products, improving accessibility of compliance information and assistance to businesses											
European Portal on voluntary measures *(n° notifications)*												
TOTAL COST		**8.450**										

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77 As described in point 1.4.2. 'Specific objective(s)…'

78 As described in point 1.4.2. 'Specific objective(s)…'

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

☐ The proposal/initiative does not require the use of appropriations of an administrative nature

☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year **2020**[79]	Year -	Year -	Year -	Enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
HEADING 5 of the multiannual financial framework								
Human resources	4.033							
Other administrative expenditure	0.093							
Subtotal HEADING 5 of the multiannual financial framework	4.126							

Outside HEADING 5[80] of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 5 of the multiannual financial framework								

TOTAL	4.126				

The appropriations required for human resources and other expenditure of an administrative nature will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

79 Year N is the year in which implementation of the proposal/initiative starts.

80 Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former 'BA' lines), indirect research, direct research.

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3.2.3.2. Estimated requirements of human resources

☐ The proposal/initiative does not require the use of human resources.

☒ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full time equivalent units

	Year **2020**	Year -	Year -	Year -	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
• Establishment plan posts (officials and temporary staff)							
02 01 01 01 (Headquarters and Commission's Representation Offices - GROW)	5.7						
02 01 01 01 (Headquarters and Commission's Representation Offices – GROW – Secretariat Union Product Compliance Network)	22						
XX 01 01 02 (Delegations)							
XX 01 05 01 (Indirect research)							
• External staff (in Full Time Equivalent unit: FTE)[81]							
XX 01 02 01 (AC, END, INT from the 'global envelope')	3						
XX 01 02 02 (AC, AL, END, INT and JED in the delegations)							
XX 01 04 **yy** [82] - at Headquarters							
XX 01 04 **yy** [82] - in Delegations							
XX 01 05 02 (AC, END, INT - Indirect research)							
10 01 05 02 (AC, END, INT - Direct research)							
Other budget lines (specify)							
TOTAL	**30.7**						

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

81 AC= Contract Staff; AL = Local Staff; END= Seconded National Expert; INT = agency staff; JED= Junior Experts in Delegations.

82 Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

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Description of tasks to be carried out:

Officials and temporary staff (Commission)	In the set-up phase (2020-2022) preparation of implementing/delegated acts, set-up of the Union Product Compliance Network, pilot national enforcement strategies, study to set the baseline for perfomance indicators and monitoring of the Regulation. AD staff for the Head of the Union Product Compliance Network Secretariat, market surveillance technical and legal analysis, IT and data-systems supervision and design. AST staff for support to meeting organisation, administrative and financial management tasks.
External staff	Contract agents - routine IT maintenance and specific development projects Seconded national experts (SNE) – joint actions management, specific market surveillance expertise. The possibility to recruit SNE to the Network is kept open as an option as national expertise. Market surveillance authorities currenlty critically lack resources so that it is highly uncertain that they could second staff to the Network, especially in the initial phases of the Network.

Estimated phasing in of staff in the set-up phase of the Union Product Compliance Network (Secretariat hosted by the Commission) within the time-span of the current multi-annual framework upto 2020 included.

Function group and grade	Year 2020	Year -	Year -		
AD 9-15	1				
AD 5-12	17				
AD Total	**18**				
AST 1-11 / AST/SC 1-6	4				
AST/SC Total	**4**				
GRAND TOTAL	**22**				

Estimated phasing in of staff in the set-up phase and total staff of the Union Product Compliance Network – external personnel

Contract agents	Year 2020	Year –	Year -		
Function group III/IV	3				
Total	3				

Seconded National Experts	Year 2020	Year -	Year -		
Total	pm				

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3.2.4. *Compatibility with the current multiannual financial framework*

☒ The proposal/initiative is compatible the current multiannual financial framework.

☐ The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts. […]

☐ The proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework.

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts. […]

3.2.5. *Third-party contributions*

☒ The proposal/initiative does not provide for co-financing by third parties.

☐ The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to three decimal places)

	Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

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3.3. Estimated impact on revenue

☒ The proposal/initiative has no financial impact on revenue.

☐ The proposal/initiative has the following financial impact:

- ☐ on own resources
- ☐ on miscellaneous revenue

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[83]						
		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
Article …….								

For miscellaneous 'assigned' revenue, specify the budget expenditure line(s) affected.

[…]

Specify the method for calculating the impact on revenue.

[…]

[83] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25 % for collection costs.

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ANNEX to the LEGISLATIVE FINANCIAL STATEMENT

Name of the proposal/initiative:

Proposal for a European Parliament and Council Regulation

on Compliance and Enforcement of Union Harmonisation Legislation on Products

(1) NUMBER and COST of HUMAN RESOURCES CONSIDERED NECESSARY

(2) COST of OTHER ADMINISTRATIVE EXPENDITURE

(3) METHODS of CALCULATION USED for ESTIMATING COSTS

(a) Human resources

(b) Other administrative expenditures

(4) SUMMARY of all COSTS (human resources, other administrative expenditure and operational budget)

This annex must accompany the legislative financial statement when the inter-services consultation is launched.

The data tables are used as a source for the tables contained in the legislative financial statement. They are strictly for internal use within the Commission.

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(1) Cost of human resources considered necessary

☐ The proposal/initiative does not require the use of human resources

☒ The proposal/initiative requires the use of human resources, as explained below:

EUR million (to three decimal places)

HEADING 5 of the multiannual financial framework		Year 2020		Year 2021		Year 2022		Year 2023 and onwards		... enter as many years as necessary to show the duration of the impact (see point 1.6)		TOTAL	
		FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations	FTE	Appropriations
• Establishment plan posts (officials and temporary staff)													
02 01 01 01 (Headquarters and Commission's Representation Offices) GROW	AD	5	0,690	5	0,690	4,5	0,621	4	0,552				
	AST	0,7	0,097	0,7	0,097	0,5	0,069	0,5	0,069				
02 01 01 01 (Headquarters and Commission's Representation Offices) GROW – secretariat Union Product Compliance Network	AD	18	2,484	33	4,554	42	5,796	42	5,796				
	AST	4	0,552	7	0,966	10	1,380	10	1,380				
33 01 01 01 (Headquarters and Commission's Representation Offices) JUST – portal for publication of voluntary measures economic operators	AD			0,5	0,069	0,5	0,069	0,5	0,069				
	AST												
XX 01 01 02 (in Union Delegations)	AD												
	AST												
• External staff [84]													
XX 01 02 01 ('global envelope') secretariat Union Product Compliance Network	AC	3	0,210	5	0,350	7	0,490	7	0,490				
	END	pm	pm	pm	pm	pm	pm	pm	pm				
	INT												
XX 01 02 02 (in Union Delegations)	AC												
	AL												
	END												

[84] AC = Contract Staff; AL = Local Staff; END = Seconded National Expert; INT= agency staff; JED = junior experts in delegations.

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	INT												
	JED												
Other budget lines (*specify*)													
Subtotal – HEADING 5 of the multiannual financial framework		30,7	4,033	51,2	6,726	64,5	8,425	64	8,356				

XX is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

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(2) Cost of other administrative expenditure

☐ The proposal/initiative does not require the use of administrative appropriations

☒ The proposal/initiative requires the use of administrative appropriations, as explained below:

EUR million (to three decimal places)

	Year 2020	Year 2021	Year 2022	Year 2023 and onwards	... enter as many years as necessary to show the duration of the impact (see point 1.6)			TOTAL
HEADING 5 of the multiannual financial framework								
At headquarters:								
02 01 02 11 01 - Mission and representation expenses	0,003	0,005	0,008	0,008				
XX 01 02 11 02 - Conference and meeting costs								
02 01 02 11 03 - Committees[85]	0,090	0,090	0,030	pm				
XX 01 02 11 04 - Studies and consultations								
XX 01 02 11 05 – Information and management systems								
XX 01 03 01 – ICT equipment and services[86]								
Other budget lines (*specify where necessary*)								
In Union delegations								
XX 01 02 12 01 - Missions, conferences and representation expenses								
XX 01 02 12 02 - Further training of staff								
XX 01 03 02 01 - Acquisition, renting and related expenditure								
XX 01 03 02 02 Equipment, furniture, supplies and services								
Subtotal HEADING 5 of the multiannual financial framework	0,093	0,095	0,038	0,008				

XX is the policy area or budget title concerned.

[85] Specify the type of committee and the group to which it belongs.

[86] ICT: Information and Communication Technologies: DIGIT must be consulted.

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TOTAL HEADING 5 and Outside HEADING 5 of the multiannual financial framework	4,126	6,821	8,463	8,364				

The administrative appropriations required will be met by the appropriations which are already assigned to management of the action and/or which have been redeployed, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of existing budgetary constraints.

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(3) Methods of calculation used to estimate costs

(a) Human resources

This part sets out the method of calculation used to estimate the human resources considered necessary (workload assumptions, including specific jobs (Sysper 2 work profiles), staff categories and the corresponding average costs)

HEADING 5 of the multiannual financial framework

NB: The average costs for each category of staff at Headquarters are available on BudgWeb: https://myintracomm.ec.europa.eu/budgweb/EN/pre/legalbasis/Pages/pre-040-020_preparation.aspx

- Officials and temporary staff

Committee management, Implementing/delegated acts: 1 AD, 0.2 AST in 2020, 1 AD, 0.2 AST in 2021, 0.5 AD in 2022

Pilot national enforcement strategies, performance indicators, reference levels study:
first pilots in 2020: 1 AD 2020 and 2021
Continued support to new strategies from 2021 onward (1AD)

Market surveillance policy
Market surveillance policy development, enlargement and international aspects, monitoring of the Regulation's implementation; COM representation in Union product compliance board and liasion to the network; Handling of mutual assistance request/safeguard cases, follow-up of peer review findings: 3 AD/year, 0,5 AST from 2020 onwards

Secretariat Union Product Compliance Network:

AD staff: 18 in 2020, +15 (33 total) in 2021, +9 (42 total) in 2022. From 2023 onwards: 42
AST staff: 4 in 2020, + 3 (7 total), in 2021 +3 (10 total) in 2022. From 2023 onwards: 10

DGJUST Voluntary portal RAPEX monitoring/verification content: 0,5 AD/year from 2021 onwards

- External staff

Union Product Compliance network
Contract agents : 2020: 3, 2021: +2 (5 total), 2022: +2 (7 total). 2023 onwards: 7/year total.

Seconded national experts: pm. Seconded National Experts (SNE) could be valuable to the Union Product Compliance Network, but is more difficult to factor in specifically for the start-up of the Network. The number of staff that authorities could second to form a structural part of the Network is uncertain. A key problem which the Network should overcome is the very limited resources that authorities can make available for cross-border cooperation (i.e. limited candidates for ADCO chairs, project coordinators, and limited skills for EU project coordination). The possibility for secondments should nonetheless be kept open (pm).

Note: no external staff counted for heading 5 for IT 'intra-muros' staff - charged to operational budget lines (part of IT costs Union product compliance network; DGJUST maintenance voluntary portal RAPEX: 0.2 AC/year from 2021 onwards (Consumer Programme 33 04 in current Multiannual Financial Framework))

Outside HEADING 5 of the multiannual financial framework

- Only posts financed from the research budget

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• External staff

(b) Other administrative expenditure

Give details of the method of calculation used for each budget line and in particular the underlying assumptions (e.g. number of meetings per year, average costs, etc.)

HEADING 5 of the multiannual financial framework
Committee meetings: for discussion, adoptiof on implementing/delegated acts 30.000 €/meeting 2020: 3 meetings; 2021 3 meetings; 2022: 1 meeting. Mission costs COM Secretariat Union Product Compliance Network – missions to meetings held in Member States, international meetings enforcement cooperation: Mission costs: 4/year 2020 @ 750€ = 3 000€, 6/year 2021 @750€ = 4 500€ , 10/year from 2022 @750 = 7 500 €

Outside HEADING 5 of the multiannual financial framework

(4) SUMMARY of all COSTS (human resources, other administrative expenditure and operational budget

This section gives a summary of all estimated impacts on human resources, other administrative costs and operational budget expenditure related to the set-up phase (up to 2020 included in the current multi-annual financial framework) and the estimated yearly costs once the full implementation stage is reached of the proposal, from 2023 onwards:

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(a) Indicative operational appropriations(up to 2025):

		Year **2020**[87]	Year **2021**	Year **2022**	Year **2023**	Year **2024**	Year **2025**
Union Product Compliance Network	Commitments	4.450	6.950	9.450	9.950	9,950	9,950
Other measures Compliance and Enforcement initiative (pilot strategies, benchmark study)	Commitments	4.000	3.000	3.000	3,000	3,000	3,000
Supporting the functioning and modernisation of the customs union – set-up costs interface MSA-customs systems (incl. Single Window)	Commitments		0,550	0,660	0,560	0,710	0,710
Portal for publication of volutary measures by economic operators	Commitments		0,059	0,029	0,029	0,029	0,029
TOTAL operational appropriations	Commitments	8.450	10.559	13.139	13,539	13,689	13.689

Commitment appropriations in EUR million (to three decimal places)

Measures and outputs			Year **2020**		Year **2021**		Year **2022**		Each year from **2023 and onwards**	
	Type [88]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost
SPECIFIC MEASURES										
National strategies *(n° co-funded pilot strategies/yr)*			3	3,000	3	3,000	3	3,0000	3	3,000

87 Year N is the year in which implementation of the proposal/initiative starts.

88 Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

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Peer review/performance indicators *(baseline study)*	1	1.000						
Union Product Compliance Network *(headline indicator: n° of joint control campaigns)**	15	4.450	20	6.950	30	9.450	30 - 40	9.950
Set-up costs interface customs – market surveillance systems (2021-2025)			1	0.550	1	0.660	1	0.660 *(average/year 2023-2025)*
European Portal on voluntary measures *(n° notifications)*			250	0.059	500	0.029	800	0.029
TOTAL COST		**8.450**		**10.559**		**13.139**		**13.639**

* Key tasks and outputs of the Union Product Compliance Network

Strategy & workprogramme (organisation Union Product Compliance Board meetings, priorities for joint actions, market studies, performance indicators, peer reviews of national enforcement strategies): 2 to 3 meetings/year; 2 to 3 market studies/year; 5 in-depth reviews/year.

Coordination of enforcement and support to joint actions (support to administrative coordination groups, financing of joint control campaigns, joint procurement, monitoring mutual assistance requests): 30 to 40 coordinated control campaigns/year, 2 to 3 joint procurement/partnership projects (5 year period).

International cooperation (development of enforcement cooperation protocols, exchange of information/best-practice): 3 cooperation protocols (5 year period).

Training (mapping of training needs market surveillance, training events, e-learning materials).

Dissemination and development and management of communication and IT tools, including exhange of information and linking of market surveillance and customs systems. (Set-up costs to interface MSA and customs sustems (e.g. Single Windows) amount to around on average 640K€/year and would be spread over 5 years, indicatively 2021-2025).

(b) Human resources and other administrative costs:

	Year **2020**	Year **2021**	Year **2022**	Each year from **2023 and onwards**
DG: GROW				
Human resources	*0.787*	*0.787*	*0.690*	***0.621***
Secretariat Union Product Compliance Network	*3.246*	*5.870*	*7.666*	***7.666***
• Human resources (total)	4.033	6.657	8.356	**8.287**
• Other administrative expenditure	0.093	0.095	0.038	**0.008**
TOTAL DG GROW	4.126	6.752	8.394	**8.295**
DG: JUST				

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• Human resources			0.069	0.069	0.069
• Other administrative expenditure					
TOTAL DG JUST	**Appropriations**		**0.069**	**0.069**	**0.069**

TOTAL appropriations	(Total commitments = Total payments)	4.126	6.821	8.463	**8.364**

Estimated phasing in of staff in the set-up phase and cumulative total staff of the Union Product Compliance Network (Secretariat hosted by the Commission)

Function group and grade	Year 2020	Year 2021	Year 2022	Cumulative total
AD 9-15	1	0	0	1
AD 5-12	17	15	9	41
AD Total	**18**	**15**	**9**	**42**
AST 1-11 / AST/SC 1-6	4	3	3	10
AST/SC Total	**4**	**3**	**3**	**10**
GRAND TOTAL	**22**	**18**	**12**	**52**

Estimated phasing in of staff in the set-up phase and total staff of the Union Product Compliance Network – external personnel

Contract agents	Year 2020	Year 2021	Year 2022	Cumulative total
Function group III/IV	3	2	2	7
Total	3	2	2	7

Seconded National Experts	Year 2020	Year 2021	Year 2022	Cumulative total
Total	pm	pm	pm	pm

(c) Total costs (operational budget, human resources and other administrative costs (4(c) = 4(a) + 4(b))

EUR million (to three decimal places)

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		Year **2020**[89]	Year **2021**	Year **2022**	Each year from **2023 and onwards**
TOTAL appropriations Total costs	Commitments	12.576	17.380	21.602	**22.003**
	Payments	8.736	15.130	20.012	**21.383**

89 Year N is the year in which implementation of the proposal/initiative starts.

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