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WORKING PAPER

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WORKING DOCUMENT

From: To:	Presidency Working Party on Technical Harmonisation (Goods package)
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 - comparison between ST 15950/17 and WK 9693/18 REV 1

New text compared to the Commission's proposal is indicated in **bold/underlined** and deletions are marked with ~~strikethrough~~.

HAVE ADOPTED THIS REGULATION:

Chapter I

General provisions

Article 1

Subject matter

1. **The objective of t**his 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.~~ **is to improve the functioning of the internal market by strengthening the market surveillance of products covered by legislative acts of the Union, with a view** ~~It also provides a framework for the market surveillance of such products~~ to ensure that ~~those~~ **only compliant** products **that** fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, the protection of consumers, protection of the environment and **public** security**, are made available on the Union market.**

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

3. This Regulation also provides a framework for controls on 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 **I** to this Regulation ('Union harmonisation legislation').

1a. **Articles 3(11), (12), (12a,), 4 and 4a shall apply to the Union harmonisation legislation set out in the Annex II.**

1b. **Articles 26, 27, 28 and 30 (Chapter VII - Products entering the Union market) shall apply to all products covered by Union legislation in so far as other Union legislation does not contain specific provisions relating to the organisation of controls on products entering the Union market.**

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:

(0) **'product' means a substance, preparation or good produced through a manufacturing process other than food, feed, living plants and animals, products of human origin and products of plants and animals relating directly to their future reproduction;**

(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~~ **set out in the applicable** Union harmonisation legislation and ~~do not endanger health, safety or any other aspect~~ **ensure protection** of **the** public interest ~~protection~~ **covered by that legislation**;

(4) 'market surveillance authority' means an authority designated by a Member State under Article 11 as ~~a~~ **responsible for carrying out** 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~~ **or the requirements of this Regulation**;

(8) 'manufacturer' means**:**

(a) 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 **or, where provided for in the applicable Union harmoinsation legislation, uses it for his own purposes, or**

(b) **any natural or legal person who modifies a product already placed on the market in such a way that compliance with the applicable Union harmonisation legislation may be affected, and places it on the market, or**

(c) **any other natural or legal person who places a product on the market under his name or trade mark**;

(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)~~ **online intermediation service providers or** 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~~ **subject to obligations in relation to the manufacture of products, making them available on the market or putting them into service in accordance with the relevant Union harmonisation legislation**;

(12a) 'online intermediation services' means services which meet all of the following requirements:

(a) they constitute information society services within the meaning of Article 1(1)(b) of Directive (EU) No 2015/1535 of the European Parliament and of the Council;

(b) they allow economic operators to offer goods or services to end users, with a view to facilitating the initiating of direct transactions between those economic operators and end users, irrespective of where those transactions are ultimately concluded;

(c) they are provided to economic operators on the basis of contractual relationships between, on the one hand, the provider of those services and, on the other hand, both those economic operators and the end user to which those economic operators offer goods or services;

(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~~ **where requested by market surveillance authorities or on his own initiative**;

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

(14a) 'voluntary measure' means any measure carried out by an economic operator to end the non-compliance of a product, without prior intervention of a market surveillance authority;

(14b) 'risk' means the combination of the probability of an occurrence of a hazard causing harm and the degree of severity of that harm;

(14c) 'product presenting a risk' means a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, protection of consumers, the environment, public security and other public interests, protected by the applicable Union harmonisation legislation. This to a degree which goes beyond that considered reasonable and acceptable in relation to its intended purpose or under the normal or reasonably foreseeable conditions of use of the product concerned, including the duration of use and, where applicable, its putting into service, installation and maintenance requirements;

(15) '**product presenting a** serious risk' means ~~any serious~~ **a product presenting a** risk, **for which the combination of the probability of occurrence of a hazard causing harm and the degree of severity of the harm is considered serious. This based on a risk assessment,** including ~~a serious risk~~ **cases** where the effects are not immediate, **and thus** 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~~ **whose personal or legal interests may be affected by the goods in question**;

(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~~ Economic operator responsible for compliance ~~information~~

1. A product **listed in Annex I** may be made available on the market only if ~~the following conditions are met~~ **there is an economic operator established in the Union who is responsible for compliance with the applicable legislation in respect to this product.**

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

(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)~~**(aa)** an importer**, when the manufacturer is not established in the Union**;

~~(ii)~~**(ab)** ~~a natural or legal person~~ **an authorised representative, when no other economic operator is** established in the Union ~~who has, having a written mandate from the manufacturer designating him as a person being responsible for performing the tasks listed in paragraph 3 and requiring him to perform those tasks on the manufacturer's behalf;~~

~~(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. **Without prejudice to any obligations and responsibilities of economic operators under the applicable Union harmonisation legislation, t**he ~~person~~ **economic operator** responsible for compliance ~~information~~ shall perform the following tasks **as a minimum**:

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

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

(c) cooperating with the market surveillance authorities~~, at their request, on ony action taken to~~ **and taking immediate action to remedy any case of non-compliance with the requirements set out in Union harmonisation legislation applicable to the product in question,** ~~eliminate~~ or, if that is not possible, mitigate the risks posed by ~~the~~ **that** product **at their own initiative or when required to do so by the market surveillance authorities.**

3a. The name, registered trade name or registered trade mark and the contact details, including the postal address, of the economic operator responsible for compliance with respect to the product shall be indicated on the product or, where that is not possible because of the size or physical characteristics of the product, on its packaging, the parcel or an accompanying document.

3b. Economic operators offering a product for sale online shall indicate with their offer for sale the name, registered trade name or registered trade mark and the contacts details of the economic operator responsible for compliance with respect to the product. With this regard, online marketplaces shall facilitate the display of abovementioned information for the products sold through them.

~~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 4a

Authorised representative

1. For the purposes of article 4(1a)(ab), the manufacturer shall mandate an authorised representative to perform those tasks listed in article 4(3), notwithstanding tasks mandated under the relevant Union harmonisation legislation.

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

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

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

~~*Article 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.~~

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.~~

1. **The Commission shall be responsible for making available relevant information on Union harmonisation legislation to economic operators free of charge. For this purpose, the Commission shall establish a centralised system in the framework of the single digital gateway. This system shall enable the economic operator to determine the harmonization legislation applicable to his product, and its requirements.**

2. **In addition, Member States shall have procedures in place for providing economic operators at their request with advice and guidance in respect to the national transposition of Union harmonisation legislation and its applicable to a product. This information shall be provided generally within 15 working days and free of charge.**

3. **Consulting on the technical standards, the appropriate design of a specific product, or pre-market approvals shall not be tasks of Member States under this article.**

~~*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**~~ **Joint awareness raising and information campaigns**

1. Market surveillance authorities may**, in compliance with national legislation,** ~~enter into memoranda of understanding~~ **agree** with ~~businesses~~ **other relevant authorities,** ~~or~~ organisations representing ~~businesses~~ **economic operators** or end-users ~~for~~ **on** ~~the~~ carrying out~~, or financing, of~~ joint activities aimed at ~~identifying non-compliance or~~ promoting compliance**, raising awareness and providing advice and guidance in relation to the Union harmonisation legislation** ~~in specific geographical areas or~~ with respect to ~~specific~~ categories of product**s, in particular the ones that are often found to be presenting a serious risk, including the products sold online**.

~~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.~~

~~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, activities and ~~general principles~~ obligations of market surveillance authorities

~~*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;~~

~~(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

Designation of market surveillance authorities and the 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 **representing the coordinated position** of the market surveillance authorities **and the** market surveillance **authorities** designated by that Member State **under Article 26(1)**.

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

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

Article 12

Activities of market surveillance authorities and use of findings

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

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

   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;

      (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.

6. 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~~ **based on** ~~a representative~~ **an adequate** sample **in accordance with the national market surveillance strategy referred to in Article 13**.

7. In deciding what checks to perform and on what scale, market surveillance authorities shall **follow a risk based approach** take**ing** into account~~,~~ in particular~~, established principles of risk assessment~~ **the possible hazards associated with the product and its number on the market,** ~~and~~ complaints **and other information**.

8. 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.

9. 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.

10. **Market surveillance authorities shall actively participate in administrative coordination groups according to Article 32(6) to ensure communication and coordination with their counterparts in other Member States.**

11. **Market surveillance authorities shall establish adequate procedures in connection with products subject to the Union harmonisation legislation set out in Annex I as follows:**

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

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

12. 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 operator can provide~~ evidence to the contrary **is provided or a Member State has raised objections in accordance with the applicable Union safeguard procedure**.

Article 13

National market surveillance strategies

1. Each Member State shall draw up a**n** **overarching** national market surveillance strategy, as a minimum, every ~~3~~ **5** years**, at first after 3 years after coming into force of this regulation**. The strategy shall promote a consistent, comprehensive and integrated approach to market surveillance and enforcement of Union harmonisation legislation within the territory of the Member State**. When drawing up the strategy** ~~and shall include~~ all sectors and stages of the product supply chain, including imports and digital supply chains **shall be considered.**

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

(a) an assessment of the occurrence of non-compliant products, in particular taking into account the ~~risk-based~~ controls referred to in Articles 12(6) and 26(3), and**, where applicable,** market trends that may affect non-compliance rates in the categories of product;

(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 **I** ~~to this Regulation~~ **and shall provide them with the necessary resources in that regard**.

1a. Market surveillance authorities shall exercise their powers set out in this Article in accordance with the principle of proportionality, to the extent that relates to the subject matter, and the purpose of the their actions and the nature and the overall actual or potential harm of the instance of non-compliance. Powers shall be exercised efficiently and effectively and in accordance with Union and national law, including the principles of the Charter of Fundamental Rights of the European Union, applicable procedural safeguards and the Union rules on data protection, in particular Regulation (EU) 2016/679 of the European Parliament and of the Council.

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) **where appropriate, upon** by recourse to other public authorities**, in accordance with the division of powers and the institutional and administrative organisation of the Member State in question**;

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

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;~~

(e) 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 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.~~

(o) powers to carry out on-site inspections, including entering premises, physical controls, and acquire product samples;

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

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

(s) powers, where there are no other effective means available to prevent a serious risk, to require information society service providers to restrict access to content referring to the related product;

(t) powers to recover costs according to Art. 14a.

~~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.~~

6. 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.

Article 14a

~~Financing and r~~**R**ecovery 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~~ **may authorise their market surveillance authorities to charge the relevant economic operator administrative fees in cases of non-compliant products** ~~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.~~ in order to enable the authorities to recover totality of the the costs of their activities with respect to these instances of non-compliance.

2. Those costs may include the costs of carrying out testing for the purposes of 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.

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.~~

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

1b. For the purpose of paragraph 1a, market surveillance authorities shall request appropriate and proportionate corrective action to be taken, which may include inter alia:

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

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

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

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

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

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

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

1c. Corrective actions referred to in points (e), (f) and (g) may only be taken in cases where a product is liable to present a risk only in certain conditions or only to certain persons and where such risk is not addressed by requirements of Union harmonisation legislation.

1d. Where products are withdrawn, recalled, prohibited or restricted, market surveillance authorities shall ensure that the Commission and the other Member States are informed accordingly through the system referred to in Article 34. This information also fulfils notification requirements of legislation listed in Annex I.

1e. If a national measure is considered justified, the competent market surveillance authorities in the other Member States shall take the corrective actions necessary in respect to the non-compliant product, and shall enter the related information in the system referred to in Article 34.

2. Market surveillance authorities shall ~~take appropriate measures, without delay, to~~ alert **or have alerted, within an adequate timeframe,** 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.

2a. ~~The authorities~~ **Economic operators** shall cooperate with ~~economic operators~~ **market surveillance authorities** 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

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~~ **necessary** in order to protect the interests of end-users in the Union.

Article 17

~~Restrictive measures~~ Judicial protection and due process

1. Any measure, decision or order taken or made by market surveillance authorities pursuant to Union harmonisation legislation or this Regulation ~~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~~ **according to Article 15** shall state the exact grounds on which it is based.

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

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

3a. 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.

1a. Where a product presents a serious risk, market surveillance authorities shall request the relevant economic operator to take appropriate corrective actions.

1b. When the relevant economic operator fails to do so, market surveillance authorities shall take the necessary measures to ensure that such products are recalled, withdrawn, or that their being made available on the market is prohibited. Market surveillance authorities shall inform the Commission of such measures without delay, in accordance with Article 19.

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

Article 19

~~Exchange of information —~~ Union Rapid Alert System (RAPEX)

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

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

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

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

Article 20

~~Union t~~Testing facilities~~y~~ support

~~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;~~

~~(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.~~

4a. **Objective of the testing facility support is ensuring sufficient laboratory capacity, as well as reliability and consistency of testing, for the purposes of market surveillance within the Union.**

4b. **When the Commission determines on its own initiative or on request of the Network, that testing capacity for specific harmonisation legislation or product categories is missing, it shall set up a programme for the establishment of new testing facilities or to encourage existing facilities to increase their scope or capacity. All testing facilities under this programme shall be accredited in accordance with the requirements of Chapter II of Regulation (EC) No 765/2008.**

5. The Commission shall adopt implementing acts ~~specifying the procedures for designating Union testing facilities~~ **on testing facility support programmes**. 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~~ Cross-border 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 requests for information under paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.~~

Article 22a

Mutual Assistance

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

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

3. The applicant authority remains responsible for the case it has initiated.

4. Information or documentation referred to in paragraph 1 shall be processed via the system referred to Article 34.

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

~~*Article 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.~~

2a. The applicant authority shall carry out itself all investigations reasonable possible before launching a request for assistance.

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

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

3a. **Generally, communication shall take place directly between the involved authorities. Differing procedures can be foreseen in national legislation.**

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.~~

7. **The system referred to in Article 34 shall provide structured information on mutual assistance cases to the single liaison offices involved. Single liaison offices shall follow these cases and give any support necessary to facilitate assistance.**

~~*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.

   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~~ **and the rules of market surveillance according to this regulation and the relevant hamonized EU legislation**.

~~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 i~~**I**nformation ~~shall~~ **may, if appropriate in accordance with national legislation,** be exchanged between:

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

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

   Where, in relation to products subject to Union 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~~ **inform** the Member State**s** ~~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 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~~ **checks** ~~referred to in~~ **pursuant to** Article 26, **paragraph 3,** 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~~ **an economic operator** responsible for compliance ~~information~~ with respect to the product is not indicated or identifiable in accordance with Article 4(3b);

(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**s** 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 **by means of the system referret to in Article 34**.

3. Where the market surveillance authorities have reason to believe that a product ~~will~~ **does** not comply with the Union harmonisation legislation applicable to it or ~~will~~ pose**s** 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**~~y~~ies** with the Union harmonisation legislation applicable to it.

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.

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

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

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

3. To perform the tasks set out in Article 32a, the Network shall be assisted by the Commission by means of an executive secretariat that provides technical and logistic support to the Network, to its sub-groups, and the ADCOs.

Article 32

Composition and operation of the ~~Union Product Compliance~~ Network

1. The Network shall be composed of ~~a Union Product Compliance Board ('EUPC Board')~~ **representatives from the single liaison offices according to Article 11, assisted by national experts, the chairs of** administrative coordination groups **of market surveillance authorities,** and ~~a secretariat~~ **representatives from the Commission**.

~~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.~~

~~4. The secretariat shall be composed of Commission staff.~~

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

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

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

8. The Network shall use its best endeavours to reach consensus. Decisions are legally non-binding recommendations.

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

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

11. The Network shall establish its rules of procedure.

Article 32a

Tasks of the Network

1. The Network shall be concerned with general matters of market surveillance and focus on horizontal issues. It shall intensify the cooperation between the Single Liaison Offices and the Commission.

2. The Network shall have the following tasks:

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

(b) to prepare and validate system approvals for the execution by a third country of product export controls to ensure that these products comply with applicable Union harmonized legislative provisions;

(c) to define and approve processing of collected data as referred to Article 34;

(d) to take up any other issues in activities under the purview of the Network;

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

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

(g) to provide input to the Commission for testing facility support according to Article 20;

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

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

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

(k) to facilitate the organisation of information campaigns and joint visit programmes;

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

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

(n) to propose the financing of activities foreseen in Article 36;

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

(p) to provide advice and assist the Commission with issues related to the further development of RAPEX and ICSMS;

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

Article 32b

Tasks of administrative coordination groups

1. Administrative coordination groups shall be concerned with specific matters of market surveillance and focus on sector specific issues.

2. ADCO meetings are closed meetings frequently dealing with confidential issues. However, ADCOs may organize open sessions to exchange views inviting on a case-by-case basis stake holders such as organisations representing the interests at Union level of industry, small and medium-sized enterprises, consumers, laboratories, standardisation and conformity assessment bodies.

3. ~~The a~~**A**dministrative coordination groups **(ADCOs)** shall have the following tasks:

(a) to coordinate the ~~enforcement~~ **uniform application** 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;~~

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

(e) to establish and coordinate common actions such as cross-border **(joint)** 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 33

~~**Coordinated enforcement tasks**~~ **Tasks of the Commission**

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

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

(mb) to determine the need for additional testing capacity and to provide taylored solutions;

(mc) to apply the instruments of international cooperation referred to in Article 35(1) and (2);

(md) to provide support for the establishment of separate or joint ADCOs for the instruments of Union harmonisation legislation listed in Annex I to this Regulation;

(me) to provide comprehensive logistic support via the executive secretariate to the Network and the ADCOs;

(mf) to develop and maintain the system referred to in Article 34, including the interface with the EU Single Window referred to in paragraph 8 of that Article, and provide information to the general public by means of that system;

(mg) 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;

(mh) supplementing the provision of Article 32a paragraph (i), to organise 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;

(mi) 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;

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

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

~~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 **further** develop and maintain an information and communication system for the collection and storage of information, in a structured form, on issues relating to the enforcement of Union harmonisation legislation. The Commission, **market surveillance authorities,** 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~~.~~**;**

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

3. Market surveillance authorities shall enter the following:

   ~~(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**, and where applicable, in relation to products entering the Union market for which the process for the release for free circulation has been suspended in accordance with Article 27, in their territory**, ~~the following~~ information **concerning**:

   ~~(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;~~

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

(viib) reports of testing carried out by them;

(viic) corrective action taken by economic operators concerned and the follow up by those economic operators;

(viid) 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;

(viii) failures by ~~a person responsible for compliance information~~ **an authorised representative** to comply with Article 4(3);

(ix) failures by manufacturers to comply with Article 4(3a).

~~(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 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.~~

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

8. 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.

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. **All requirements of data protection and confidentiality have to be considered.**

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 of 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:

   (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 31.

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 provision of ~~Union~~ testing facilit~~ies~~**y** **support** 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;

(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(8) 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[1], 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.

[1] 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).

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

3. The European Anti-fraud Office (OLAF) may carry out investigations, including on-the-spot controls and inspections, in accordance with the procedures laid down in Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[2] and Council Regulation (Euratom, EC) No 2185/96[3] 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.

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2 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).

3 OJ L292, 14.11.1996, p.2.

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.

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.

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.

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

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**, according to national legislation,** 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.

1a. The penalties provided for shall be effective, proportionate and dissuasive.

1b. The Member States shall notify those provisions to Commission~~,~~ by [31 March 2020]~~,~~ **and shall** 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.~~

~~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**6**] 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 addition, the evaluation should also assess the effectiveness of the market surveillance activities that receive Union financing in the light of the requirements of Union policies and legislation.

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 63a

Repeal

1. Articles 15 to 29 of Regulation EG (No) 765/2008 are repealed.

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

Article 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 202~~0~~**2**].

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*