Council of the European Union
General Secretariat

Interinstitutional files:
2017/0353(COD)

Brussels, 26 October 2018

WK 13028/2018 INIT

LIMITE

ENT
MI
COMPET
CONSOM
UD
CHIMIE
COMER
CODEC

WORKING PAPER

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

WORKING DOCUMENT

From:	FI delegation
To:	Working Party on Technical Harmonisation (Goods package)
Subject:	FI comments on the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down rules and procedures for compliance with and enforcement of Union harmonization 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 - Presidency discussion paper- Articles - doc. WK 12491

Council of the European Union
General Secretariat

Interinstitutional files:
2017/0353(COD)

Brussels, 18 October 2018

WK 12491/2018 INIT

LIMITE

ENT
MI
COMPET
CONSOM
UD
CHIMIE
COMER
CODEC

WORKING PAPER

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

WORKING DOCUMENT

From:	Presidency
To:	Working Party on Technical Harmonisation (Goods package)
Subject:	Presidency discussion paper (articles) on 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

Chapter I General provisions

Article 1

Subject matter

1. The objective of this Regulation is to improve the functioning of the internal market by strengthening the market surveillance of products covered by Union harmonisation legislation ~~set out in Annex I~~, with a view to ensure ~~fair competition between economic operators, and~~ that only compliant products that fulfil requirements providing a high level of protection of public interests such as health and safety in general, health and safety in the workplace, the protection of consumers, protection of the environment and public security **and any other public interests**, 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 shall apply to all products that are subject to the Union harmonisation legislation set out in the Annex I to this Regulation **('Union harmonisation legislation')**, in so far as there are no specific provisions with the same objective in this Union harmonisation legislation, which regulate in a more specific manner particular aspects of market surveillance and enforcement.
2. ~~Articles 3(12), (13), (14), 4 and 4a shall apply to the products covered by Union harmonisation legislation set out in the Annex II.~~

Note: Term "Annex I" is kept, as there are two more Annexes. (2) deleted on request of most delegations in 10th CWP.

3. Articles 26, 27, 28, 29 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.

Note: Par. (3) closes the gap caused by the repeal of Art.15-29 of Reg. 765/2008..

4. *Note: Lex specialis provision moved to (1)*
5. The application of this Regulation shall not prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC.
6. This Regulation is without prejudice to Articles 12, 13, 14 and 15 of Directive 2000/31/EC.

Recital 5:

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

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

Article 3

Definitions

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

~~(1) '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.~~

~~(2)~~ '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;

~~(3)~~ 'placing on the market' means the first making available of a product on the Union market;

~~(4)~~ 'market surveillance' means the activities carried out and measures taken by market surveillance authorities to ensure that products comply with the requirements set out in the applicable Union harmonisation legislation and ensure protection of the public interest covered by that legislation;

~~(5)~~ 'market surveillance authority' means an authority designated by a Member State under Article 11 **or Article 26** as responsible for carrying out market surveillance in the territory of that Member State;

~~(6)~~ 'applicant authority' means the market surveillance authority that makes a request for mutual assistance;

~~(7)~~ 'requested authority' means the market surveillance authority that receives a request for mutual assistance;

~~(8)~~ 'non-compliance' means any failure ~~by an economic operator~~ to comply with any of the requirements under the Union harmonisation legislation or the requirements of this Regulation;

~~(9)~~ 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark, **or, where provided for in the applicable Union harmonisation legislation, uses it for his own purposes, or**

(a) 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

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

Note: Reverted back to WK 7227/2018 following the request by delegations during the 10th CWP.

~~(10)~~ 'importer' means any natural or legal person established within the Union who places a product from a third country on the Union market;

~~(11)~~ '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;

(11a) 'fulfilment service provider' means ~~a business~~ **any legal or natural person** offering the service of warehousing, picking, packaging or shipping ~~to economic operators~~ without having ownership of the products involved. Services provided according to Article 1(1) of Directive 97/67/EC (Community postal services), Article 2(2) of Regulation (EU) 2018/644 (cross-border parcel delivery services), **any other postal services,** or freight transport services are not considered fulfilment services;

Note: Directive 97/67/EC (Community postal services): postal services: services involving the clearance, sorting, transport and delivery of postal items; postal item: an item addressed in the final form in which it is to be carried by the universal service provider.
Reg. (EU) 2018/644: 'parcel delivery services' means services involving the clearance, sorting, transport and distribution of parcels.

Picking: The order picking or order preparation operation is one of a logistic warehouse's processes. It consists in taking and collecting articles in a specified quantity before shipment to satisfy customers' order (Wikipedia).

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

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

(13a) 'information society service provider' means a provider of a service within the meaning of Article 1(1)(b) of Directive 2015/1535/EU;

Note: 'service' means any Information Society service, that is to say, any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services.

For the purposes of this definition:

(i) 'at a distance' means that the service is provided without the parties being simultaneously present;

(ii) 'by electronic means' means that the service is sent initially and received at its destination by means of electronic equipment for the processing (including digital compression) and storage of data, and entirely transmitted, conveyed and received by wire, by radio, by optical means or by other electromagnetic means;

(iii) 'at the individual request of a recipient of services' means that the service is provided through the transmission of data on individual request.

(13b) 'online marketplace' means a provider on an intermediary service that allows economic operators, on the one hand, and end-users, on the other hand, to conclude transactions via online sales either on the online marketplace's website or on an economic operator's website that uses computing services provided by the online marketplace;

(13c) 'online interface' means any software, including a website, part of a website or an application, that is operated by or on behalf of an economic operator, and which serves to give end-users access to the economic operator's products;

(14) *deleted*

(15) 'corrective action' means any action taken by an economic operator to bring any noncompliance to an end where requested by market surveillance authorities or on his own initiative;

(16) *deleted*

Note: As the term is no longer used, the definition could be removed.

(17) 'voluntary measure' means a corrective action, which is not the result of ~~an order given~~ **a request** by a market surveillance authority;

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

(19) 'product presenting a risk' means a product having the potential to affect adversely health and safety of persons in general, health and safety in the workplace, protection of consumers, the environment, public security and other public interests, protected by the applicable Union harmonisation legislation. 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;

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

(21) 'end-user' means any natural or legal person, residing or established in the Union, to whom a product was made available either as a consumer, outside any trade, business,

craft or profession, or as a professional end-user in the course of his industrial or professional activities;

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

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

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

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

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

Chapter II Compliance

Article 4

Economic operator responsible for compliance

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

2. For the purpose of paragraph 1, **the** economic operator~~s~~ ~~shall be~~ responsible for compliance **means any of** ~~in~~ the following ~~order~~:

   (a) the manufacturer established in the Union;

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

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

   (bb) a fulfilment service provider established in the Union;

   (c) an authorised representative~~, when no other economic operator is~~ established in the Union.

Note: With the last changes, we have provided more flexibility for manufacturers to appoint an authorized representative. Who is the economic operator responsible for compliance is always clear: he is indicated on the package.

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

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

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

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

   (c) cooperating with the market surveillance authorities and taking immediate **corrective** action to remedy any case of non-compliance with the requirements

set out in Union harmonisation legislation applicable to the product in question, or, if that is not possible, mitigate the risks posed by that product at their own initiative or when required to do so by the market surveillance authorities;

4**a**. 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. **When there is more than one economic operator indicated, the economic operator responsible for compliance shall be clearly identified.**

5. 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, including the postal address~~ **information as described in paragraph 4**, 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.

6. This Article shall ~~not~~ **only** apply in relation to ~~a~~ product**s** that ~~is~~ **are** subject to ~~Regulation (EC) No 1223/2009, Regulation (EU) 2017/745, Regulation 2017/746 or Regulation 2017/1369~~ **regulations (EU) 305/2011 ('construction products'), (EU) 2016/425 (EU) ('personal protective equipment'), 2016/426 ('gas appliancies') and directives: 2000/14/EC ('outdoor noise'), 2006/42/EC ('machinery directive'), 2009/48/EU ('toy safety'), 2009/125/EC ('ecodesign'), 2010/35/EU ('transportable pressure equipment'), 2013/29/EU ('pyrotechnics'), 2013/53/EU ('recreational craft'), 2014/28/EU ('civil explosives'), 2014/29/EU ('simple pressure vessels'), 2014/31/EU (non-automatic weighing instruments'), 2014/32/EU ('measuring instruments'), 2014/34/EU ('ATEX'), 2014/35/EU ('low voltage directive'), 2014/53/EU ('radio equipment'), 2014/68/EU ('pressure equipment')**.

7. **The Commission may adopt delegated acts to extend the scope of this Article to further directives or regulations listed in the Annex I.**

   Such extension of the scope shall be based on evidence that a substantial amount of non-compliant products falling within the scope of those directives or regulations concerned are shipped directly or through fulfilment service providers from third countries to end users in the Union and their non-compliance would endanger a high level of protection of public interests according to Article 1.

Note: Recalling the interventions at the 11th CWP, the benefit of the proposed Art. 4 was not the question. Nevertheless, proportionality in relation to burdens for economic operators was considered insufficiently taken into account.

Our proposed solution is to take an idea of the Dutch proposal WK 9595/2018 on board: to select those legislation from the Annex dealing with higher risk products. In practice, this are most of the directives and regulations foreseeing CE- and similar markings. This legislation is covering most of the products relevant for consumers and other end-users sold online, and largely includes already a comprehensive set of obligations for traditional economic operators. Thus, one can argue that we are mainly closing a loophole opened by the recent development of online trade, and in parallel concentrate the measure on sectors where mostly needed. See also related new task of the Network Art. 33 (g1)

Recital 7

~~Safety of consumers largely depends on the active enforcement of Union harmonisation legislation on products providing for safety requirements. It is therefore necessary to strengthen enforcement measures. These measures should be continuously improved and increasingly effective with a view to meeting the current challenges of a global market and an increasingly complex supply chain.~~ **Practical experience of market surveillance has shown that these increasingly complex supply chains sometimes involve economic operators whose novel form means that they do not fit easily into the traditional legal framework. Such is the case, in particular, with fulfilment service providers, which perform many of the same functions as importers but which might not always correspond to the traditional definition of importer in Union law. In order to ensure that market surveillance authorities can carry out their responsibilities effectively and also to avoid a gap in the enforcement system, it is appropriate to include fulfilment service providers within the list of economic operators against whom enforcement measures may be taken by market surveillance authorities. By including such fulfilment centres within the scope of the present Regulation, market surveillance authorities will be better able to deal with new forms of economic activity in order to ensure the safety of consumers and the smooth functioning of the internal market, including where the operator acts both as a distributor as regards certain products but as a fulfilment service provider as regards other products.**

There is Union harmonisation legislation in the scope of this regulation using specific terms for economic operators, among them: the operators as defined in Regulation (EC) No 273/2004, the producer of an article and the downstream user as defined in each case in Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008, the installer as defined in Directives 2006/42/EC and 2014/33/EU, the supplier and the distributor as defined in Regulation (EC) No 1222/2009, or the dealer as defined in Regulation (EU) 2017/1369. Art. (4)(2)(ba) should clarify that also these economic operators have responsibilities according to this Article.

Recital 11 (Note: unchanged)

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

Recital 14

A fairer single market should ensure equal conditions for competition to all economic operators and protection against unfair competition. To this purpose, strengthened enforcement of Union harmonisation legislation on products is necessary. Good cooperation between manufacturers and the market surveillance authorities is a key element allowing immediate intervention and

corrective action in relation to the product. It is important that there should be a contact person established in the Union so that market surveillance authorities have someone to whom questions can be addressed regarding a product's compliance with Union harmonisation legislation **and who can be required to take corrective action in case a non-compliance cannot be resolved otherwise.** The person responsible for ~~providing such~~ compliance ~~information~~ should be the manufacturer, ~~or~~ the importer, ~~or~~ **any** ~~an~~other **natural or legal** person ~~designated by the manufacturer for this purpose, for example another economic operator~~ **established in the Union subject to obligations in relation to the manufacture of products or placing on the market, a fulfilment service provider established in the Union and finally an authorized representative**. The role of a person responsible for compliance ~~information~~ established in the Union is essential for providing market surveillance authorities with an interlocutor established in the Union, and for performing specific tasks in a timely manner to ensure that the products comply with the requirements of Union harmonisation legislation, for the benefit of consumers, workers and businesses within the Union.

Recital 14a

However, t~~T~~he provisions in this Regulation requiring there to be a person established in the Union responsible for compliance ~~information should~~ **need only** ~~not~~ apply where **a risk-based approach indicates that this would be appropriate, having regard to the principle of proportionality, taking into account high level of protection of end-users in the Union.** ~~Moreover, those provisions need not apply where the specific requirements set out in certain legal instruments on products achieve the same result in effect, namely Article 4 of Regulation (EC) No 1223/2009, Article 15 of Regulation (EU) 2017/745 and Article 15 of Regulation 2017/746 and Regulation 2017/1369.~~

To target specific product groups that in practice show most cases of non-compliance, the requirement limited to Union harmonisation legislation that require products to bear a CE-marking. Market surveillance authorities indicate that non-compliance is especially an issue in these product groups.

Moreover, those provisions need not apply where the specific requirements set out in certain legal instruments on products achieve the same result in effect, namely ~~Article 4 of~~ Regulation (EC) No 1223/2009 **('cosmetics'),** ~~Article 15 of~~ Regulation (EU) 2017/745 **('medical devices'),** ~~Article 15 of~~ Regulation 2017/746 **('in-vitro diagnostics')** and Regulation 2017/1369 **('energy labelling').**

Taking into account experiences with the provisions up to this point and developments in the rapidly evolving e-commerce market, it should be possible to include other Union harmonisation legislation by means of delegated acts. In this case, there should be an evidence-based proof that a product group contains a substantial amount of noncompliant products. The type of risk caused by these products should be part of the assessment as well.

Article 4a

Authorised representative

1. For the purposes of Article 4(2)(c), the manufacturer shall mandate an authorised representative to perform those tasks listed in Article 4(4), notwithstanding tasks mandated under the relevant Union harmonisation legislation.
2. The mandate shall be valid only when accepted in writing by the authorised representative and shall be signed by both parties.
3. The authorised representative shall perform the tasks specified in the mandate. He shall provide a copy of the mandate to the market surveillance authorities upon request, in an Union language as determined by the authority.
4. Authorised representatives shall have the appropriate means available to be able to fulfil their tasks.

Note:

We took great efforts to ensure consistency with the existing system of economic operators, following the intention of decision 768/2008/EC of aligning all harmonisation legislation. Consequently, we have avoided to create a new economic operator 'person responsible for compliance' but used the 'Authorized representative' also for those cases when it is not yet foreseen in the respective harmonisation legislation. We have also ensured that the obligations are in line with those of the authorized representative and the importer according to decision 768/2008, however streamlining them to the absolutely necessary thus requesting only what can be actually fulfilled by the representative and in parallel keeping additional efforts on the side of businesses at a minimum.

As The Netherlands have proposed, we have separated the tasks of the authorized representative for the sake of clarity. To take care of a comment of SK, Art. 4a (1) also clarifies that the voluntary AR as defined in Art. 3(12) takes the additional tasks on board, when the condition of Art. 4 (2) (c) applies. Art. 4a(4) is aimed to take care of concerns regarding 'letterbox firms'.

Article 4b

Obligation of cooperation

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

Note: moved from Art. 15(7) Market Surveillance measures

2. ~~Hosting~~ **Information society** service providers shall cooperate with the market surveillance authorities, at their request, to facilitate any **corrective** action taken to eliminate or, if that is not possible, mitigate the risks posed by a product that is or was offered for sale online through their services.

Article 5

Declaration of conformity

Note: Deleted: many delegations did see the provision problematic without much benefit for the MSAs.

Chapter III Assistance to and cooperation with economic operators

Note: The whole chapter has been re-written in the light of overwhelming concerns regarding workload, conflict of interests and impartiality.

Article 6

Information to economic operators

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 system accessible in accordance with Article 4 (2) of Regulation xxxx/2019 (Single digital gateway regulation). This system shall enable the economic operator to determine the harmonisation legislation applicable to his product, and its requirements.
2. In addition, Member States shall have procedures in place for providing economic operators at their request with specific information ~~and guidance~~ in respect to the national transposition of Union harmonisation legislation applicable to a product in accordance with Article 4(1) of Regulation xxxx/2019. This information shall be provided generally within 15 working days and free of charge.
3. ~~Guidance on the technical standards, the design of a specific product, or pre-market approvals is not required from Member States under this article~~.

Recital 15:

~~Member States should provide assistance to economic operators either through information on the applicable Union harmonisation legislation by the Product Contact Points established under Regulation (EU) [*Reference to new Regulation on mutual recognition to be inserted*][56], or through guidance on the applicable Union harmonisation legislation by the market surveillance authority within the framework of compliance partnership arrangements. Market surveillance authorities should able to build on the existing cooperation with stakeholders and be permitted to conclude memoranda of understanding with stakeholders, with a view to promoting compliance or identifying non-compliance with regard to categories of product within a given geographical area.~~

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

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

Note: We propose an up-to-date IT solution for the first level support by COM, ensuring consistent information across the Union. Details ("second level support") should then be provided by the MS when needed. Par. 3 ensures a clear borderline to the tasks of consultancy services and testing labs, which should not suffer under competition of public authorities.

The period of 15 working days is foreseen in the SDG Regulation and was therefore retained, while allowing for the necessary flexibility for difficult cases like novelty products ("generally..").

Article 7

Compliance partnership arrangements

Note: Substantive contents ("provide the economic operator with advice and guidance") included in Art. 6. Procedural provisions (par. 2-4) seem unnecessary and counterproductive, as information and support should be open to all economic operators and not depend on a special relationship with the authority.

Article 8

Joint awareness raising and information campaigns

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

Note: The amendment keeps the useful ideas for improving awareness about the applicable legislation among economic operators, however in line with contemporary compliance rules. It also reflects what is already part of some legislation, e.g. Reg. (EU) 2017/1369 (Labelling) Art. 7(3).

Article 9

Publication of voluntary measures

Note: Deleted, as a similar function already exists as 'GPSD Product Safety Business Alert Gateway'; see: https://webgate.ec.europa.eu/gpsd/

In addition, the OECD has already a 'Global portal on product recalls' online, see: https://globalrecalls.oecd.org/Content.aspx?Context=AboutUs_Introduction&lang=En

Chapter IV Organisation, activities and obligations of market surveillance authorities

Note: Following several interventions, the articles of Ch. IV have been rearranged, starting with provisions on the designation of market surveillance authorities, followed by the description of their activities and obligations. Duplications have been removed.

Article 10

Procedures of market surveillance

Note: Amended contents included in Art. 12

Article 10a

General requirements

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

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

Article 11

Designation of market surveillance authorities and the single liaison office

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

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

3. The single liaison office shall **at least** be responsible for representing the coordinated position of the market surveillance authorities and the authorities designated under Article 26(1) and for the national strategies as set out in Article 13. It shall also assist in the cooperation between market surveillance authorities in different Member States as set out in Chapter VI.

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

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

Article 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 products that are subject to Union harmonisation legislation ~~set out in Annex I~~;
   (b) the taking by economic operators of appropriate and proportionate corrective action in relation to compliance with that legislation and this Regulation;
   (c) when the economic operator fails to take corrective action, the taking ~~by market surveillance authorities~~ of appropriate ~~and proportionate~~ measures.
2. Market surveillance authorities shall exercise their powers and carry out their duties independently, impartially and without bias.
3. Market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory controls based on an adequate sample in accordance with the national market surveillance strategy referred to in Article 13.
4. In deciding what checks to perform and on what scale, market surveillance authorities shall follow a risk-based approach taking into account in particular the possible hazards and non-compliances associated with the product and when available, its occurrence on the market, activities and operations under the control of the economic operator, complaints and other information.
5. Where economic operators present test reports or certificates attesting conformity of their products with Union harmonisation legislation issued by an accredited conformity assessment body, market surveillance authorities shall take due account of such reports or certificates.
6. The evidence that is used by a market surveillance authority in one Member State may be used as part of investigations to verify product compliance carried out by market surveillance authorities in another Member State without any further formal requirements.
7. Market surveillance authorities shall actively participate in administrative coordination groups according to Article 32(2) to ensure communication and coordination with their counterparts in other Member States.
8. Market surveillance authorities shall establish adequate procedures in connection with products subject to the Union harmonisation legislation ~~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;

Note: several delegations have pointed out that the task of an authority is to enforce legislation. Dealing with scientific knowledge (lit. d) would therefore go too far. With the strengthening of the Network and COM to carry out studies etc., such knowledge will be collected and disseminated via the network in the future. (b) (monitoring accidents) has also become outdated, as this data will be readily available in ICSMS (see new requirement Art. 34 (iii1).

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

Article 13

National market surveillance strategies

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

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

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

   (b) the areas identified by the Member State as a priority for the enforcement of Union harmonisation legislation ~~when this information does not compromise market surveillance activities~~;

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

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

Chapter V Market surveillance powers and measures

Article 14

Powers and duties of market surveillance authorities

Note: this article has been universally criticized as too heavy handed, detailed and restrictive to individual situation in MS. The proposed amendments keep the idea of more closely specifying the powers above the notion of "necessary for the proper performance of their tasks" of Reg. 765 Art. 18(3), by outlining five classes of powers to be provided.

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

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

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

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

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

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

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

   (a0) powers to start investigations on their own initiative in order to identify noncompliances and bring them to an end;

   (a) powers to carry out, without prior announcement, on-site inspections, physical controls, and acquire product samples**, including under a cover identity;**

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

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

(c) 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;

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

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

(ii) **where a request according to (i) is not observed, to require information society service providers to restrict access ~~to content referring to the related product~~ to the online interface; including by requesting a third party to implement such measures.**

Note: Adapted from CPC-Regulation Art. 9(4)(g) and recital 14.

(e) Powers to ~~recover costs according to Art. 14a~~ **impose penalties according to Art. 61**.

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

Recital 47:

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

The implementation and exercise of powers in the application of this Regulation should also comply with other Union and national law, including with applicable procedural safeguards and principles of the fundamental rights. Member States should remain free to set out conditions and limits for the exercise of the powers in national law, in accordance with Union law. Where, for example, in accordance with national law, prior authorization to enter the premises of natural persons and legal persons is required from the judicial authority of the Member State concerned, the power to enter such premised should be used only after such prior authorization has been obtained.

~~Powers to acquire product samples should be understood in a broad sense and could include the possibility to buy products when necessary under a cover identity.~~

Recital 47a

In the digital environment in particular, the market surveillance authorities should be able to stop infringements covered by Union harmonisation legislation and this Regulation quickly and effectively, and in particular where the economic operator selling products conceals his identity or relocates within the Union or to a third country in order to avoid enforcement. In cases where there is a serious risk, market surveillance authorities should

be able to adopt measures in accordance with national law, including the removal of content from a website or ordering the explicit display of a warning to end-users when they access an online interface. Such measures should not go beyond what is necessary to achieve the objective of bringing to an end or prohibiting a serious risk covered by Union harmonisation legislation or this Regulation.

Article 14a

Recovery of costs by market surveillance authorities

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

2. Those costs may include the costs of carrying out testing ~~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 or their placing on the market.

Article 15

Market surveillance measures

Note: We feel the amendment is important as it gives clear and concrete directions to market surveillance authorities what options for "proportionate measures" are available thus contributing to a uniform enforcement.

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

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

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

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

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

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

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

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

Commented [HA(1]: Important change!

Commented [HA(2]: Referring to the discussions at the WP on 24.10. and to our previous comments, in our opinion the term 'corrective' could be deleted in these 2 places, because in certain situations MSA can require actions without any voluntariness on the side of the EO.

We read the term corrective actions so that they are voluntary in a way that EO makes them either fully on his own initiative or after request of MSA (not Order!)

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

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

4. Where products are withdrawn, recalled, prohibited or restricted, and where the noncompliance is not restricted to its national territory, market surveillance authorities shall ensure that the Commission and the other Member States are informed accordingly through the system referred to in Article 34. This information also fulfils notification requirements of **Union harmonisation** legislation ~~listed in Annex I~~.

5. If a national measure is considered justified according to Article 12(9) or the applicable safeguard procedure, the competent market surveillance authorities in the other Member States shall take the measures necessary in respect to the non-compliant product and where applicable the economic operator ~~and fulfilment~~ **or** ~~and hosting~~ **information society** service provider, and shall enter the related information in the system referred to in Article 34.

6. *deleted*

7. *deleted*

Note: moved to Art. 4b

Article 16

Use of information, professional and commercial secrecy

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

Article 17

Judicial protection and due process

1. Any measure, decision or order taken or made by market surveillance authorities pursuant to Union harmonisation legislation or this Regulation 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.

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

5. *deleted*

Note: Deleted on request of many delegations.

Article 18

Products presenting a serious risk

~~1.~~ *deleted*

~~2.~~ Where a product presents a serious risk, market surveillance authorities shall require the relevant economic operator to take appropriate ~~corrective~~ actions.

~~3.~~ ~~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.

~~4.~~ 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.

Note: Par. 1 has been deleted to provide for the correct order of activities and avoid duplications, eg. Information of COM (par. 3).

Article 19

Union Rapid Alert System (RAPEX)

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

Commented [HA(3]: Referring to the discussions at the WP on 24.10. and to our previous comments, in our opinion the term 'corrective' could be deleted in these 2 places, because in certain situations MSA can require actions without any voluntariness on the side of the EO.

We read the term corrective actions so that they are voluntary in a way that EO makes them either fully on his own initiative or after request of MSA (not Order!)

Commented [HA(4]: Since para 2 says "require" (which is a good change), this para is not synchronized with it.

On the basis of para 2 MSA has already requested EO to do the things listed in para 3. Now, on the basis of para 3, MSA would be required to do the same again if the EO fails to act on basis of what MSA did based on para 2.

So when we are talking about serious risk products, MSA requires EO to do the actions which are listed in para 3. **Thus we propose to delete the beginning of para 3 and add the rest of para 3 after para 2.**

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

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

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

5. The Commission shall provide and maintain a data interface between the RAPEX system to the system referred to in Article 34 so that the need for double data entry is reliably avoided.

Article 20

Testing facility support

Note: The presidency is aware that Union testing facilities as proposed did not find much support. However, there is anecdotal evidence that some sectors or product categories lack testing capacities, resulting in high prices, long waiting times and complicated procedures. Therefore, the initiative of the Commission to support the MSAs in this respect is certainly helpful. The new article 20 aims at addressing these positive aspects while avoiding the issues already identified. First step should be certainly the mapping of the existing testing lab landscape in the EU, which could be done in the framework of the Network.

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

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

2a. The establishment of new testing facilities or the increase of the scope or capacity of existing facilities and request of tests by market surveillance authorities may be financed by the Union in conformance with the ~~paragraph 2 of the~~ **A**rticle 36**(2)** ~~of the legislation. Such financing shall follow public procurement rules~~.

3. The Commission shall adopt implementing acts on testing facility support programmes. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63(3).

Article 21

Recovery of costs by market surveillance authorities

Note: moved to Art. 14a

Chapter VI Cross-border mutual assistance

Note: While all delegations were very positive about mutual assistance, it was also clear that such assistance must not have a detrimental effect on the own activities and should not be used to have others carry out the own work. The new chapter V balances these aspects.

The procedure is now clear: the applicant authority, remaining responsible, decides the case based on documents acquired with the help of mutual assistance. After the end the safeguard procedure, all MS are required to take appropriate measures in their territories.

Article 22

Mutual Assistance

1. There shall be efficient cooperation and exchange of information among the market surveillance authorities of the Member States, and between market surveillance authorities and the Commission and the relevant Union agencies.
2. When an authority has undertaken all appropriate efforts to obtain information itself, and nevertheless cannot conclude its investigations, it may put forward a motivated request to the authority of another Member State where access to this information can be enforced.
3. The applicant authority remains responsible for the case it has initiated, unless the requested authority expressively agrees to take over responsibility.
4. ~~Information referred to in paragraph 1 shall be processed via the system referred to Article 34~~.

Note: Covered by Art. 24(3)

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.

Note: Par. 5 must not be misused to significantly weaken mutual assistance: therefore, a number of safeguards are implemented. The requested authority needs to give good reasons and show that own duties are significantly impaired. If not satisfied, the applicant authority may ask the Single Liaison Office for support (Art. 24(7)), they may discuss the case in the Network (Art. 33a(2) lit. l) and finally COM can initiate proceedings. Considering Art. 22(1), this should be sufficient to encourage good cooperation.

Recital

Professional and commercial secrecy as laid down in Article 16 should not establish a reason to refuse acquiring or exchanging legally required documentation, like the declaration of conformity, or the technical documentation.

Article 23

Requests for enforcement measures

Note: Art. 23 could be deleted, as taking appropriate measures is a general obligation for all MS according to Art. 15(5), which applies to all Union harmonisation legislation, and Dec 768 R32(3) for the NLF, respectively. There is no longer a need for individual requests.

The case when a non-compliant product is only placed on the market in one MS, but originates from a different MS (where it is not placed on the market) is covered by Art. 15(5) as well: all MS are required to take measures, and are informed via ICSMS.

Article 24

Procedure for mutual assistance requests

1. The applicant authority shall carry out itself all investigations reasonable possible before launching a request for assistance.
2. The requested authority shall without delay, and in any event within 4 weeks unless otherwise agreed, give assistance on an adequate scale by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measures, and by participating in investigations initiated by the applicant authority.
3. Requests for mutual assistance and all communication linked to them shall be made using electronic standard forms by means of the system referred to in Article 34.
4. Communication shall take place either directly between the involved authorities or through the single liaison office.
5. The languages to be used for requests for mutual assistance and for all communication linked to them shall be agreed upon by the competent authorities concerned.
6. Where no agreement about the languages can be reached between the competent authorities concerned, the requests for mutual assistance shall be sent in the official language of the Member State of the applicant authority and the replies to such requests in the official language of the Member State of the requested authority. In that instance, the applicant authority and the requested authority shall arrange for the translation of the requests, replies or other documents that it receives from the other.
7. The system referred to in Article 34 shall provide structured information on mutual assistance cases to the single liaison offices involved. Utilizing this information, single liaison offices shall give any support necessary to facilitate assistance.

Recital:

The system referred to Article 34 should provide the functions enabling an automated indication to the single liaison offices when the period of time according to Article 24(2) is not met.

Article 25

Use of evidence and investigation findings

Note: moved to Art. 12

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 legislation that are to be placed under the customs procedure 'release for free circulation' shall be subject to controls performed by the authorities designated under paragraph 1. They shall perform those controls on the basis of a risk analysis in accordance with articles 46 and 47 of Regulation (EU) No 952/2013 and on the basis of risk-based approach as referred to in Article 12(4).

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

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

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

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

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

6. By 31 March each year, Member States shall submit to the Commission statistical data by means of the system referred to in Article 34 covering controls performed by the authorities designated under paragraph 1 with respect to products subject to Union legislation during the previous calendar year covering the number of interventions in the field of controls on such products, including product safety and compliance.

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

Note: As customs will enter the information related to (b) and the MSAs related to (c) and (d) for *each case in ICSMS, statistical data can be processed and do not need to be reported by MS*

separately. The interventions include also controls in respect to customs rules, which are not to be entered in ICSMS, and therefore need to be reported separately. Those related to product safety and compliance need interactions with MSAs and are therefore continuously entered in ICSMS.

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

8. The Commission shall specify further by means of implementing acts the details of the data to be submitted under paragraph 6. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63**(2)**.

Recital:

Importers should be reminded that the UCC Articles 256-258 foresee that products entering the Union market that require further processing in order to be in compliance with Union harmonisation legislation applicable to them shall be placed under the appropriate customs procedure allowing such processing by the importer.

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 checks 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 **or the documentation accompanying the product is false**;

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

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

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

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

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

3. Where the market surveillance authorities have reason to believe that a product does not comply with the Union harmonisation legislation applicable to it or poses a serious risk,

they shall require the authorities designated under Article 26(1) to suspend the process for its release for free circulation.

4. ~~All communication between authorities designated under Article 26(1) and market surveillance authorities~~ **Notifications according to paragraph 2 and requests according to paragraph 3** shall take place by means of the product specific functions of the system referred to in Article 34.

Note: The related provision in Art. 27 of Reg 765 covers 'products', which is not restricted to harmonised products. To maintain this scope when the customs-related articles of Reg. 765 are repealed, references in this article should not refer to harmonisation legislation only. Otherwise, customs would e.g. no longer deal with products under the GPSD.

Article 28

Release of products

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

(a0) the non-compliance established according to Art. 27(1) has been rectified;

(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 of its approval for release for free circulation.

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

Note: The last provision applies generally, as the majority of consignment is released for free circulation without checks.

Article 29

Cooperation with authorised economic operators

Note: deleted, as the criteria for AEOs have nothing to do with their willingness and ability to place only conforming products on the market. Consequently, there is no objective reason for MSAs to grant a preferential treatment.

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, as appropriate:

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

Market surveillance authorities shall immediately enter that information into the system referred to in Article 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, as appropriate:

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

Market surveillance authorities shall immediately enter that information into the system referred to in Article 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. **Member States'** ~~A~~**a**uthorities ~~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~~ **measure** shall be borne by the person declaring the product for free circulation.

Note: From Reg 765 Art.29(4)

Commented [HA(5]: We suggest here the same change as was done in para. 1, because it is not always necessary to add this to documents but to electronical systems.

Commented [HA(6]: We are not sure that this term will cover all entities that can be responsible for this. It would be a good idea to check Customs legislation to see which term is used there.

Perhaps better would be "natural or legal person", or something else.

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

Note: taking EP AM 174 on board

3. *deleted*

Article 32

Composition and operation of the Network

1. The network shall be composed of representatives from each Member State, including a representative of the single liaison offices according to Art. 11, and an optional national expert, the chairs of administrative cooperation groups of market surveillance authorities (ADCOs), and representatives from the Commission.
2. Administrative cooperation groups of market surveillance authorities (ADCOs), set up by the Member States for the implementation of Union harmonisation legislation are composed of representatives of the national market surveillance authorities.
3. The Network shall meet at regular intervals and, where necessary, at the duly motivated request of the Commission or a Member State.
4. The Network shall use its best endeavours to reach consensus. Decisions taken by the Network shall be legally non-binding recommendations.
5. The Network may invite experts and other third parties to attend meetings or provide written contributions.
6. The Network may establish standing or temporary sub-groups.
7. The Network shall establish its rules of procedure.

Note: Art. 32(9) of WK 8193/2018 has been deleted as it is unclear why this particular forum has been highlighted (there are others, too). Furthermore, it is unclear what exactly the two forums should cooperate on.

A recital can clarify that 'administrative cooperation groups of market surveillance authorities' is to be understood in a general sense and also includes groups which do not bear the name 'ADCO'.

Article 33a

Role and tasks of the Network

1. In carrying out the tasks set out in paragraph 2, the Network shall address general horizontal issues of market surveillance with a view to facilitating the cooperation among Single Liaison Offices as well as the Commission.
2. The Network shall have the following tasks:

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

deleted

~~(c)~~ *deleted*

Note: both moved after the related Article on ICSMS, (b) slightly adapted. ~~(d)~~

deleted

Note: Moved at the bottom.

(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, in particular by identifying the needs of specific testing facility support according to Art. 20;

(gg) to prepare with the Commission delegated acts according to Article 4(7);

(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) **in collaboration with the Commission,** to ~~facilitate the organisation of~~ **organise** information campaigns and **voluntary** ~~joint~~ **mutual** visit programmes **between market surveillance authorities**;

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

(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 the information system referred to in Article 34;

(pp) to define ~~and approve~~ processing of collected data as referred to in Article 34;

(ppp) to prepare ~~and validate~~ system approvals for the execution by a third country related to pre-export product controls as referred to in Article 35 to ensure that these products comply with applicable Union harmonisation legislation;

(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;

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

Article 33b

Role and tasks of administrative coordination groups

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

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

3. ADCOs shall have the following tasks:

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

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

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

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

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

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

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

Article 33c

Role and tasks of the Commission

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

Note: shifted from Art.31(2)

2. The Commission shall have the following tasks:

(a00) to assist the Network, its sub-groups, and the ADCOs by means of an executive secretariat that provides technical and logistic support;

(a0) to keep and make available to the single liaison offices and ADCO-chairs an updated list of ADCO chairs including their nationality and contact information;

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

(aa) to support the functioning of Product Contact Points having duties assigned by Member States according to Article 6(2);

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

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

Comment: Several delegations have raised the point that the approval of export control systems in third countries this should be left for the Member States

(d) 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~~;

(e) *deleted*

(f) to develop and maintain the system referred to in Article 34, including the interface with the EU Single Window referred to in paragraph 5 of that Article, as well as the interface with national market surveillance databases, and provide information to the general public by means of that system;

(fa) to provide for the processing of collected data referred to in Article 34 in collaboration with the Network;

(g) 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,~~ laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work;

Note: IT-tools are covered in (f), guidelines in (k)

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

(h) 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;

(i) 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;

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

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

Article 34

Information and communication system

1. The Commission shall further develop and maintain an information and communication system for the collection and storage of information, in a structured form, on issues relating to the enforcement of Union ~~harmonisation~~ legislation, with the aim of improving the sharing of data between Member States and providing a comprehensive overview of market surveillance activities, results and trends. The Commission, market surveillance authorities, single liaison offices, and authorities designated in accordance with Article 26 (1) shall have access to that system.

Note: ICSMS is in use for GPSD, too, therefore the reference to Union legislation.

~~1a. The Commission shall specify by means of implementing acts the processing that will be applied according to paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.~~

Note: Included in par. 6

1b. The Commission shall further develop and maintain an interface to national systems.

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 information into the system:

in relation to products made available on the market ~~in their territory~~ for which **an in-depth check of compliance has been carried out** ~~compliance has been assessed by them, including at a minimum the products for which samples have been collected and analysed,~~ 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, information concerning:

Note: the amendment (based on the 2013 draft) strikes a balance between being too restrictive, as only a few percent of checked products are actually tested, and including all brief visual checks, where data entry would be too burdensome.

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

(ii) reports of testing carried out by them;

(iii) corrective action taken by economic operators concerned;

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

(iv) 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;

(v) when available, failures by authorized representatives to comply with Article 4a(2) and (3);

(vi) when available, failures by manufacturers to comply with Article 4a(1).

4. 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.

4a. Where relevant for the enforcement of Union harmonisation legislation and for the purpose of minimising risk, customs authorities shall extract from national customs systems information relating to products placed under the customs procedure 'release for free circulation' related to the enforcement of Union harmonisation legislation and transmit it to the information and communication system.

5. 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.

6. The Commission shall adopt implementing acts specifying the details of implementation arrangements for paragraphs 1 to 5**, in particular on the data processing that will be applied in accordance with Article 1** and defining the data to be transmitted in accordance with paragraph 5. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63**(2)**.

Addition to Recital 41:

ICSMS should be open to information considered helpful for other market surveillance authorities, including checks undertaken in the context of market surveillance programmes, regardless of the outcome of the tests.

Commented [HA(7]: Has the term been mentioned elsewhere?

Commented [HA(8]: What about the Customs?

Article 35

International cooperation

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

exchange of selected information ~~is set up as referred to in paragraph 2 of Article 35 of this Regulation~~ **has been established in accordance with paragraph 1a** ~~and where it has concluded confidentiality arrangements based on reciprocity with those authorities or organisations. All requirements of data protection and confidentially 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 **corrective** actions;

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

1a. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 63(3) in order to establish each framework for cooperation and information exchange.

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

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

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

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

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

   Authorities designated under Article 26(1) may however carry out controls those products or categories of product entering the Union market, in order to ensure that the pre-export controls carried out by the third country are effective to determine compliance with Union harmonisation legislation.

5. *deleted*

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 4 reveal significant non-compliance, the market surveillance authorities shall notify immediately the Commission through the system referred to in Article 34 and adapt the level of controls on such products.

8a. The Commission shall adopt implementing acts ~~for the implementation of the~~ **to approve each specific** 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(3).

9. The Commission shall by means of an implementing act withdraw an approval granted under paragraph 3 where it is revealed that the products entering the Union market do not comply with Union harmonisation legislation in a significant number of instances. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63(3). The Commission shall inform the affected third country of the outcome of the decision of the committee accordingly.

10. ~~*deleted*~~

10a. The system of product-related pre-export control shall be evaluated in accordance with Article 62(2) in this Regulation.

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~~**33a**.

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

   (a) the functioning of the Product Contact Points **having duties according to Article 6(2) assigned by Member States** ~~referred to in Article 6~~;

   (b) the ~~establishment and functioning of Union testing facilities~~ **provision of testing facility 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

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

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

Note: missing text from Regulation 765/2008

   (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(5) shall be shared between the Union and the Member States. The Union shall be responsible for financing the central module and the development allowing that the system referred to in Article 34 can receive automatic flows of electronic data from national customs systems

according to Article 34(5). Member States shall be responsible for financing the developments allowing the connection of their national systems to the interface.

3a. The Union shall finance the interface according to Article 34(1b) allowing the exchange of data with national market surveillance 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~~ **activities**, including corporate communication of the political priorities of the Union insofar as far as they are related to the general objectives of market surveillance activities, expenses linked to information technology networks focusing on information processing and exchange together with all other related technical and administrative assistance expenses incurred by the Commission.

Article 37

Protection of the Union's financial interests of the Union

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

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

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

[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).

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.

[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.

Chapter X Final provisions

Article 38

Applicability

Note: deleted, as the respective parts of Reg. 765 will be repealed.

Article 39

Amendments to Directive 2004/42/EC

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

Article 40

Amendments to Regulation (EC) No 765/2008

1. The words in the title "and market surveillance relating to the marketing of products", ~~Recitals (4) (7), (26) (36), (39), (40),~~ Article 2(1), **(2),** ~~to 8~~**(14), (15), (17) to (19),** ~~and~~ Articles 15 to 29 **and Article 32(1e)** of Regulation (EC) No 765/2008 are deleted.

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

.

.

.

Article 60

Amendments

Note: Deleted, as the respective parts of Reg. 765 will be repealed.

Article 61

Penalties

1. The Member States shall lay down the rules on penalties applicable to infringements of ~~Article 4, 4a and 4b~~ **the provisions of this Regulation** that impose obligations on economic operators and of Union **harmonisation** legislation listed in Annex I**I**, ~~where that legislation does not provide for penalties~~ and shall take all measures necessary to ensure that they are implemented according to national legislation.

Commented [HA(9]:
Should the obligations of EOs be mentioned here? Penalties can only be set for breaching obligations

We would like to know has it been checked that all legislation listed in Annex II includes obligations?

E.g. Directive of 23 April 2009 relating to common provisions for both measuring instruments and methods of metrological control (OJ L 106, 28.4.2009, p. 7–24);
➔ It is our understanding that in this directive everything else except the form of e-mark has been repealed. The obligations relating to e-mark apply via Directive on pre-packed products.

E.g. Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement and on the repeal of Directive 71/354/EEC (OJ L 39, 15.2.1980, p. 40–50);
➔It is our understanding that while this Directive sets the measurement units, actual obligations relating to those measurement units are legislated in other instruments.
➔We would suggest to consult the COM metrological experts

We might still get sectoral comments to Annex II.

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

3. The Member States shall notify those provisions to the Commission by [31 March 2022] and shall notify it without delay of any subsequent amendment affecting them.

Commented [HA(10]: If we have already implemented penalties for obligations in legislation listed in Annex II and notified them to the Commission when the implementation was done, do we now need to notify those provisions to the Commission again?

Note: Annex II lists only those pieces of Union harmonisation legislation that does not include provisions on penalties.

Article 62

Evaluation

1. By [31 December 2026] and every five years thereafter, the Commission shall carry out an evaluation of this Regulation against the objectives it pursues and present a report on the main findings to the European Parliament, to the Council and to the European Economic and Social Committee.

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.

2. By the latest [four years] after the first approval of a system for product-related preexport control according to Article 35(3), the Commission shall carry out an evaluation of its effects and cost efficiency. The report shall especially assess whether the productrelated pre-export control was useful for market surveillance authorities and improved their preconditions to carry out controls on products from third countries.

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.

3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. ~~However, the draft implementing act may not be adopted where no opinion is delivered or a simple majority of the component members of the committee opposes it.~~ **Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.**

Note: Implementing acts in this Regulation:
Art. 26(8): details of the data to be submitted by Member States
Art. 34(1-5): details of implementing arrangements
No opinion clause (Art. 63(3))
Art. 20(3): testing facility support programmes
Art. 35(1a): framework for cooperation
Art. 35(8a): system of product-related pre-export controls
Art. 35(9): withdraw of approval

~~*Article 63a*~~

~~*deleted*~~

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 the date of entry into force except for Articles 4, 4a, 6, 14 and 61 which shall apply~~ 2 years after entering into force.

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

Done at Brussels,

For the European Parliament	For the Council
The President	The President

ANNEX I Union harmonisation legislation

ANNEX II

Union harmonisation legislation without provisions on penalties

ANNEX III Correlation table