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WORKING PAPER

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WORKING DOCUMENT

From:	DK delegation
To:	Working Party on Technical Harmonisation (Goods package)
Subject:	DK written comments on the proposal on compliance and enforcement

EUROPEAN
COMMISSION

Brussels, 19.12.2017
COM(2017) 795 final

2017/0353 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

(Text with EEA relevance)

{SWD(2017) 466 final} - {SWD(2017) 467 final} - {SWD(2017) 468 final} -
{SWD(2017) 469 final} - {SWD(2017) 470 final}

Chapter VI

Cooperation and procedure for mutual assistance

Article 22

Requests for information

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

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

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

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

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

Article 23

Requests for enforcement measures

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

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

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

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

   (a) whether temporary measures have been imposed;

   (b) whether the non-compliance has ceased;

Commented [F1]: We generally support the intention to enhance mutual assistance. However, we see a need for clarification in this chapter so that it becomes clear that the responsibility stays with the applicant authority and that the applicant authority is obliged to do as much as it can itself.

We would like to recall the initiating authority principle which has been described in several documents, amog others in "Good practice for market surveillance" from Jauary 2017.

Commented [F2]: In our opinion, time limits should be made clear in the regulation itself and not through implementing acts.

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

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

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

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

Commented [F3]: In our opinion, time limits should be made clear in the regulation itself and not through implementing acts.

Article 24

Procedure for mutual assistance requests

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

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

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

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

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

Commented [F4]: We are worried about the administrative burden in this paragraph. It seems unbalanced that an applicant authority can impose a big administrative burden on a requested authority. This point would need some more consideration. Perhaps the requested authority should have a bigger say on the choice of language.

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

Article 25

Use of evidence and investigation findings

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

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

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

Commented [F5]: We cannot support that market surveillance authorities lose the right to challenge decisions from other authorities. It is not clear to us which problem is being solved and we are worried about the relationship with the safeguard clause procedure. As a minimum "shall" would need to be changed to "may".

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

Chapter VII

Products entering the Union market

Article 26

Controls on products entering the Union market

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

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

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

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

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

5. Risk-related information shall be exchanged between:

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

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

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

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

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

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

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

   (c) the results of controls on such products;

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

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

Commented [F6]: We are not convinced that this list of data and the level of detail is necessary and proportionate.

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

Commented [F7]: We would prefer a different wording. The Commission shall inform Member States concerned about the risk but it is the responisibilityu of the Member State to asses which measures are the appropriate ones to take.

9. The Commission shall specify further by means of implementing acts the details of the data to be submitted by Member States under paragraph 7. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.

Article 27

Suspension of release for free circulation

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

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

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

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

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

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

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

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

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

Article 28

Release of products

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

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

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

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

Article 29

Cooperation with authorised economic operators

Commented [F8]: We do not see the relation between the concept of "authorised economic operators" and product compliance.

Unless requirements related to product compliance become part of the requirments to obtain status as an authorised econmic operator, we would find it difficult to be supportive of these provisions.

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

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

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

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

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

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

Article 30

Refusal to release

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

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

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

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

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

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

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

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

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

Chapter VIII

Coordinated enforcement and international cooperation

Article 31

Union Product Compliance Network

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

Article 32

Composition of the Union Product Compliance Network

1. The Network shall be composed of a Union Product Compliance Board ('EUPC Board'), administrative coordination groups and a secretariat.
2. The EUPC Board shall consist of one representative from each of the single liaison offices referred to in Article 11, and two representatives from the Commission, and their respective alternates.
3. The Commission shall establish separate or joint administrative coordination groups for all the instruments of Union harmonisation legislation listed in the Annex to this Regulation. Each administrative coordination group shall be composed of representatives of the competent national market surveillance authorities and, if appropriate, representatives of the single liaison offices, and representatives of the relevant business associations and of consumer associations.
4. The secretariat shall be composed of Commission staff.
5. The Commission may attend the meetings of the administrative coordination groups.

Article 33

Coordinated enforcement tasks

1. The Commission shall have the following tasks:
   (a) to adopt and monitor the implementation of the work programme of the Network on the basis of a proposal from the Secretariat;
   (b) to support the functioning of the Product Contact Points referred to in Article 6;
   (c) to coordinate the activities of the single liaison offices referred to in Article 11;
   (d) to support the establishment and functioning of Union testing facilities referred to in Article 20;
   (e) to apply the instruments of international cooperation referred to in Article 35;
   (f) to organise cooperation and the effective exchange of information and best practices between market surveillance authorities;
   (g) to develop and maintain the system referred to in Article 34, including the interface with the EU Single Window referred to in paragraph 4 of that Article, and provide information to the general public by means of that system;

Commented [F9]: To us, it is not clear how the flow of data and information will be secured between the different layers of the network.

Commented [F10]: Referring to the discussions on the WP, we find it necessary to maintain fora where authorities, when necessary, can discuss practice and measures in confidentiality without the participaton of external representatives. This option must be ensured.

Who should decide which external parties to involve in the different ADCO groups?

Commented [F11]: We could be worried that the powers of the Commission become too far reaching. For all teasks of network, it must be kept in mind that market surveillance is basically an MS responsibility.

Commented [F12]: A clarification of the procedure foressen and the potential involvement of e.g. the Board would be desirable.

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

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

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

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

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

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

2. The EUPC Board shall have the following tasks:

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

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

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

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

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

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

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

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

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

Commented [F13]: We are missing a clear link between this part and the tasks of the network.

Commented [F14]: We cannot support the Commission powers to set standards for minmum penalties.

Commented [F15]: How should this happen in practice and on the basis of which criteria? Should the ADCO's be involved?

Commented [F16]: How is this to be ensured by the Board?

Commented [F17]: What is the intention? Should the Board draft guidelines or should they be involved in and follow every concrete memoranda of understanding?

Commented [F18]: We believe that the ADCO's should be involved in the adoption of the rules of procedure for their work.

Commented [F19]: What will be their role of the current ADCO-chairs in the future?

Commented [F20]: We do see the need for more sector based cooperation. However, we are somewhat worried about the outlined tasks of the ADCO-groups. They go rather far and we are not sure, if it is at all possible in practice.

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

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

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

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

Article 34

Information and communication system

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

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

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

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

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

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

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

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

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

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

(i) any non-compliance;

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

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

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

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

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

Commented [F21]: The market surveillance authorities seem to be missing in this paragraph.

Commented [F22]: We are generally worried that the expected workload of MSA's becomes too big and goes beyond what is proportionate to achive the overall aim of having information available in the system.

Commented [F23]: Should this not be the responsibility of the single laison office?

Commented [F24]: Should this not be the responsibility of the single laison office?

Commented [F25]: To enter all complaints does not seem proportionate. This should be limited to complaints validated by MSA's for their relevance.

Commented [F26]: The relation to RAPEX should be clarified further.

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

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

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

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

(i) any non-compliance;

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

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

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

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

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

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

4. Where relevant for the enforcement of Union harmonisation legislation and for the purposes of minimising risk and combating fraud, customs authorities shall extract from national customs systems and transmit to the information and communication system data relating to the placing of products under the customs procedure 'release for free circulation' and the results of controls related to product safety.

Commented [F27]: Fraud is not a term normally related to product compliance. We would prefer a different wording.

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

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

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

Article 35

International cooperation

1. The Commission may exchange confidential market surveillance related information with regulatory authorities of third countries or international organisations where it

has concluded confidentiality arrangements based on reciprocity with those authorities or organisations.

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

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

   (b) coordinated product recalls or other similar actions;

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

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

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

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

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

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

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

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

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

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

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

10. The Commission shall adopt implementing acts for the implementation of the system of product-related pre-export controls, referred to in paragraph 3, for specifying a

Commented [F28]: We agree that international cooperation with third countries is an aspect to take into account, considering the challenges we face within the area of market surveillance. However, as this is new compared to the current 765/2008 regulation, we would like to have further information on the background and the need for this provision.

Commented [F29]: This is already a part of the GPSD and should therefore be deleted.

Commented [F30]: It is unclear to us what the relationship is between these approvals and the market surveillance carried out by MSA's.

Commented [F31]: What does "significant non-compliance" mean?

Commented [F32]: How is "significant number" to be understood?

model for the certificates of compliance or verification to be used. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 63.

Chapter IX

Financial provisions

Article 36

Financing activities

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

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

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

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

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

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

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

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

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

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

4. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council[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.

[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).

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

Article 37

Protection of the Union's financial interests of the Union

1. The Commission shall take appropriate measures to ensure that, when actions financed under this Regulation are implemented, the financial interests of the Union are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective controls and, if irregularities are detected, by the recovery of the amounts wrongly paid and, where appropriate, by effective, proportionate and dissuasive administrative and financial penalties.
2. The Commission or its representatives and the Court of Auditors shall have the power of audit, on the basis of documents and of on-the-spot inspections, over all grant beneficiaries, contractors and subcontractors who have received Union funds under this Regulation.
3. The European Anti-fraud Office (OLAF) may carry out investigations, including on-the-spot controls and inspections, in accordance with the procedures laid down in 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 of Regulation (EC) 765/2008 and amendments to Union harmonisation legislation

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

Commented [F33]: According to the discussions in the WP, there is a need to clarify what is still covered by regulation 765/2008. If the articles 15-29 no longer have relevance for any acts, we believe that they should be withdrawn.

Article 39

Amendments to Directive 2004/42/EC

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

Article 40

Amendments to Directive 2009/48/EC

Directive 2009/48/EC is amended as follows:

(1) Article 40 is deleted;

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

(3) Article 44 is deleted.

Article 41

Amendments to Directive 2010/35/EU

Directive 2010/35/EU is amended as follows:

(1) Article 16 is deleted;

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

Article 42

Amendments to Regulation (EU) No 305/2011

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

Article 43

Amendments to Regulation (EU) No 528/2012

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

> 'Regulation (EU) 2018/*[XX Please insert number of this Regulation]* of the European Parliament and of the Council* shall apply accordingly.'

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

Article 44

Amendments to Directive 2013/29/EU

Directive 2013/29/EU is amended as follows:

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

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

Article 45

Amendments to Directive 2013/53/EU

Directive 2013/53/EU is amended as follows:

(1) Article 43 is deleted;

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

Article 46

Amendments to Directive 2014/28/EU

Directive 2014/28/EU is amended as follows:

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

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

Article 47

Amendments to Directive 2014/29/EU

Directive 2014/29/EU is amended as follows:

(1) Article 34 is deleted;

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

Article 48

Amendments to Directive 2014/30/EU

Directive 2014/30/EU is amended as follows:

(1) Article 37 is deleted;

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

Article 49

Amendments to Directive 2014/31/EU

Directive 2014/31/EU is amended as follows:

(1) Article 36 is deleted;

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

Article 50

Amendments to Directive 2014/32/EU

Directive 2014/32/EU is amended as follows:

(1) Article 41 is deleted;

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

Article 51

Amendments to Directive 2014/33/EU

Directive 2014/33/EU is amended as follows:

(1) Article 37 is deleted;

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

Article 52

Amendments to Directive 2014/34/EU

Directive 2014/34/EU is amended as follows:

(1) Article 34 is deleted;

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

Article 53

Amendments to Directive 2014/35/EU

Directive 2014/35/EU is amended as follows:

(1) Article 18 is deleted;

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

Article 54

Amendments to Directive 2014/53/EU

Directive 2014/53/EU is amended as follows:

(1) Article 39 is deleted;

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

Article 55

Amendments to Directive 2014/68/EU

Directive 2014/68/EU is amended as follows:

(1) Article 39 is deleted;

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

Article 56

Amendments to Directive 2014/90/EU

Directive 2014/90/EU is amended as follows:

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

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

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

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

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

Article 57

Amendments to Regulation (EU) 2016/424

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

(1) Article 39 is deleted;

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

Article 58

Amendments to Regulation (EU) 2016/425

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

(1) Article 37 is deleted;

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

Article 59

Amendments to Regulation (EU) 2016/426

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

(1) Article 36 is deleted;

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

Article 60

Amendments to Regulation (EU) 2017/1369

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

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

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

Chapter XI

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

Article 61

Penalties

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

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

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

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

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

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

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

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

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

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

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

Commented [F34]: In our opinion, this paragraph challenges the fact that sanctions are a national competence.

Commented [F35]: Paragraph 3 is a challenge to the Danish system of penalties. We only have penalties issued by the Courts and therefore only have criminal penalties.

Commented [F36]: This is national competence.

Article 62

Evaluation

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

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

Article 63

Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 64

Entry into force and application

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

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

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

Done at Brussels,

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