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WORKING PAPER

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WORKING DOCUMENT

From:	FR delegation
To:	Working Party on Technical Harmonisation (Goods package)
Subject:	FR comments on the Compliance and Enforcement Regulation Proposal - Presidency discussion paper: doc. WK 9693 REV 1

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RÉPUBLIQUE FRANÇAISE

Paris, 21/09/2018

NOTE DES AUTORITÉS FRANÇAISES

Objet : **Commentaires et propositions sur la proposition de règlement relative à la surveillance du marché des produits.**

Regulation 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

Les autorités françaises souhaitent communiquer leurs propositions d'amendements sur l'ensemble du texte.

You will find below the proposals of amendments of the French authorities (FA) and comments.

FR comments on the Compliance and Enforcement Regulation Proposal

Chapter I- General provisions

Article 1: Subject matter

We thus propose the following draft:

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

FA do not have any comments on this article.

Article 3: Definitions

The following modifications of the paragraphs 9, 13, 16, 17, 20, 21 are proposed:

"(9) 'manufacturer' means:

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

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

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

The responsibilities of the manufacturer apply also to 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 or to any other natural or legal person who places a product on the market under his name or trade mark."

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

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

*"(17) 'voluntary measures': means any measure carried out by an economic operator to end the non-compliance of a product, ~~without prior intervention of a market surveillance authority~~ **which is not the result of an order given by the authorities;**"*

"(20) 'product presenting a serious risk' means ~~any serious risk, including a serious risk~~ 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~~ **require a** rapid intervention by the market surveillance authorities **including cases where the effects are not immediate**;"*

~~"(21) 'end-user' means any natural or legal person, residing or established in the Union, whose personal or legal interests may be affected by the goods in question;"~~

Chapter II: compliance information

This chapter should come after the chapter relative to market surveillance (see our observations on the subject matter).

Article 4 : person responsible for compliance information

The following modifications of the paragraphs 3 and 5 are proposed:

"3. 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 action to remedy any case of non-compliance with the requirements set out in Union harmonisation legislation applicable to the product in question, or, if that is not possible, mitigate the risks posed by that product at their own initiative or when required to do so by the market surveillance authorities;"

*"5. 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**, 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."*

Article 5: Declaration of conformity

FA do not have any comments on this article.

Chapter III: assistance to and cooperation with economic operators

Article 6: information to economic operators

FA recall that French Product Contact Points (PCP) already provides responses to economic operators' questions on the full scope of product legislation be it in harmonized or non-harmonized sectors.

They believe that the maximum delay for responses should not be inferior to 25 workdays.

The following modifications of the paragraph 2 are proposed:

"*2. In addition, Member States shall have procedures in place for providing economic operators at their request with advice and guidance in respect to the national transposition of Union harmonisation legislation and its applicable to a product. This information shall be provided generally within ~~15~~ **25** working days and free of charge.*"

Article 7: compliance partnership arrangement

FA do not have any comments on this article.

Article 8: Joint awareness raising and information campaigns

FA do not have any comments on this article.

Article 9: publication of voluntary measures

FA do not have any comments on this article.

Chapter IV: organisation and obligations of market surveillance authorities

Article 10: Procedures of market surveillance

FA do not have any comments on this article.

Article 11: market surveillance authorities and single liaison offices

FA do not have any comments on this article.

Article 12: Activities of market surveillance authorities and use of findings

The following modifications of the paragraph 4 and 8 are proposed:

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

2. Market surveillance authorities shall 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 associated with the product ***and when available,*** *its number on the market, complaints and other information.* ***So, market surveillance authorities shall take into account, as a minimum, the following factors:***

*a****) the identified risks associated with:***

(i) the product and any hazards associated with that product;

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

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

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

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;

(c) procedures for following up scientific and technical knowledge concerning safety issues

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 to the contrary is provided or a Member State has raised objections in accordance with the applicable Union safeguard procedure."

Article 13: National market surveillance strategies

It is proposed to modify paragraphs 1, 2 and 3 and create a new paragraph 4 as follows:

« *1. Each Member State shall draw up an overarching national market surveillance strategy, as a minimum, every ~~5~~ **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 and stages of the product supply chain, including imports and digital supply chains shall be considered.*

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

- *(a) ~~an assessment~~ **The available information** on the **presence** occurrence of non-compliant products, in particular taking into account the risk-based controls referred to in Articles 12(2) and 26(3), and, where applicable, market trends **provided by the European Commission** 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 planned in order to reduce the occurrence of non-compliance in those areas identified as a priority, including, where relevant, the minimum control levels envisaged for categories of product which have significant levels of non-compliance;*
- *~~(d) an assessment of the effective performance and coordination of market surveillance activities pursuant to this Regulation, and, where applicable, the identification of capacity building needs and measures;~~*
- *~~(e) an assessment of the cooperation with market surveillance authorities in other Member States and of joint actions, where applicable;~~*
- *~~(f) a monitoring programme for the purposes of measuring progress in the implementation of the strategy and verifying compliance with this Regulation.~~*

*3. Member States shall communicate their national market surveillance strategy through the system referred to under Article 34. **An implementing act shall define the list of data which will be made public;***

4. On the basis of the national market surveillance strategy mentioned in 1 and in 2, a peer review is organized in the framework fixed by the article 33 j) and covers:

- ***(a) an assessment of the enforcement and the coordination of market surveillance activities required by the present legislation and where necessary, the definition of the requirements and the strengthening needs of the devoted resources ;***
- *(b) **an assessment of the cooperation with market surveillance authorities of another member States and of the joint activities if applicable; »***

Chapter V- Market surveillance powers and measures

Article 14: Powers and duties of market surveillance authorities

It is proposed to modify paragraph 4 as follows:

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

(a) Powers to carry out, ***without prior warning****, on-site inspections, including entering premises, physical controls, and acquire product samples* ***or take samples of products free of charge in order to detect non-compliance and obtain evidence.***

(a1) In the case of products offered for sale by means of distance communication, samples ordered from economic operators by the MSA without identifying themselves may be used for the purposes of an official control.

(a2) Power to perform system audits of economic operators' organisations, including audits of any procedures that they have in place to ensure compliance with this Regulation and with applicable Union harmonisation legislation;

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

(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, to require information society service providers to restrict access to content referring to the related product;

(d1) the power to take temporary measures, where there are no other effective means available to prevent a serious risk, including in particular temporary measures requiring hosting service providers to remove, disable or restrict access to content or to suspend or restrict access to a website, service or account or requiring domain registries or registrars to put a fully qualified domain name on hold for a specific period of time;

(e) Powers to recover costs according to Art. 14a.

(e1) the power to impose penalties on an economic operator, including fines or periodic penalty payments, for non-compliance or for failure to comply with any decision, order, temporary measure or other measure taken by the market surveillance authority;"

Article 14a: Recovery of costs by market surveillance authorities

It is proposed to modify paragraphs 1 and 2 as follows:

"*1. Member States* ~~*may*~~ ***shall have the power to*** *authorize their market surveillance authorities to charge the relevant economic operator administrative fees in cases of non-compliant products* ~~*in order to enable the authorities to recover totality of the costs of their activities*~~ *with respect to these instances of non-compliance.*

2. Those costs may include the costs of carrying out testing for the purposes of risk assessment, the costs of taking measures in accordance with Article 30(1) and (2) and the costs of their activities relating to products that are found to be non-compliant and subject to corrective action prior to their release for free circulation ***or their placing on the market****."*

Article 15: Market surveillance measures

It is proposed to delete paragraph 1 as follows:

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

2. Where a product presents a serious risk, market surveillance authorities shall request 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 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."

Article 16: use of information, professional and commercial secrecy

FA do not have any comments on this article.

Article 17: Judicial protection and due process

FA therefore believe that the opportunity provided by this legislative initiative must be used to clarify and simplify procedural provisions present in different regulations, including in sectorial legislation texts. Thus, they believe that a product which has been subject to a RAPEX notification relative to directive 2001/95/EC must not, on top of that, be subject to the notification procedure of a safeguard clause as provided for in harmonized legislation aligned on decision 768/2008. In that specific case, a unique information procedure for the Commission and other Member States should be maintained by considering, on a transversal level, that a RAPEX notification can be interpreted as a safeguard clause notification. French authorities thus request the introduction of such a provision at article 17 with a reminder of the application of the *lex specialis* principle, notably in view of safeguard procedures.

Consequently, it is proposed to create a new paragraph 5 as follows:

5. When the product is the object of an information in following article 18 § 1 of the present legislation, market surveillance authorities at the origin of this information are considered to have informed the European Commission and the other member states of the results of the product assessment and the measures associated with the product.

Article 18: Products presenting a serious risk

FA do not have any comments on this article.

Article 19: Exchange of information- Union Rapid Alert System

FA do not have any comments on this article.

Article 20: Testing facility support

It is proposed to create a new paragraph 2bis:

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, 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.

2bis. 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 article 36 of the legislation.

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."

Article 21: Financing and recovery of costs by market surveillance authorities

FA do not have any comments on this article.

Chapter VI – Cross-border mutual assistance

Article 22: Mutual Assistance

It is proposed to modify paragraphs 3 and 4 as follows:

"*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, which includes for example technical documentation, 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. ***If the requested authority also wants to handle this case in its territory, It can remain responsible there.***

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

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

Article 23: Requests for enforcement measures

FA do not have any comments on this article.

Article 24: Procedure for mutual assistance requests

It is proposed to modify paragraphs 2, 3, 4 and 7 as follows:

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~~ **8** 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, ***whenever possible****, made using electronic standard forms by means of the system referred to in Article 34.*

~~*4. Generally, communication shall take place directly between the involved authorities. Differing procedures can be foreseen in national legislation.*~~

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. ~~*Single liaison offices shall follow these cases and give any support necessary to facilitate assistance.*~~

Article 25: Use of evidence and investigation findings

FA do not have any comments on this article.

Chapter VII – Products entering the Union market

Article 26: Controls on products entering the Union market

It is proposed to modify paragraphs 3 and 6 as follows:

"…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 ~~*and the rules of market surveillance according to this regulation and the relevant harmonized EU legislation.*~~ ***They shall perform those controls on the basis of risk analysis in accordance with articles 46 et 47 of R(UE) n°952/2013.***

6. 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…."

Article 27: Suspension of release for free circulation

It is proposed to modify paragraphs 1 as follows:

"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;

(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 will not comply with the requirements set out in the Union harmonisation legislation applicable to it ***with the aim of its putting on the market****, or that it* ***will*** *pose a serious risk."*

Article 28: Release of products

FA consider that the text is unclear and consider that it is necessary to describe the various options which can justify the release of products.

Consequently, the following modifications are proposed:

"*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*~~ ***the absence of answer of market surveillance authorities, including with the aim of an extension of suspension of the release beyond the deadline of 5 days*** *;*

(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*~~ ***the positive answer of the market surveillance authorities****.*

The release of the product shall not be opposite to the surveillance authority as proof of conformity, especially in the case of release in compliance with the point a). ~~*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

FA do not have any comments on this article.

Article 30: Refusal to release

FA consider that the reference of the paragraph 4 to the articles 197, 198 and 199 of the legislation n0 952/2013 is not desirable.

Consequently, the following modifications are proposed:

"*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

FA do not have any comments on this article.

Article 32: Composition of the Union Product Compliance Network

FA do not have any comments on this article.

Article 33- Coordinated enforcement tasks

Article 33a: Tasks of the Network

The following modifications are proposed:

"1. The network shall be concerned with general matters of market surveillance and focus on horizontal issues. It shall intensify the cooperation Single Liaison Offices and the Commission.
2. The Network shall have the following tasks:

(a) to prepare, adopt and monitor the implementation of the work programme of the Network;
(b) to prepare and validate system approvals for the execution by a third country of product export controls to ensure that these products comply with applicable Union harmonized legislative provisions;
(c) to define and approve processing of collected data as referred to article 34;
~~(d) to take up any other issues in activities under the purview of the Network;~~
(e) to facilitate evaluations of products including risk assessment, test methods and results, recent scientific developments and other aspects relevant to control activities;
(f) to provide coordination of ADCOs and their activities
(g) to provide input to the Commission for testing facility support according to Art. 20 ***and to participle in choosing the solution with the Commission****;;*
(h) to organise cross-sector joint market surveillance and testing projects and define their priorities;
(i) to exchange expertise and best practices, in particular regarding the implementation of market surveillance strategies;
(j) to facilitate the organisation of training programmes and exchanges of national officials;
(k) to facilitate the organisation of information campaigns and joint visit programmes;
(l) to discuss questions arising from cross-border mutual assistance;
(m) to contribute to the development of guidance to ensure the effective and uniform implementation of this Regulation;
(n) to propose the financing of activities foreseen in Article 36;
(o) to contribute to uniform administrative practices with regard to market surveillance in the Member States;
(p) to provide advice and assist the Commission with issues related to the further development of RAPEX and ICSMS;
(q) in collaboration with the Commission, organize peer reviews;

(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.
(d) to take up any other issues ~~in activities under the purview of the Network~~ ***related to Network's tasks****"*

Article 33b: Tasks of the administrative coordination groups

FA do not have any comments on this article.

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

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

3. Administrative coordination groups (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 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 develop and promote best practices;

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

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

Article 33c: Tasks of the Commission

The following modifications are proposed:

The Commission shall have the following tasks:

(a) to assist the Network in preparing and monitoring its work programme;
<u>(a1) to support the functioning of the Product Contact Points referred to in Article 6;</u>
(b) to determine the need for additional testing capacity and to provide tailored solutions;
*(b1) **<u>In collaboration with the network, to award financing of tests carried out upon request of a Member State by additional testing capacity, referred to in Article 20</u>***
(c) to apply the instruments of international cooperation referred to in Article 35 (1) and (2);
(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) to provide comprehensive logistic support via the executive secretariat to the Network and the ADCOs;
(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, and provide information to the general public by means of that system;
<u>(f1) to define and approve, in collaboration with the network, the processing of collected data referred to in article 34;</u>
(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, 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;
(h) in addition to the provision of Article 33a paragraph (i), to organise common training programmes and facilitate exchanges of personnel between market surveillance authorities and, where appropriate, with the market surveillance authorities of third countries or with international organisations;

(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

The following modifications are proposed:

"1. The Commission shall further develop and maintain an information and communication system for the collection and storage of information, in a structured form, on issues relating to the enforcement of Union harmonisation legislation. ***The aim is to enable sharing of this data between Member States and allow the Commission to monitor market surveillance activities.*** *The Commission, market surveillance authorities, single liaison offices, and authorities designated in accordance with Article 26 (1) shall have access to that system.*

The Commission makes sure that this system offers an information exchange capability maintained over time allowing, where appropriate, easy linkages with Member states market surveillance and custom authorities' information systems.

1bis. Processing criteria that will be applied to data stored in information and communication systems referred to in paragraph 1 must be presented for approbation to Member States within the framework of the Network.

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 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:*

(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 ~~and the follow up by those economic operators;~~

(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 an authorized representative to comply with Article 4 (3);*

(vi) ***when available****, failures by manufacturers to comply with Article 4 (4);*

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.

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."

Article 35 - International cooperation

The following modifications of the article 35 are proposed:

*"1. **In order to improve the efficiency of market surveillance in the Union,** the Commission may exchange confidential market surveillance related information 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 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, **following approval by the Network,** 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, **following approval by the Network,** 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 **in the customs nomenclature**.*

*4. Where such an approval has been granted, **the risks assessment applied to** ~~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~~ **will include the granted approvals**.*
Customs authorities may however carry out controls those products or categories of product entering the Union market, in order to ensure that the pre-export controls carried out by the third country are effective to determine compliance with Union harmonisation legislation.

*5. Approval may only be granted to a third country under paragraph 3 following ~~an~~ audit**s** within the **relevant third country and, where appropriate, in the Union** demonstrating that the following conditions are satisfied:*
(a0) the third country possesses an efficient verification system of the compliance of products exported to the Union;
(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 34 reveal significant non-compliance, the market surveillance authorities shall notify immediately the Commission through the system referred to in Article ~~3~~**4** and ~~increase the number~~ **adapt the level** of controls on such products.*

*9. The Commission, **~~following approval of the Network,~~** shall **submit to the Network a proposal to** 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.* ***The Commission immediately informs the affected third country when the Network withdraws such an approval.***

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

CHAPTER IX – FINANCIAL PROVISIONS

Article 36 – Financing activities

FA consider that the paragraph 3 has to be completed to add a mention relative to costs falling to the Union and member States for developments of the interface between the information system of the article 34 and the national systems used by the market surveillance authorities or the customs.
Consequently, the following modifications of the article 36 are proposed:

3. The financing of the electronic interface ***of the system*** 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 the developments allowing that the information system can receive automatic flows of electronic data which come from the information system of the market surveillance authorities or Customs*** ~~link to the Network~~. Member States shall be responsible for financing ***the developments allowing the connexion*** ~~adaptation~~ of their national systems ***with the information system of the Commission***.

Article 37 – Protection of the Union's financial interests of the Union
FA do not have any comments on this article.

CHAPTER X – FINAL PROVISIONS

Article 36 to 60
FA do not have any comments on this article.

Article 61: Penalties

"1. The Member States shall, according to national legislation, lay down the rules on penalties applicable to infringements of the provisions of this Regulation that impose obligations on economic operators and shall take all measures necessary to ensure that they are implemented.
2. The penalties provided for shall be effective, proportionate and dissuasive.
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 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."