Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation

Compliance with and enforcement of Union harmonisation legislation on products
- Amending Regulation (EU) No 528/2012 2009/0076(COD)
- Amending Directive 2014/30/EU 2011/0351(COD)
- Amending Directive 2014/31/EU 2011/0352(COD)
- Amending Directive 2014/33/EU 2011/0354(COD)
- Amending Directive 2014/34/EU 2011/0356(COD)
- Amending Regulation (EU) 2016/424 2014/0107(COD)
- Amending Regulation (EU) 2016/425 2014/0108(COD)
- Amending Regulation (EU) 2016/426 2014/0136(COD)
- Amending Regulation (EU) 2017/1369 2015/0149(COD)
- Amended by 2020/0353(COD)

Subject
- 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance
- 4.60.08 Safety of products and services, product liability
- 6.20.02 Export/import control, trade defence, trade barriers

Procedure completed

Key players

European Parliament

Committee responsible | Rapporteur | Appointed
--- | --- | ---
IMCO Internal Market and Consumer Protection | DANTI Nicola | 23/01/2018

Shadow rapporteur

KARAS Othmar

DALTON Daniel

SELMOVIC Jasenko

DURAND Pascal

ZULLO Marco
Committee for opinion

Rapporteur for opinion

The committee decided not to give an opinion.

Committee appointed

International Trade

Environment, Public Health and Food Safety

01/03/2018

Industry, Research and Energy

The committee decided not to give an opinion.

Council of the European Union

Council configuration

Meeting

Date

Employment, Social Policy, Health and Consumer Affairs

3699

14/06/2019

European Commission

Commission DG

Commissioner

Internal Market, Industry, Entrepreneurship and SMEs

BIEŃKOWSKA Elżbieta

European Economic and Social Committee

Key events

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Technical information

Procedure reference

2017/0353(COD)
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**Documentation gateway**

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<td>PE622.182</td>
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PURPOSE: to ensure that products placed on the Union market comply with the requirements of Union harmonisation legislation.


ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure on an equal footing with the Council.

BACKGROUND: within the single market, the free movement of goods generates around 25% of EU GDP and 75% of intra-EU trade. However, much remains to be done to achieve a deep and fair European Single Market. The increasing number of illegal and non-compliant products on the market distorts competition and puts consumers at risk.

The evaluation of Regulation (EC) No 765/2008 indicated that it has been only partly effective in achieving its specific and strategic objectives. This is mainly because coordination and cooperation have still not reached a satisfactory level. Tools such as the Union Rapid Alert System for dangerous non-food products (RAPEX) and the Information and Communication System on Market Surveillance (ICSMS) are in place to ensure cross-border market surveillance cooperation, but they are not sufficiently used by Member States.

Furthermore, Regulation (EC) No 765/2008 is not yet uniformly applied, due to the significant differences in how Member States implement it. This concerns the organisation of market surveillance at national level, the availability of financial, human and technical resources, the strategies of market surveillance, the powers of inspection and of sanctions and the systems of monitoring and reporting.

Lastly, border controls on imported products seem insufficient.

As announced by the Commission in the 2017 work programme, the initiative aims to address the growing number of non-compliant products on the Union market, while offering incentives to boost compliance with the regulation and ensure fair and equal treatment that will benefit businesses and citizens. In particular, it provides for appropriate incentives for businesses, increased compliance checks and enhanced cross-border law enforcement cooperation.

IMPACT ANALYSIS: the preferred option is to improve existing tools and cooperation mechanisms. In addition, effective enforcement strategies deployed by Member States that include control activities and capacity building at the national level require the establishment of a Union product compliance network.

CONTENT: the purpose of this proposal for a Regulation on compliance with and enforcement of Union harmonisation legislation on products is to contribute to a deeper and fairer internal market for goods by promoting greater cooperation between national market surveillance authorities.

In concrete terms, the proposal:

- introduces the concept of a person responsible for compliance information established within the Union as a necessary condition for making the products available on the market. The person responsible for compliance information can be the manufacturer, the
importer or any other economic operator designated by the manufacturer. The tasks of the person responsible for compliance information are essentially to provide information on the product to market surveillance authorities and to cooperate with the authorities;

- defines how to designate competent authorities and single liaison offices for this Regulation and clarifies the roles of the single liaison offices;
- sets out the Member States obligations as regards organisation of market surveillance within their territory and lays down the procedures they must establish to follow up complaints or issues relating to risks; monitor accidents and harm to the health of end-users; verify corrective actions taken by economic operators; and follow up scientific and technical knowledge of safety issues;
- provides for a set of powers for market surveillance authorities, defined with the view to ensure effective enforcement of Union harmonisation legislation on products is enforced effectively across borders. These powers include the power to access data and documents related to an instance of non-compliance, to require economic operators and public entities to provide all information related to an instance of non-compliance; to carry out on sit inspections; to initiate investigations or procedures aimed at ceasing non-compliance; to prohibit the supply of products, or withdraw and recall and destroy them; to impose penalties and order the recovery of profits obtained as a result of non-compliance; and to publish decisions;
- provides for the exchange of information on illegal products and on-going investigations so that governments can take effective action against non-compliant products;
- imposes stricter mutual assistance obligations and the legal presumption that products declared to be non-compliant in one Member State are also non-compliant across the EU;
- provides for a strengthened framework for controls on products entering the Union market and strengthens the exchange of information between market surveillance authorities and customs authorities, in particular through procedures for releasing products, suspending and refusing of release for free circulation;
- establishes a Union product compliance network (the network) within the Commission to coordinate enforcement tasks, thereby boosting market surveillance cooperation at EU level.

BUDGETARY IMPLICATIONS: the proposal requires human and administrative resources, as well as operational appropriations. The total impact on expenditure is estimated at EUR 12.576 million up to the year 2020 inclusive.

Compliance with and enforcement of Union harmonisation legislation on products


The committee recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the Commission's proposal as follows.

Strengthen market surveillance: the proposed Regulation shall aim to improve the functioning of the internal market by strengthening product surveillance of products 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, are made available on the Union market.

Under the amended text, market surveillance authorities shall take appropriate measures, including ensuring that the making available of the product on the market is prohibited or restricted or that a product is withdrawn or recalled from the market if the product is liable to compromise the health or safety of end-users; if the product does not conform to applicable requirements under Union harmonisation legislation or if it is counterfeit.

Reference person: all companies wishing to sell products on the single market, including those from third countries, shall first designate a reference person in the EU for these products. This person shall be responsible for contacting the manufacturer in the event of non-compliance and taking action to remedy any case of non-compliance.

Compliance partnership agreements: the proposal introduces the possibility for a market surveillance authority to enter into partnership agreement with an economic operator established in its territory. Members are against harmonised provisions on compliance partnership agreements.

Enhanced cooperation between Member States' supervisory authorities: market surveillance authorities shall develop appropriate and effective communication and cooperation mechanisms with customs authorities for the identification and examination of potential risks related to counterfeit products and withdrawal of such products from the market.

To ensure that the same rules are applied in the same manner by the different market surveillance authorities in the Member States, Members propose harmonising the methodology and criteria for assessing risks and the checks in order to ensure a level playing field for all economic operators. They also suggested creating an effective peer review system to help market surveillance authorities ensure the uniform implementation of the Regulation.

EU Product Compliance Network: Members specified that the purpose of the Network is to serve as a platform for structured cooperation between authorities of the Member States and the Commission and to streamline the practices of market surveillance within the Union making market surveillance activities more effective.

It is proposed to strengthen the role of the Network, in particular by providing it with the possibility of (i) adopting its bi-annual work programme setting out priorities for common market surveillance actions, (ii) regularly discussing a general risk assessment methodology, (iii) discussing the uniform conditions of checks, criteria for determination of the frequency of checks or amount of samples to be checked in relation to certain products, and (iv) facilitating the exchange of information on non-compliant products.

E-commerce and Internet of Things: the development of e-commerce poses certain challenges for market surveillance authorities with regard to ensuring the compliance of products sold online and effectively enforcing the Union harmonisation legislation.
Members proposed that each Member State should provide for the efficient organisation of market surveillance activities for products sold online and ensure that there is an appropriate number of inspectors, dealing with products sold online (online inspectors), within their national market surveillance authorities.

Economic operators offering a product for sale online shall indicate with their offer for sale the name, registered trade name or registered trade mark and the contacts details of a reference person with respect to the product.

Information and communication system: the system shall allow data to be shared between Member States and allow the Commission to monitor market surveillance activities. This system shall have a public interface with key information in all Union languages and inform end-users about market surveillance activities and their results.

Consumers who have purchased non-compliant products shall be informed, through an online portal, of rights relating to non-compliant products which they have acquired, such as the right to obtain a replacement for a product or to receive compensation, the right of recourse and contacts from which all appropriate information can be obtained.

### Compliance with and enforcement of Union harmonisation legislation on products


The European Parliament’s position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

#### Strengthening market surveillance

The proposed Regulation aims to improve the functioning of the internal market by strengthening the market surveillance of products covered by the Union harmonisation legislation, with a view to ensuring 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, the protection of the environment and public security and any other public interests protected by that legislation, are made available on the Union market.

This Regulation lays down rules and procedures for economic operators regarding products subject to certain Union harmonisation legislation and establishes a framework for cooperation with economic operators.

#### Tasks of economic operators

A product covered by Union legislation may only be placed on the market if an economic operator established in the Union performs the following tasks with regard to that product:

- verify that the EU declaration of conformity or the declaration of performance and technical documentation have been drawn up and ensure that the technical documentation can be made available to these authorities upon request;

- provide the authorities with all the information and documentation necessary to demonstrate the conformity of the product in a language that can be easily understood by that authority;

- cooperate with market surveillance authorities, including, following a reasoned request, ensuring that the immediate and necessary corrective action is taken to remedy any case of non-compliance with the requirements laid down in the Union harmonisation legislation applicable to the product in question.

Economic operators shall be required to cooperate with market surveillance authorities with a view to adopting measures that would eliminate or reduce the risks posed by products made available on the market by these operators.

#### Activities of market surveillance authorities

These authorities shall ensure effective market surveillance of products made available online and offline on their territory and the adoption of appropriate and proportionate measures if the operator does not take corrective measures.

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

They shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks based on adequate samples. This shall be based on a risk-based approach taking into account factors such as potential hazards associated with the product, the economic operator's history of non-compliance and consumer complaints.

In order to assist market surveillance authorities to strengthen consistency in their activities related to the application of this Regulation, an effective peer review system should be established for those market surveillance authorities wishing to participate.

#### Market surveillance powers and measures

The powers conferred on market surveillance authorities shall include at least the following:

- to require economic operators to provide relevant documents, technical specifications, data or information on compliance and technical aspects of the product;

- to require economic operators to provide relevant information required for the purpose of ascertaining the ownership of websites;

- to carry out unannounced on-site inspections and physical checks of products;
Market surveillance authorities shall exercise their powers and carry out their duties independently, impartially and without bias.

If the operator does not take corrective measures, appropriate and proportionate measures shall be taken.

These authorities shall ensure effective market surveillance of products made available online and offline on their territory and the adoption of Union harmonisation legislation with respect to specific categories of products, in particular categories of products that are often found to present a serious risk, including products offered for sale online.

Each Member State shall appoint a single liaison office.

Activities of market surveillance authorities

Market surveillance authorities may agree with other relevant authorities or with organisations representing economic operators or end users on the carrying out of joint activities that have the aim of promoting compliance, identifying non-compliance, raising awareness and providing guidance in relation to the Union harmonisation legislation with respect to specific categories of products, in particular categories of products that are often found to present a serious risk, including products offered for sale online.

Activities of market surveillance authorities

Each Member State shall designate one or more market surveillance authorities in its territory. Each Member State shall inform the Commission and the other Member States of its market surveillance authorities and the areas of competence of each of those authorities, using the information and communication system.

Each Member State shall appoint a single liaison office.

These authorities shall ensure effective market surveillance of products made available online and offline on their territory and the adoption of appropriate and proportionate measures if the operator does not take corrective measures.

Market surveillance authorities shall exercise their powers and carry out their duties independently, impartially and without bias.
They shall perform appropriate checks on the characteristics of products on an adequate scale, by means of documentary checks and, where appropriate, physical and laboratory checks based on adequate samples. This shall be based on a risk-based approach taking into account factors such as potential hazards associated with the product, the economic operator's history of non-compliance and consumer complaints.

In order to assist market surveillance authorities to strengthen consistency in their activities related to the application of this Regulation, an effective peer review system should be established for those market surveillance authorities wishing to participate.

Market surveillance powers and measures

The Regulation establishes a set of powers for market surveillance authorities to ensure the effective enforcement of EU product legislation in a cross-border context. This includes power:

- to access data related to a non-compliance event,
- to obtain information on the supply chain or for the purpose of identifying the owner of a website,
- to carry out on-site inspections,
- to make test purchases, including under a false identity,
- to bring the product into compliance, including by rectifying formal non-compliance as defined by the applicable Union harmonisation legislation, or by ensuring that the product no longer presents a risk;
- to prevent the product from being made available on the market;
- to withdraw or recall the product immediately and alerting the public to the risk presented;
- to impose sanctions and
- to alert the end users at risk immediately and in an appropriate form, including by publication of special warnings in the language or languages determined by the Member State in which the product is made available on the market.

Union Product Compliance Network

The Regulation establishes a Union product compliance network within the Commission which will serve as a platform for coordination and structured cooperation between the supervisory authorities of the Member States and the Commission.

Information and communication system for market surveillance (ICSMS) and RAPEX have been developed in order to increase the level of cooperation and exchange of information between Member States and the Commission.

The Regulation also sets out a reinforced framework for controls on products entering the EU market and reinforces the exchange of information between market surveillance and customs authorities.

ENTRY INTO FORCE: 15.7.2019.

APPLICATION: from 16.7.2021. However, certain provisions are applicable from 1.1.2021.