

Procedure file

Basic information	
<p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p> <p>2017/0353(COD)</p>	<p>Procedure completed</p>
<p>Compliance with and enforcement of Union harmonisation legislation on products</p> <p>Amending Directive 2004/42/EC 2002/0301(COD) Amending Directive 2009/48/EC 2008/0018(COD) Amending Regulation (EU) No 305/2011 2008/0098(COD) Amending Regulation (EU) No 528/2012 2009/0076(COD) Amending Directive 2010/35/EU 2009/0131(COD) Amending Directive 2013/53/EU 2011/0197(COD) Amending Directive 2014/28/EU 2011/0349(COD) Amending Directive 2014/29/EU 2011/0350(COD) Amending Directive 2014/30/EU 2011/0351(COD) Amending Directive 2014/31/EU 2011/0352(COD) Amending Directive 2014/32/EU 2011/0353(COD) Amending Directive 2014/33/EU 2011/0354(COD) Amending Directive 2014/34/EU 2011/0356(COD) Amending Directive 2014/35/EU 2011/0357(COD) Amending Directive 2013/29/EU 2011/0358(COD) Amending Directive 2014/53/EU 2012/0283(COD) Amending Directive 2014/90/EU 2012/0358(COD) Amending Directive 2014/68/EU 2013/0221(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)</p> <p>Subject</p> <p>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</p>	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 Internal Market and Consumer Protection		23/01/2018
		 DANTI Nicola	
		Shadow rapporteur	
		 KARAS Othmar	
		 DALTON Daniel	
		 SELIMOVIC Jasenko	
		 DURAND Pascal	
	 ZULLO Marco		

	Committee for opinion	Rapporteur for opinion	Appointed
	INTA International Trade	The committee decided not to give an opinion.	
	ENVI Environment, Public Health and Food Safety		01/03/2018
		 MIKOLÁŠIK Miroslav	
	ITRE 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 Affairs3699		14/06/2019
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs	BIENKOWSKA Elżbieta	
European Economic and Social Committee			

Key events

19/12/2017	Legislative proposal published	COM(2017)0795	Summary
05/02/2018	Committee referral announced in Parliament, 1st reading		
03/09/2018	Vote in committee, 1st reading		
03/09/2018	Committee decision to open interinstitutional negotiations with report adopted in committee		
06/09/2018	Committee report tabled for plenary, 1st reading	A8-0277/2018	Summary
10/09/2018	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 71)		
12/09/2018	Committee decision to enter into interinstitutional negotiations confirmed by plenary (Rule 71)		
21/02/2019	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE643.161 GEDA/A/(2019)003073	
17/04/2019	Results of vote in Parliament		
17/04/2019	Decision by Parliament, 1st reading	T8-0397/2019	Summary
14/06/2019	Act adopted by Council after Parliament's 1st reading		
20/06/2019	Final act signed		
20/06/2019	End of procedure in Parliament		
25/06/2019	Final act published in Official Journal		

Technical information

Procedure reference	2017/0353(COD)
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Procedure type	COD - Ordinary legislative procedure (ex-codicedision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	<p>Amending Directive 2004/42/EC 2002/0301(COD)</p> <p>Amending Directive 2009/48/EC 2008/0018(COD)</p> <p>Amending Regulation (EU) No 305/2011 2008/0098(COD)</p> <p>Amending Regulation (EU) No 528/2012 2009/0076(COD)</p> <p>Amending Directive 2010/35/EU 2009/0131(COD)</p> <p>Amending Directive 2013/53/EU 2011/0197(COD)</p> <p>Amending Directive 2014/28/EU 2011/0349(COD)</p> <p>Amending Directive 2014/29/EU 2011/0350(COD)</p> <p>Amending Directive 2014/30/EU 2011/0351(COD)</p> <p>Amending Directive 2014/31/EU 2011/0352(COD)</p> <p>Amending Directive 2014/32/EU 2011/0353(COD)</p> <p>Amending Directive 2014/33/EU 2011/0354(COD)</p> <p>Amending Directive 2014/34/EU 2011/0356(COD)</p> <p>Amending Directive 2014/35/EU 2011/0357(COD)</p> <p>Amending Directive 2013/29/EU 2011/0358(COD)</p> <p>Amending Directive 2014/53/EU 2012/0283(COD)</p> <p>Amending Directive 2014/90/EU 2012/0358(COD)</p> <p>Amending Directive 2014/68/EU 2013/0221(COD)</p> <p>Amending Regulation (EU) 2016/424 2014/0107(COD)</p> <p>Amending Regulation (EU) 2016/425 2014/0108(COD)</p> <p>Amending Regulation (EU) 2016/426 2014/0136(COD)</p> <p>Amending Regulation (EU) 2017/1369 2015/0149(COD)</p> <p>Amended by 2020/0353(COD)</p>
Legal basis	Treaty on the Functioning of the EU TFEU 207; Treaty on the Functioning of the EU TFEU 033; Treaty on the Functioning of the EU TFEU 114
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	IMCO/8/12041

Documentation gateway

Legislative proposal	COM(2017)0795	19/12/2017	EC	Summary
Document attached to the procedure	SWD(2017)0466	19/12/2017	EC	
Document attached to the procedure	SWD(2017)0467	19/12/2017	EC	
Document attached to the procedure	SWD(2017)0468	19/12/2017	EC	
Document attached to the procedure	SWD(2017)0470	19/12/2017	EC	
Document attached to the procedure	SWD(2017)0469	19/12/2017	EC	
Committee draft report	PE620.871	17/04/2018	EP	
Amendments tabled in committee	PE622.181	24/05/2018	EP	
Amendments tabled in committee	PE622.182	24/05/2018	EP	

Committee opinion	ENVI	PE620.896	12/07/2018	EP	
Committee report tabled for plenary, 1st reading/single reading		A8-0277/2018	06/09/2018	EP	Summary
Coreper letter confirming interinstitutional agreement		GEDA/A/(2019)003073	15/02/2019	CSL	
Text agreed during interinstitutional negotiations		PE643.161	15/02/2019	EP	
Text adopted by Parliament, 1st reading/single reading		T8-0397/2019	17/04/2019	EP	Summary
Draft final act		00045/2019/LEX	20/06/2019	CSL	
Commission response to text adopted in plenary		SP(2019)440	08/08/2019	EC	

Additional information

Research document

[Briefing](#)

Final act

[Regulation 2019/1020](#)

[OJ L 169 25.06.2019, p. 0001](#) Summary

Compliance with and enforcement of Union harmonisation legislation on products

PURPOSE: to ensure that products placed on the Union market comply with the requirements of Union harmonisation legislation.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

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 site 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 on the Internal Market and Consumer Protection adopted the report by Nicola DANTI (S&D, IT) on the proposal for a regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union 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.

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 adopted by 562 votes to 60, with 33 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council laying down rules and procedures for compliance with and enforcement of Union 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.

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;

- to require economic operators to take appropriate action to bring an instance of non-compliance to an end or to eliminate the risk;
- to take appropriate measures where an economic operator fails to take appropriate corrective action or where the non-compliance or the risk persists, including the power to prohibit or restrict the making available of a product on the market or to order that the product is withdrawn or recalled;
- to impose penalties in accordance with Article 41;
- the power to acquire product samples, including under a cover identity, to inspect those samples and to reverse-engineer them in order to identify non-compliance and to obtain evidence;
- to require the removal of content referring to the related products from an online interface or to require the explicit display of a warning to end users when they access an online interface. or

Corrective actions that may be imposed on the economic operator shall include (i) bringing the product into compliance, (ii) preventing the product from being made available on the market, (iii) immediately withdrawing or recalling the product and warning the public of the risk involved, (iv) destroying the product or rendering it inoperable, (v) immediately alerting end-users exposed to the risk, including by publishing specific 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 amended text specifies that the purpose of the Network is to serve as a platform for structured coordination and cooperation between enforcement authorities of the Member States and the Commission, and to streamline the practices of market surveillance within the Union, thereby making market surveillance more effective.

The role of the network shall be strengthened. In particular, it would be able to (i) adopt its work programme defining priorities for joint market surveillance actions; (ii) facilitate the identification of common priorities for market surveillance activities and the exchange of information across sectors on evaluations of products; (iii) promote cooperation and the exchange of expertise and best practices between market surveillance authorities and authorities in charge of controls at the Unions external borders.

Lastly, a number of existing tools, such as the 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.

Compliance with and enforcement of Union harmonisation legislation on products

PURPOSE: to improve the functioning of the internal market by strengthening product surveillance in the market.

LEGISLATIVE ACT: Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011.

CONTENT: the Regulation aims to ensure that only compliant products which comply with the requirements guaranteeing a high level of protection of public interests such as health and safety in general, health and safety at work, consumer protection, protection of the environment and public safety and any other public interest protected by the said legislation, are placed on the market in the Union.

The Regulation establishes rules and procedures for economic operators with regard to products subject to certain provisions of EU harmonisation legislation and creates a framework for cooperation with economic operators. It also sets out a framework for controls on products entering the Union market.

Tasks of economic operators

Economic operators (manufacturers, importers, agents, fulfilment service providers established in the Union in respect of the products they handle) shall in particular be required to:

- 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 the supervisory authorities at their request;
- provide the authorities with all the information and documents 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, and ensure that the immediate and necessary corrective action is taken to remedy any case of non-compliance.

Joint activities to promote compliance with legislation

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.