Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2013/0048(COD)
Procedure lapsed or withdrawn	

Market surveillance of products

Amending Directive 95/16/EC 1992/0394(COD)
Amending Directive 97/23/EC 1993/0462(COD)
Amending Directive 2000/9/EC 1994/0011(COD)
Amending Directive 1999/5/EC 1997/0149(COD)
Amending Directive 2000/14/EC 1998/0029(COD)
Amending Directive 2001/95/EC 2000/0073(COD)
Amending Directive 2006/42/EC 2001/0004(COD)
Amending Directive 2004/108/EC 2002/0306(COD)
Amending Directive 2006/95/EC 2003/0094(COD)
Amending Directive 2007/23/EC 2005/0194(COD)
Amending Directive 2008/57/EC 2006/0273(COD)
Amending Regulation (EC) No 764/2008 2007/0028(COD)
Amending Regulation (EC) No 765/2008 2007/0029(COD)
Amending Directive 2009/142/EC 2007/0225(COD)
Amending Directive 2009/48/EC 2008/0018(COD)
Amending Directive 2009/105/EC 2008/0076(COD)
Amending Regulation (EU) No 305/2011 2008/0098(COD)
Amending Directive 2011/65/EU 2008/0240(COD)

Subject
2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance
2.80 Cooperation between administrations
3.45.08 Business environment, reduction of the administrative burdens
4.60 Consumers' protection in general
4.60.08 Safety of products and services, product liability
6.20.02 Export/import control, trade defence, trade barriers
8.50.02 Legislative simplification, coordination, codification

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
IMCO Internal Market and Consumer Protection		20/02/2013
	PPE PIETIKÄINEN Sirpa	
	Shadow rapporteur	
	S&D SCHALDEMOSE Christel	

Committee for opinion	Rapporteur for opinion	Appointed
INTA International Trade		
BUDG Budgets		
ECON Economic and Monetary Affairs		
ENVI Environment, Public Health and Food Safety		
ITRE Industry, Research and Energy		
AGRI Agriculture and Rural Development		
JURI Legal Affairs		
LIBE Civil Liberties, Justice and Home Affairs		

Council of the European Union

Council configuration	Meeting	Date
Competitiveness (Internal Market, Industry, Research and Space)	3353	04/12/2014

	Competitiveness (Internal Market, Industry, Research and Space)	3276	03/12/2013
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs	TAJANI Antonio	
European Economic and Social Committee			

Key events

13/02/2013	Legislative proposal published	COM(2013)0075	Summary
12/03/2013	Committee referral announced in Parliament, 1st reading		
17/10/2013	Vote in committee, 1st reading		
22/10/2013	Committee report tabled for plenary, 1st reading	A7-0346/2013	Summary
03/12/2013	Debate in Council	3276	
15/04/2014	Results of vote in Parliament		
15/04/2014	Debate in Parliament		
15/04/2014	Decision by Parliament, 1st reading	T7-0384/2014	Summary
04/12/2014	Debate in Council	3353	
16/04/2019	Debate in Parliament		
29/09/2020	Proposal withdrawn by Commission		

Technical information

Procedure reference	2013/0048(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Directive 95/16/EC 1992/0394(COD) Amending Directive 97/23/EC 1993/0462(COD) Amending Directive 2000/9/EC 1994/0011(COD) Amending Directive 1999/5/EC 1997/0149(COD) Amending Directive 2000/14/EC 1998/0029(COD) Amending Directive 2001/95/EC 2000/0073(COD) Amending Directive 2006/42/EC 2001/0004(COD) Amending Directive 2004/108/EC 2002/0306(COD) Amending Directive 2006/95/EC 2003/0094(COD) Amending Directive 2007/23/EC 2005/0194(COD) Amending Directive 2008/57/EC 2006/0273(COD) Amending Regulation (EC) No 764/2008 2007/0028(COD) Amending Regulation (EC) No 765/2008 2007/0029(COD) Amending Directive 2009/142/EC 2007/0225(COD) Amending Directive 2009/48/EC 2008/0018(COD)

	Amending Directive 2009/105/EC 2008/0076(COD) Amending Regulation (EU) No 305/2011 2008/0098(COD) Amending Directive 2011/65/EU 2008/0240(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114; Treaty on the Functioning of the EU TFEU 207; Treaty on the Functioning of the EU TFEU 033
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure lapsed or withdrawn
Committee dossier	IMCO/7/11996

Documentation gateway

Legislative proposal		COM(2013)0075	13/02/2013	EC	Summary
Document attached to the procedure		SWD(2013)0033	13/02/2013	EC	
Document attached to the procedure		SWD(2013)0034	13/02/2013	EC	
Economic and Social Committee: opinion, report		CES1607/2013	22/05/2013	ESC	
Document attached to the procedure		N7-0091/2013 OJ C 253 03.09.2013, p. 0008	30/05/2013	EDPS	Summary
Committee draft report		PE513.324	13/06/2013	EP	
Amendments tabled in committee		PE516.934	11/09/2013	EP	
Committee opinion	INTA	PE513.014	18/09/2013	EP	
Committee report tabled for plenary, 1st reading/single reading		A7-0346/2013	22/10/2013	EP	Summary
Text adopted by Parliament, 1st reading/single reading		T7-0384/2014	15/04/2014	EP	Summary
Commission response to text adopted in plenary		SP(2014)471	09/07/2014	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Market surveillance of products

PURPOSE: Commission proposal on a single regulation on market surveillance of products aimed at simplifying the Union framework on market surveillance (product safety and market surveillance package).

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

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

BACKGROUND: in a single market in which products circulate freely through 27 Member States, market surveillance needs to be highly coordinated and capable of reacting rapidly over a huge area. However, market surveillance has not kept pace with developments in the Union regulatory framework. Whilst advances have been made over the last decade, in particular with the implementation of Directive 2001/95/EC (General Product Safety Directive) and Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance, the overlap of market surveillance rules and the obligations of economic operators laid down in various pieces of Union legislation has led to

confusion on the part of both economic operators and national authorities and has seriously hampered the effectiveness of market surveillance activity in the Union. Different product evaluation requirements and procedures apply depending on the category of product involved. The proposal aims to simplify the rules.

It should be noted that in response to calls from the European Parliament, the proposal was added to the Product Safety and Market Surveillance Package, which also includes a proposal for a regulation on consumer product safety (replacing the GPSD) and a proposal on multi-annual action plan for market surveillance covering the period 2013-2015.

IMPACT ASSESSMENT: the Commission carried out an impact assessment and a favourable opinion was delivered by the Impact Assessment Board in 2012.

LEGAL BASIS: Articles 33, 114 and 207 of the Treaty on the Functioning of the European Union.

CONTENT: this proposal aims at clarifying the regulatory framework for market surveillance in the field of non-food products. It merges the rules on market surveillance of the GPSD, Regulation (EC) 765/2008 and many sector-specific pieces of Union harmonisation legislation into a single legal instrument that applies horizontally across all sectors. The main aims are as follows:

- to reduce the number of pieces of legislation containing market surveillance rules: the 3 tier system spread across the GPSD, Regulation (EC) 765/2008 and a range of sector-specific legislation will be reduced to a one tier system in which all those rules are brought together in a single instrument;
- to eliminate overlaps in the current system: the new regulation will (a) dispense with the distinction between consumer and professional products for market surveillance purposes; (b) avoid making a distinction between harmonised products and non-harmonised products except where this is unavoidable in applying certain specific provisions. To the greatest extent possible the applicable rules will be the same for all products;
- to dovetail the RAPEX and Union evaluation procedures: at present, there are two separate procedures operating, sometimes in parallel, which require Member States to notify to the Commission and to other Member States certain market surveillance action taken at national level. This is an especially problematic aspect of the overlapping categories of products mentioned above. Under the new Regulation the two procedures become a single procedural flow with certain events triggering a single notification to the other Member States and the Commission (made using either the proven RAPEX rapid alert system or the Information and Communication System for Market Surveillance in accordance with the distinction made in the Regulation). In urgent situations the Commission is empowered to adopt measures requiring consistent action across the EU against products presenting a serious risk;
- to make the legislation more accessible: current market surveillance provisions are not based around a chronological flow of events. The new Regulation sets out the whole process of a market surveillance exercise in a chronological, sequential manner. It presents a chain of events, incorporating relevant provisions on publication of information, notification etc. at each stage of the procedure. This approach substantially improves the accessibility and user-friendliness of the legislation, and hence its effectiveness.

BUDGETARY IMPLICATIONS: the budgetary implications are already envisaged in existing or proposed programmes and the initiative will be financed through redeployment of existing resources. According to the financial statement, the total appropriations (operational appropriations, human resources and administrative expenditure) amount to EUR 39 276 million in commitments for 2015-2020.

Market surveillance of products

Opinion of the European Data Protection Supervisor (EDPS).

The EDPS appreciates that the regulation of the European Parliament and of the Council on market surveillance of products takes into account data protection issues to a certain extent. However, he gives some recommendations on how the Proposal could be further improved:

The EDPD particularly recommends:

- including a substantive provision to clarify that the Proposal is not meant to provide for general derogations from data protection principles and that relevant personal data processing legislation remain fully applicable in the market surveillance context;
- to amend the proposal so as to ensure that only personal information which is strictly necessary is processed for market surveillance purposes in the Rapid Information System (RAPEX) and the Information and Communication System on Market Surveillance (ICSMS), respectively;
- providing for fixed retention periods for the personal data processed in RAPEX and ICSMS;
- maintaining the approach whereby the public is informed about unsafe products (via the RAPEX website) without making public personal information on economic operator(s) responsible for those products;
- explicit substantive provisions that would at least specify what kind of personal data may be made public and for what purpose(s), if it is the intention of the legislator to provide for the publication of personal information on economic operators;
- supplementing the provisions on participation of applicant countries, third countries or international organisations in RAPEX, as well as on international exchange of confidential information with explicit references to specific provisions about personal data protection corresponding to those applicable in the Union.

Market surveillance of products

The Committee on the Internal Market and Consumer Protection adopted the report by Sirpa PIETIKÄINEN (EPP, FI) on the proposal for a regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council.

The committee recommended that Parliament adopt its position in first reading following the ordinary legislative procedure, and amend the Commission proposal as follows:

Precautionary principle: Members wanted the provisions of the Regulation to be based on the precautionary principle. The principle, is a fundamental principle for the safety of products and for the safety of consumers and should be taken into due account by market surveillance authorities when assessing the safety of a product.

Intermediary service providers: these intermediaries, such as online hosts and registrars, should be obliged to cooperate with market surveillance authorities and take corrective actions where required, like other economic operators, in order to prevent the selling of unsafe or otherwise non-compliant products online.

Product presenting an emerging risk: market surveillance authorities should also tackle products presenting an emerging risk. A definition is proposed in order to be easily applied in a harmonised manner across the EU

Market surveillance: this should be carried out with a view to ensuring that products presenting a risk and non-compliant products are not placed or made available on the Union market and, where such products have been made available, effective and proportionate measures are taken to remove the risk presented by the product or to resolve non-compliance.

Member States shall report on the market surveillance activities and external border controls to the Commission every year. The Commission shall make that information available to the public electronically and, where appropriate, by other means.

Market surveillance authorities: each Member State shall grant market surveillance authorities the powers and entrust them with the resources and means necessary for the proper performance of their tasks. The Commission shall evaluate whether those powers and resources are sufficient for the proper performance of that Member State's market surveillance obligations.

Effective surveillance: Market surveillance authorities shall organise their activities in such a way that maximum effectiveness can be achieved. They shall, accordingly, carry out the sample checks on sufficient numbers of products made available on the market, enabling conformity and the real risk posed to be assessed.

Market surveillance authorities must also:

- alert users in their territories without delay of the identity of products that those authorities have identified as presenting a risk. Where available, that information shall also include data on the manufacturer, retail channel and period of sales;
- cooperate with economic operators and other competent national authorities to prevent or reduce risks caused by products;
- follow up consumer complaints within a reasonable time frame;
- verify that corrective action has been taken in a timely manner;
- monitor accidents and damage to health which are suspected to have been caused by those products;
- be encouraged to participate in national standardisation activities aimed at the development or revision of standards requested by the Commission.

The levels and methods for calculation of fees applicable to economic operators must be included in the general market surveillance programmes.

Market surveillance programmes: general and sector-specific programmes must be drawn up with the input of key stakeholders concerned, including professional organisations, business organisations and consumer organisations,

General obligations of economic operators: the latter must make available to market surveillance authorities information that enables the precise identification of the product and facilitates the tracing of the product.

Economic operators shall cooperate with market surveillance authorities at their request, on any action taken to eliminate the risks presented by or non-compliance of products that they have placed or made available on the market.

Cooperation and exchange of information: Members considered that the European Market Surveillance Forum should serve as a platform for cooperation not only between the authorities but also between the authorities and the economic operators as well as other stakeholders such as consumer groups.

They stressed the importance of structured cooperation under the auspices of this Forum, which is yet to be established. They wished to strengthen the future role of the Forum and suggest that the Commission should consider proposing, when this Regulation is next reviewed, that the Forum is given the power to set binding recommendations as to the quality and practices of market surveillance.

Products presenting a risk: if the products in question present a serious risk, Members considered that preventing the product from being placed or made available on the market must be done Immediately.

Measures taken by market surveillance authorities: the relevant economic operator shall bear all of the expenses related to the destruction of products and the expenses incurred by the market surveillance authorities. Furthermore, market surveillance authorities shall charge fees for the relevant economic operators which are caught placing or making available non-compliant products and products presenting a risk on the Union market.

The Union rapid information system (RAPEX): this system must be constantly updated. RAPEX should also include notifications related to Food Contact Materials, moved there from the Rapid Alert System for Food and Feed (RASFF) platform.

Pan-European Injuries Database: the report required the Commission to adopt, two years after entry into force of the Regulation, delegated acts establishing a Pan-European Injuries Database which would cover all types of injuries, and in particular those related to products used at home and for leisure, transportation and work activities. The database shall be coordinated and operated by the Commission.

Deterrent penalties: Members proposed the introduction of EU-wide, harmonised administrative penalties. To add to the deterrent effect sought, the penalties imposed under the Regulation should also be made public. In addition to this the report proposed establishing a public blacklist of operators who repeatedly breach this Regulation.

Market surveillance of products

The European Parliament adopted by 573 votes to 18, with 52 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council.

Parliament adopted its position at first reading following the ordinary legislative procedure, and amend the Commission proposal as follows:

Precautionary principle: Parliament wanted the provisions of the Regulation to be based on the precautionary principle. The principle, is a fundamental principle for the safety of products and for the safety of consumers and should be taken into due account by market surveillance authorities when assessing the safety of a product.

This Regulation should apply to all forms of supply of products, including distance selling. Member States and the Commission should develop a common approach for the market surveillance of products sold online.

Intermediary service providers: these intermediaries, such as online hosts and registrars, should be obliged to cooperate with market surveillance authorities and take corrective actions where required, like other economic operators, in order to prevent the selling of unsafe or otherwise non-compliant products online.

Product presenting an emerging risk: market surveillance authorities should also tackle products presenting an emerging risk. A definition was proposed in order to be easily applied in a harmonised manner across the EU

Market surveillance: this should be carried out with a view to ensuring that products presenting a risk and non-compliant products are not placed or made available on the Union market and, where such products have been made available, effective and proportionate measures are taken to remove the risk presented by the product or to resolve non-compliance.

Member States should report on the market surveillance activities and external border controls to the Commission every year. The Commission should make that information available to the public electronically and, where appropriate, by other means.

Market surveillance authorities: each Member State shall grant market surveillance authorities the powers and entrust them with the resources and means necessary for the proper performance of their tasks. The Commission shall evaluate whether those powers and resources are sufficient for the proper performance of that Member State's market surveillance obligations.

Effective surveillance: Market surveillance authorities should organise their activities in such a way that maximum effectiveness can be achieved. They should, accordingly, carry out the sample checks on sufficient numbers of products made available on the market, enabling conformity and the real risk posed to be assessed.

Market surveillance authorities should also:

- alert users in their territories without delay of the identity of products that those authorities have identified as presenting a risk. Where available, that information shall also include data on the manufacturer, retail channel and period of sales;
- cooperate with economic operators and other competent national authorities to prevent or reduce risks caused by products;
- follow up consumer complaints within a reasonable time frame;
- verify that corrective action has been taken in a timely manner;
- monitor accidents and damage to health which are suspected to have been caused by those products;
- be encouraged to participate in national standardisation activities aimed at the development or revision of standards requested by the Commission.

Market surveillance programmes: general and sector-specific programmes should be drawn up with the input of key stakeholders concerned, including professional organisations, business organisations and consumer organisations. The Commission should evaluate the general and sector-specific programmes and, if appropriate, make recommendations to the Member States based on that evaluation.

The levels and methods for calculation of fees applicable to economic operators must be included in the general market surveillance programmes.

General obligations of economic operators: the latter must make available to market surveillance authorities information that enables the precise identification of the product and facilitates the tracing of the product. Market surveillance authorities should ensure confidentiality when that documentation and information is made available.

Economic operators shall cooperate with market surveillance authorities at their request, on any action taken to eliminate the risks presented by or non-compliance of products that they have placed or made available on the market.

Products presenting a risk: if the products in question present a serious risk, Members considered that preventing the product from being placed or made available on the market must be done Immediately.

Measures taken by market surveillance authorities: according to the amended text, the relevant economic operator should bear all of the expenses related to the destruction of products and the expenses incurred by the market surveillance authorities. Furthermore, market surveillance authorities shall charge fees for the relevant economic operators which are caught placing or making available non-compliant products and products presenting a risk on the Union market. Such fee should not exceed the actual costs of the market surveillance activity performed and may partly or entirely reflect the time taken by the staff of the market surveillance authorities to perform the market surveillance controls.

The Union rapid information system (RAPEX): this system must be constantly updated. RAPEX should also include notifications related to Food Contact Materials, moved there from the Rapid Alert System for Food and Feed (RASFF) platform.

Risk assessment: Parliament proposed using a European Union reference laboratory to carry out risk assessments. It should settle any disputes arising out of a divergent risk assessment among the market surveillance authorities of different Member States, the economic operators and the conformity assessment bodies.

Pan-European Injuries Database: the report required the Commission to adopt, two years after entry into force of the Regulation, delegated acts establishing a Pan-European Injuries Database which would cover all types of injuries, and in particular those related to products used at

home and for leisure, transportation and work activities. The database shall be coordinated and operated by the Commission.

Cooperation and exchange of information: Parliament suggested establishing a European Market Surveillance Forum composed of representatives from market surveillance authorities. The Forum should serve as a platform for structured cooperation between the authorities of the Member States and should provide a continuous and permanent means of involving all stakeholders concerned, including professional organisations, business organisations and consumer organisations.

It wished to strengthen the future role of the Forum and suggest that the Commission should consider proposing, when this Regulation is next reviewed, that the Forum is given the power to set binding recommendations as to the quality and practices of market surveillance.

Deterrent penalties: Members proposed the introduction of EU-wide, harmonised administrative penalties. Administrative penalties applicable to infringements shall at least offset the economic advantage sought through the infringement, but shall not exceed 10 % of the annual turnover or an estimate thereof. To add to the deterrent effect sought, the penalties imposed under the Regulation should also be made public. In addition to this the report proposed establishing a public blacklist of operators who repeatedly breach this Regulation.