

Basic information	
<p><b>2007/0029(COD)</b></p> <p>COD - Ordinary legislative procedure (ex-codecision procedure) Regulation</p>	Procedure completed
<p>Requirements for accreditation and market surveillance relating to the marketing of products (repeal. Regulation (EEC) No 339/93)</p> <p>See also <a href="#">2011/0349(COD)</a> See also <a href="#">2011/0350(COD)</a> See also <a href="#">2011/0351(COD)</a> See also <a href="#">2011/0352(COD)</a> See also <a href="#">2011/0353(COD)</a> See also <a href="#">2011/0354(COD)</a> See also <a href="#">2011/0356(COD)</a> See also <a href="#">2011/0357(COD)</a> See also <a href="#">2011/0358(COD)</a></p> <p><b>Subject</b></p> <p>2.10 Free movement of goods 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 4.60.08 Safety of products and services, product liability</p>	

Key players					
European Parliament	<b>Committee responsible</b>		<b>Rapporteur</b>	<b>Appointed</b>	
	<b>IMCO</b> Internal Market and Consumer Protection		BRIE André (GUE/NGL)	20/03/2007	
	<b>Committee for opinion</b>		<b>Rapporteur for opinion</b>	<b>Appointed</b>	
	<b>INTA</b> International Trade		MARKOV Helmuth (GUE/NGL)	21/03/2007	
	<b>ENVI</b> Environment, Public Health and Food Safety		LIESE Peter (PPE-DE)	10/05/2007	
	<b>ITRE</b> Industry, Research and Energy		PURVIS John (PPE-DE)	12/04/2007	
	<b>JURI</b> Legal Affairs		The committee decided not to give an opinion.		
	Council of the European Union	<b>Council configuration</b>		<b>Meetings</b>	<b>Date</b>
		Competitiveness (Internal Market, Industry, Research and Space)		2832	2007-11-22
		Competitiveness (Internal Market, Industry, Research and Space)		2852	2008-02-25
Competitiveness (Internal Market, Industry, Research and Space)		2801	2007-05-21		

	Agriculture and Fisheries	2881	2008-06-23
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter	

Key events			
Date	Event	Reference	Summary
14/02/2007	Legislative proposal published	COM(2007)0037 	Summary
13/03/2007	Committee referral announced in Parliament, 1st reading		
21/05/2007	Debate in Council		
22/11/2007	Debate in Council		
27/11/2007	Vote in committee, 1st reading		Summary
04/12/2007	Committee report tabled for plenary, 1st reading	A6-0491/2007	
19/02/2008	Debate in Parliament		
21/02/2008	Decision by Parliament, 1st reading	T6-0061/2008	Summary
21/02/2008	Results of vote in Parliament		
25/02/2008	Debate in Council		
23/06/2008	Act adopted by Council after Parliament's 1st reading		
09/07/2008	Final act signed		
09/07/2008	End of procedure in Parliament		
13/08/2008	Final act published in Official Journal		

Technical information	
Procedure reference	2007/0029(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	See also <a href="#">2011/0349(COD)</a> See also <a href="#">2011/0350(COD)</a> See also <a href="#">2011/0351(COD)</a> See also <a href="#">2011/0352(COD)</a> See also <a href="#">2011/0353(COD)</a> See also <a href="#">2011/0354(COD)</a> See also <a href="#">2011/0356(COD)</a> See also <a href="#">2011/0357(COD)</a> See also <a href="#">2011/0358(COD)</a>
Legal basis	EC Treaty (after Amsterdam) EC 133 EC Treaty (after Amsterdam) EC 095

Stage reached in procedure	Procedure completed
Committee dossier	IMCO/6/46225

Documentation gateway				
<b>European Parliament</b>				
Document type	Committee	Reference	Date	Summary
Committee draft report		PE390.753	29/06/2007	
Committee opinion	INTA	PE388.413	14/09/2007	
Committee opinion	ITRE	PE390.374	05/10/2007	
Amendments tabled in committee		PE396.408	16/10/2007	
Committee opinion	ENVI	PE390.476	23/11/2007	
Committee report tabled for plenary, 1st reading/single reading		A6-0491/2007	04/12/2007	
Text adopted by Parliament, 1st reading/single reading		T6-0061/2008	21/02/2008	Summary
<b>Council of the EU</b>				
Document type		Reference	Date	Summary
Draft final act		03614/2008/LEX	09/07/2008	
<b>European Commission</b>				
Document type		Reference	Date	Summary
Legislative proposal		COM(2007)0037 	14/02/2007	Summary
Document attached to the procedure		SEC(2007)0173 	14/02/2007	
Document attached to the procedure		SEC(2007)0174 	14/02/2007	
Commission response to text adopted in plenary		SP(2008)1767	31/03/2008	
Follow-up document		COM(2013)0077 	13/02/2013	Summary
Follow-up document		SWD(2013)0035 	13/02/2013	
Follow-up document		SWD(2013)0036 	13/02/2013	
Follow-up document		COM(2017)0789 	19/12/2017	Summary
Follow-up document		COM(2022)0679 	05/12/2022	

## Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	<a href="#">CES1693/2007</a>	13/12/2007	

## Additional information

Source	Document	Date
National parliaments	<a href="#">IPEX</a>	
European Commission	<a href="#">EUR-Lex</a>	

## Final act

[Regulation 2008/0765](#)  
[OJ L 218 13.08.2008, p. 0030](#)

[Summary](#)

# Requirements for accreditation and market surveillance relating to the marketing of products (repeal. Regulation (EEC) No 339/93)

2007/0029(COD) - 13/02/2013 - Follow-up document

This report gives an overview of the implementation of Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products which has applied from 1 January 2010. The main points are as follows:

**Accreditation:** while the Regulation has set a solid legal framework for accreditation, the major challenges in the implementation of the accreditation chapter of the Regulation for the next few years will be **to consolidate and strengthen the system as well as raising awareness and a better understanding of accreditation's benefits**. Apart from a number of legal questions surrounding accreditation, this will require:

- a further **strengthening of the peer evaluation system** as the main tool for ensuring a continued quality of certificates throughout the EU;
- greater prominence to **accreditation for notification purposes** which will have to be used more systematically in EU legislation where the latter provides for conformity assessment and the designation of conformity assessment bodies. This may also require that the Commission and the European Cooperation for Accreditation (EA) develop sectoral accreditation schemes to ensure that conformity assessment bodies meet the level of competence required by Union harmonisation legislation in fields with specific requirements.

**Union market surveillance framework for products:** with regard to the **national market surveillance programmes**, the assessment of the efforts made by Member States is **overall very positive**, despite the fact that some countries have put more emphasis on information concerning the general organisation of market surveillance, while others have chosen to privilege information on sector activities, so the information is not always fully comparable. Clarity on how Member States have organised cooperation and coordination among different authorities and with customs could be improved. In addition:

- **Products presenting a serious risk:** the report discusses the extension of the RAPEX system, which has contributed particularly to the protection of workers and the environment, although the total number of new notifications has been rather limited during the first two years of implementation of the Regulation. Overall, 9 Member States transmitted notifications on professional goods and products which may harm public interests other than health and safety and this figure will increase over time.
- **General information support system – ICSMS:** in November 2011, the Commission agreed to purchase ICSMS for EUR 1,940,940.

**CE Marking and Conformity Assessment:** upon request by the European Parliament, the Commission carried out an information campaign on CE marking financed by the Entrepreneurship and Innovation Programme in 2009 and costing EUR 2 million. Feedback and interest shows that the campaign fulfilled its goals.

# Requirements for accreditation and market surveillance relating to the marketing of products (repeal. Regulation (EEC) No 339/93)

2007/0029(COD) - 21/02/2008 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution based on the report drafted by Andre **BRIE** (GUE/NGL, DE), amending, under the first reading of the codecision procedure, the proposal for a regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products.

The main amendments were as follows:

**Objective:** Parliament made some amendments to this Article which now states that the Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities. It also provides a framework for the market surveillance of transformed products to ensure that they respect a high level of protection of public interests such as health and safety in general, of health and safety at the workplace, protection of consumers, of the environment, and of security. The Regulation further provides a framework for controls on products from third countries. It also contains provisions on **CE marking**.

**Accreditation and conformity assessment:** each Member State must appoint a single national accreditation body. The Commission shall draw up a list of the national accreditation bodies, to be made publicly available. Where accreditation is not operated directly by the public authorities themselves, Member States shall entrust the national accreditation body with the operation of accreditation as a public authority and grant it formal recognition on behalf of the government. The national accreditation body must not provide any services that conformity assessment bodies provide, nor shall it provide consultancy services, own shares in or otherwise have a financial or managerial interest in a conformity assessment body. Each Member State shall ensure that its national accreditation body has the appropriate resources for the proper performance of its tasks including for the fulfilment of special tasks, such as activities in European and international accreditation cooperation and activities that are required to support government policy and which are not self-financing. The national accreditation body shall be a member of the body recognised by the Commission as managing the European accreditation infrastructure. National accreditation bodies must maintain appropriate structures to ensure the balanced involvement of all interested parties. Member States must monitor their national accreditation bodies and take the utmost account of the results of peer evaluation. Stakeholders shall have the right to participate in the system set up for the supervision of peer evaluation activities, but not in individual peer evaluation.

**Principle of non-competition:** a new Article on the principle of non-competition states that national accreditation bodies shall not compete with conformity assessment bodies, or with other national accreditation bodies within the territory of the European Union with respect to accreditation for compulsory conformity assessment activities. National accreditation bodies shall, however, be permitted to operate across Member State borders, within the territory of another Member State, at the request of a conformity assessment body in respect of accreditation for a compulsory conformity assessment activity in certain circumstances.

Parliament added that a national accreditation body shall verify that conformity assessments are carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on undertakings and that due account is taken of the size of the undertaking, the sector in which it operates, the structure of the undertaking, the degree of complexity of the product technology in question and the mass nature of the production process.

**European accreditation infrastructure:** Parliament inserted a clause stating that the Commission shall, after consultation with the Member States, recognise a body which satisfies the requirements of the Annex to the Regulation. In order for a body to be recognised, it shall conclude an agreement with the Commission. That agreement shall contain the detailed tasks of the body, funding provisions and provisions for the supervision of the recognised body. The first body recognised under the Regulation will be the European Co-operation for Accreditation.

**Market surveillance:** provisions on market surveillance will apply in so far as there are no specific provisions with the same objective in rules of Community harmonisation legislation. The application of the Regulation will not prevent market surveillance authorities from taking more specific measures as provided for in Directive 2001/95/EC (GPSD). Market surveillance shall ensure that products covered by Community harmonisation legislation which, when used for their intended purpose or under conditions which can reasonably be foreseen and when properly installed, and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Community harmonisation legislation, are withdrawn, prohibited or restricted from being made available on the market and that the public, the Commission and the other Member States are appropriately informed. National market surveillance infrastructures shall ensure that effective measures can be taken in relation to any product category subject to Community harmonisation legislation. Such surveillance shall cover products assembled or manufactured for the manufacturer's own use where Community harmonisation legislation provides that its provisions shall apply to such products.

Parliament went on to specify that Member States shall draw up either a general market surveillance programme or sector specific programmes, covering the sectors in which they conduct market surveillance, communicate those programmes to the other Member States and the Commission and make them available to the public, including by ways of electronic communications. The first such communication shall take place by 1 January 2010. Member States shall periodically review the functioning of their surveillance activities. Such reviews and assessments shall occur at least every fourth year and the results shall be communicated to the other Member States and the Commission and made available to the public.

On the question of risk, Parliament stated that the decision as to whether or not a product represents a serious risk shall be based on an appropriate risk assessment based on the character of the hazard and the likelihood of it occurring. 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 a product to present a serious risk.

**Control of products entering the Community market:** Member States must ensure that their relevant authorities responsible for control of products entering the Community market have the necessary powers and resources in order to properly perform their tasks. Where in a Member State more than one authority is responsible for market surveillance and customs controls, those authorities shall co-operate with each other.

**CE marking:** Parliament inserted a new clause entitled "General Principles of the CE Marking". The provisions are inspired by the proposed Decision. (Please see [COD/2007/0030](#)). The CE marking shall only be affixed by the manufacturer or his authorised representative.

**Review clause:** not later than 5 years after the entry into force of the Regulation, the Commission shall submit a report on the application of the Regulation and Directive 2001/95/EC on General Product Safety and any other relevant Community instrument addressing market surveillance. In particular, the report shall analyse the coherence of Community rules in the field of market surveillance. If appropriate, the report shall be accompanied by proposals to amend and/or consolidate the instruments concerned. It will include an evaluation of the extension of the scope of Chapter III to all products.

## Requirements for accreditation and market surveillance relating to the marketing of products (repeal. Regulation (EEC) No 339/93)

2007/0029(COD) - 09/07/2008 - Final act

**PURPOSE:** to establish requirements for accreditation and market surveillance for the marketing of products.

**LEGISLATIVE ACT:** Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

**CONTENT:** This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing conformity assessment activities. It provides a framework for the market surveillance of products to ensure that those products fulfil requirements providing a high level of protection of public interests, such as health and safety in general, health and safety at the workplace, the protection of consumers, protection of the environment and security. The Regulation provides a framework for controls on products from third countries and lays down the general principles of the CE marking.

**Accreditation:** accreditation is part of an overall system, including conformity assessment and market surveillance, designed to assess and ensure conformity with the applicable requirements. The Regulation has developed comprehensive framework for accreditation and lays down at Community level the principles for its operation and organisation. Each Member State shall appoint a single national accreditation body. A national accreditation body shall, when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity. Where it is found to be competent, the national accreditation body shall issue an accreditation certificate to that effect. The accreditation body must be organised in such a manner as to make it independent of the conformity assessment bodies it assesses and of commercial pressures, and ensure that no conflicts of interest with conformity assessment bodies occur.

**Market surveillance:** this must ensure that products covered by Community harmonisation legislation which, when used in accordance with their intended purpose or under conditions which can be reasonably foreseen and when properly installed and maintained, are liable to compromise the health or safety of users, or which otherwise do not conform to applicable requirements set out in Community harmonisation legislation are withdrawn or their being made available on the market is prohibited or restricted and that the public, the Commission and the other Member States are informed accordingly. National market surveillance infrastructures and programmes shall ensure that effective measures can be taken in relation to any product category subject to Community harmonisation legislation. Market surveillance shall cover products assembled or manufactured for the manufacturer's own use where Community harmonisation legislation provides that its provisions shall apply to such products.

**Products presenting a serious risk:** Member States must ensure that products which present a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, are recalled, withdrawn or that their being made available on their market is prohibited, and that the Commission is informed without delay. The decision whether or not a product represents 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.

**CE marking:** the Regulation sets out the general principles of CE marking. The CE marking shall be affixed only by the manufacturer or his authorised representative, and it must be affixed only to products to which its affixing is provided for by specific Community harmonisation legislation.

**Review clause:** not later than 5 years after the entry into force of the Regulation, the Commission shall submit a report on the application of the Regulation and Directive 2001/95/EC on General Product Safety and any other relevant Community instrument addressing market surveillance. In particular, the report shall analyse the coherence of Community rules in the field of market surveillance. If appropriate, the report shall be accompanied by proposals to amend and/or consolidate the instruments concerned. It will include an evaluation of the extension of the scope of Chapter III to all products. By 1 January 2013, and every five years thereafter, the Commission, in cooperation with the Member States, shall produce and submit to the European Parliament and to the Council a report on the implementation of this Regulation.

**APPLICATION:** from 1/01/2010.

**ENTRY INTO FORCE:** 02/09/2008.

# Requirements for accreditation and market surveillance relating to the marketing of products (repeal. Regulation (EEC) No 339/93)

2007/0029(COD) - 14/02/2007 - Legislative proposal

PURPOSE: to establish requirements for accreditation and market surveillance for the marketing of products.

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

BACKGROUND: the free movement of goods forms a central pillar of the single market. Community technical legislation ensuring the free circulation of products has contributed considerably to the completion and proper functioning of the EU's internal market. A number of secondary legislative initiatives support the free circulation of goods across the EU. They include the "new" approach Directives; legislation on setting out the basic rules for CE marking and the application of harmonised conformity assessment procedures; legislation on recognising the role of the European standardisation organisations; and the priority of European standards and legislation on product safety.

Experience has shown, however, that obstacles to the free movement of goods remain. The obstacles identified are:

- a distortion of competition due to differing practices in the "designation of conformity" by the national assessment bodies;
- an unequal treatment of "non-complying" or dangerous products on the market through the use of very different national market surveillance regulations, rules and means;
- a certain lack of trust in conformity marking; and
- a certain lack of coherence in the implementation and enforcement of existing EU legislation.

CONTENT: the purpose of this proposal, therefore, is:

- to lay down rules on the organisation and operation of accreditation of conformity assessment bodies that perform product assessment;
- to provide a framework for market surveillance; and
- to control products from third countries.

It is being presented alongside a proposal for a Decision on a consumer framework for the marketing of products. (See [COD/2007/0030](#)). The two proposals seek to complete existing legislative tools and to reinforce Community policies on market surveillance/accreditation. They also seeks to bring coherence to existing sectoral instruments by examining how these horizontal instrument can be applied to all sectors regardless of whether they are "old" or "new" approach.

In summary, the proposed Regulation will:

- organise accreditation at both a national and a European level – irrespective of the sectors involved. The proposal insists on the public authority nature of accreditation;
- set out a framework for recognising the existing "European co-operation for Accreditation" or EA. This will allow for a rigorous peer evaluation;
- ensure that national authorities are given equivalent means of intervention and the necessary authority to intervene in the market should they need to withdraw non-compliant or unsafe products;
- ensure co-operation between the internal authorities and the customs authorities, who control products entering the market from third countries; and
- set up a framework for the exchange of information between national authorities.

In terms of the budgetary impact of the proposal, the Community's financial contribution is expected to be reduced in overall terms. On a final point, the proposal provides for the simplification of EU legislation and will lead to the repeal of Council Regulation 93/339/EEC.

**For further details of the financial impact of the proposal refer to the financial statement.**

# Requirements for accreditation and market surveillance relating to the marketing of products (repeal. Regulation (EEC) No 339/93)

2007/0029(COD) - 19/12/2017 - Follow-up document

The report presented by the Commission gives an overview of how the accreditation provisions of Regulation (EC) No 765/2008 and the CE marking were implemented between 2013 and 2017. It was prepared in cooperation with the Member States through the accreditation sub-group of the 'Internal market for products' experts group.

The main findings of the report are as follows:

**1) Accreditation:** the Regulation plays a key part in facilitating the free movement of goods in the internal market and international trade. Under its provisions, the Member States appoint a single National Accreditation Body that provides accreditation of conformity assessment bodies.

The Regulation provides for a uniformly rigorous approach to accreditation in all Member States — so that ultimately one accreditation certificate is enough to demonstrate the technical capacity of a conformity assessment body throughout Europe. Therefore, the benefit of accreditation in the EU is that once a conformity assessment body has been successfully accredited according to the Regulation, Member States' authorities are obliged to recognise the accreditation certificate. This eliminates the unnecessary overhead of being accredited separately in every Member State and having the products checked by different conformity assessment bodies. This creates an environment favourable for developing businesses in the European market.

The proportion of notifications of accredited conformity assessment bodies increased by **34 percentage points** between end 2009 and November 2017. By the end of 2016, **more than 34 450 accreditations** were delivered (in regulated and non-harmonised areas) covering a wide range of activities.

In 2016, the peer evaluation teams reported a total of 135 findings where corrective action was required by national accreditation bodies. The European accreditation is monitoring how the corrective action is being implemented. The Commission recognised the European Cooperation for Accreditation (EA) as the European accreditation infrastructure.

The Regulation established a trustworthy and stable accreditation system in **all Member States, as well as EFTA countries and Turkey**. With the provisional entry into force of the **EU-Canada** Comprehensive Economic and Trade Agreement on 21 September 2017, the Protocol on Mutual Acceptance of the Results of the Conformity Assessment of CETA extended the scope of the previous Mutual Acceptance and simplified the procedures for the designation of conformity assessment bodies. The Protocol relies on accreditation, which thus becomes an even more important pillar for international cooperation with third countries.

**Legal developments** related to accreditation have occurred in specific sectors such as data protection, food and feed and cybersecurity.

However, the **challenge is to keep the whole accreditation system** in line with the latest state of the art and ensure that it is applied with the same stringency.

It is therefore essential that the Union continues to **support the EA** to help it carry out its tasks. In addition, it is important to **maintain a high level of awareness** and understanding of the accreditation system among stakeholders in order to ensure its correct implementation, especially in new policy areas.

**2) CE marking:** the report confirmed that businesses are also **better aware** of the important role of CE marking on products in the single market. There is a need for greater consistency and to avoid having different requirements for different pieces of legislation and address the issue of products with multiple parts.

The number of visits to the CE marking web pages demonstrates the importance of this information being made available to stakeholders.