Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Decision	2007/0030(COD)
Common framework for the marketing of products See also 2011/0349(COD) See also 2011/0350(COD) See also 2011/0351(COD) See also 2011/0352(COD) See also 2011/0353(COD) See also 2011/0354(COD) See also 2011/0356(COD) See also 2011/0357(COD) See also 2011/0358(COD) Subject 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	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
IMCO Internal Market and Consumer Protection	PSE SCHALDEMOSE Christel	20/03/2007

Committee for opinion	Rapporteur for opinion	Appointed
INTA International Trade		
ENVI Environment, Public Health and Food Safety	PSE SCHEELE Karin	10/05/2007
ITRE Industry, Research and Energy	PPE-DE PURVIS John	12/04/2007
JURI Legal Affairs	PPE-DE KARAS Othmar	18/06/2007

Council of the European Union

Council configuration	Meeting	Date
Agriculture and Fisheries	2881	23/06/2008
Competitiveness (Internal Market, Industry, Research and Space)	2852	25/02/2008
Competitiveness (Internal Market, Industry, Research and Space)	2832	22/11/2007
Competitiveness (Internal Market, Industry, Research and Space)	2801	21/05/2007

European Commission

Commission DG	Commissioner

	Internal Market, Industry, Entrepreneurship and SMEs VERHEUGEN Günter

Key events

14/02/2007	Legislative proposal published	COM(2007)0053	Summary
13/03/2007	Committee referral announced in Parliament, 1st reading		
21/05/2007	Debate in Council	2801	
22/11/2007	Debate in Council	2832	
27/11/2007	Vote in committee, 1st reading		Summary
04/12/2007	Committee report tabled for plenary, 1st reading	A6-0490/2007	
19/02/2008	Debate in Parliament		
21/02/2008	Results of vote in Parliament		
21/02/2008	Decision by Parliament, 1st reading	T6-0062/2008	Summary
25/02/2008	Debate in Council	2852	
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	2007/0030(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Decision
	See also 2011/0349(COD) See also 2011/0350(COD) See also 2011/0351(COD) See also 2011/0352(COD) See also 2011/0353(COD) See also 2011/0354(COD) See also 2011/0356(COD) See also 2011/0357(COD) See also 2011/0358(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	IMCO/6/46220

Documentation gateway

Legislative proposal		COM(2007)0053	14/02/2007	EC	Summary
Document attached to the procedure		SEC(2007)0173	14/02/2007	EC	
Committee draft report		PE391.938	02/07/2007	EP	
Committee opinion	JURI	PE391.959	12/09/2007	EP	
Committee opinion	INTA	PE388.412	14/09/2007	EP	
Committee opinion	ITRE	PE390.373	05/10/2007	EP	
Amendments tabled in committee		PE396.486	12/10/2007	EP	
Committee opinion	ENVI	PE390.482	22/11/2007	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0490/2007	04/12/2007	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0062/2008	21/02/2008	EP	Summary
Commission response to text adopted in plenary		SP(2008)1767	31/03/2008	EC	
Draft final act		03615/2008/LEX	09/07/2008	CSL	
Follow-up document		COM(2011)0763	21/11/2011	EC	Summary
Follow-up document		SEC(2011)1375	21/11/2011	EC	
Follow-up document		SEC(2011)1376	21/11/2011	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Decision 2008/768
OJ L 218 13.08.2008, p. 0082 Summary

Common framework for the marketing of products

PURPOSE: to establish a common framework for the marketing of products.

PROPOSED ACT: Decision 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:

- set the general framework for future sectoral legislation;
- give guidance on how to use common elements; and
- ensure as much coherence, in future sectoral legislation, as is politically and technically feasible.

It is being presented alongside a proposal for a Regulation on accreditation and market surveillance. (See COD/2007/0029). The two proposals seek to complete the existing legislative framework. 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 set out:

- harmonised definitions;
- common obligations for economic operators;
- common criteria for the selection of conformity assessment bodies;
- common criteria for the national notifying authorities;
- rules for the notification process;
- common accreditation provisions;
- a single definition for CE marking;
- common rules of responsibility for those who affix the CE mark to their products;
- a proper information and market surveillance procedure as a prolongation of the GPSD system; and
- harmonised provisions for the future safeguard mechanisms; to complement those for market surveillance.

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.

Common framework for the marketing of products

The Committee on the Internal Market and Consumer Protection adopted a report drafted by Christel SCHALDEMOSE (PES, DK), amending, under the first reading of the codecision procedure, the proposal on a common framework for the marketing of products.

The principal amendments were as follows:

Objective and scope: a new Article stipulates that products placed on the Community market shall comply with all applicable legislation. When placing products on the Community market, economic operators are responsible for the compliance of the product with all applicable legislation. The Committee stated that the decision sets the general structure for future legislation and gives guidance on how to use the common elements to ensure as much coherence in future legislation as can be politically an technically possible. Given the legislative nature of the decision it was inappropriate to exempt a certain group of existing legislation as the Commission had proposed;

Manufacturers? obligations: manufacturers shall keep the technical documentation and the EC declaration of conformity for a maximum period of 10 years after the product has been placed on the market. They shall, in all cases where appropriate for protection of the health and safety of consumers, carry out sample testing of marketed products, investigating, and, if necessary, keeping a register of complaints, non-conforming products and product recalls. Manufacturers shall guarantee that all information they provide with regard to their products is accurate, complete and in compliance with applicable Community rules.

Importers? obligations: importers shall place only compliant products on the Community market. The Committee felt that the e level of responsibility the importers have to bear under the Commission proposal was not sufficient and needed to be increased. Accordingly, it stipulated that, before placing a product on the market, importers shall ensure (rather than ?verify? that the appropriate conformity assessment procedure has been carried out by the manufacturer, and shall also ensure that the manufacturer has drawn up the technical documentation. Where an importer discovers that the product is not in conformity with the appropriate legislation, he may not place the product on the market until the appropriate risk assessment has been carried out and the product has been brought into conformity with the applicable requirements. Importers shall, in all cases where appropriate for protection of the health and safety of consumers, carry out sample testing of marketed products, investigating, and, if necessary, keeping a register of complaints, non-conforming products and product recalls, and keeping distributors informed of such monitoring. They must guarantee that all information they provide with regard to the products they import is accurate, complete and in compliance with applicable Community rules. They must, for a maximum period of 10 years, keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities. Importers shall be deemed jointly liable, together with the foreign manufacturer, for damage caused by dangerous or non-compliant products which they placed on the market.

Harmonised standard: when a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers, the Commission or the Member State concerned shall contact the relevant European standardisation organisations ("ESOs") for an opinion. When a Member State or the Commission considers that the opinion of the ESO does not entirely satisfy the request, the Commission or the Member State concerned shall bring the matter before the relevant Commission Committee.

CE marking: Member States shall ensure the correct implementation of the regime governing the CE marking and take legal action in the case of improper use thereof. Member States shall also provide for penalties, which may include criminal sanctions for serious infringements. Such penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use. A new recital states that within one year of the publication of this Decision in the Official Journal of the EU, the Commission should present an in-depth analysis in the field of consumer safety markings, if necessary followed by legislative proposals.

Conformity assessment body: the conformity assessment body shall perform its activities taking into consideration the size, the sector, the

structure of the undertakings involved, the relative complexity of the technology used by the products and the serial character of production.

Safeguard measures: where the market surveillance authorities of one Member State provide information to the market surveillance authorities of another Member State , they shall first contact the economic operator concerned at the address stated on the product in question, on its packaging or in the document accompanying the product. The economic operator shall be permitted a reasonable period in which to respond, which shall be 28 days where there is no immediate risk to the health and safety of the public.

Where the market surveillance authorities of one Member State wish to withdraw a product manufactured in another Member State, they shall advise the economic operator concerned thereof at the address stated on the product in question, on its packaging or in the document accompanying the product.

Common framework for the marketing of products

The European Parliament adopted a resolution based on the report drafted by Christel SCHALDEMOSE (PES, DK), amending, under the first reading of the codecision procedure, the proposal on a common framework for the marketing of products.

The principal amendments were as follows:

Objective and scope: a new Article stipulates that products placed on the Community market shall comply with all applicable legislation. When placing products on the Community market, economic operators shall, in relation to their respective roles in the supply chain, be responsible for the compliance of the product with all applicable legislation. Economic operators shall be legally responsible that all information they provide with regard to their products is accurate, complete and in compliance with applicable Community rules.

Manufacturers? obligations: manufacturers shall keep the technical documentation and the EC declaration of conformity for a period to be specified, proportionate to the lifecycle of the product and the level of risk after the product has been placed on the market. The manufacturer?s address must indicate a single point at which the manufacturer can be contacted. Manufacturers shall ensure that the product is accompanied by instructions and safety information supplied in an official language easily understood by consumers and other end-users as decided by the concerned Member State .

Importers? obligations: importers shall place only compliant products on the Community market. Parliament has increased the level of responsibility the importers have to bear. Before placing a product on the market, importers shall ensure (rather than ?verify? that the appropriate conformity assessment procedure has been carried out by the manufacturer, and shall also ensure that the manufacturer has drawn up the technical documentation. Where an importer considers or has reason to believe that the product is not in conformity with the appropriate legislation, he may not place the product on the market until the product has been brought into conformity. Importers shall, in all cases where appropriate for protection of the health and safety of consumers, carry out sample testing of marketed products, investigating, and, if necessary, keeping a register of complaints, non-conforming products and product recalls, and keeping distributors informed of such monitoring.

CE marking: The CE marking shall be subjected to the general principles set out in the Regulation on market surveillance. (Please see COD/2007/0029).

Conformity assessment body: a body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, can, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered to be such a body. Such bodies shall not engage in any activity that may conflict with their independence of judgement and integrity related to conformity assessment activities for which they are notified. This applies in particular to consultancy services

Safeguard measures: with regard to procedures to deal with products presenting a risk, Parliament stipulated that the economic operators concerned shall cooperate in any necessary way with the market surveillance authorities. The market surveillance authorities shall inform the relevant notified body. Member States shall ensure that the appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.

Annex: Parliament made several amendments to the Annex, with particular reference to technical documentation the application for EC-type examination.

Common framework for the marketing of products

PURPOSE: to establish a common framework for the marketing of products.

LEGISLATIVE ACT: Decision No 768/2008/EC of the European Parliament and of the Council on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC.

CONTENT: this Decision lays down common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation.

Subject matter and scope: the Decision sets out the common framework of general principles and reference provisions for the drawing up of Community legislation harmonising the conditions for the marketing of products (Community harmonisation legislation). Community harmonisation legislation will have recourse to the general principles set out in this Decision and to the relevant reference provisions of Annexes I, II and III. However, Community legislation may depart from those general principles and reference provisions if that is appropriate on account of the specificities of the sector concerned, especially if comprehensive legal systems are already in place, as for example in the fields of feed and food, cosmetic and tobacco products, common market organisations for agricultural products, plant health and plant protection, human blood and tissues, medicinal products for human and veterinary use and chemicals. Specificities also occur where sectoral needs require specific adaptation of the common principles and reference provisions, as for example in the fields of medical devices, construction products and marine equipment.

General principles: products placed on the Community market must comply with all applicable legislation. When placing products on the

Community market, economic operators shall, in relation to their respective roles in the supply chain, be responsible for the compliance of their products with all applicable legislation.

Economic operators are responsible for ensuring that all information they provide with regard to their products is accurate, complete and in compliance with Community rules applicable.

The Regulation sets out:

- harmonised definitions;
- common obligations for economic operators;
- common criteria for the selection of conformity assessment bodies;
- common criteria for the national notifying authorities;
- rules for the notification process;
- common accreditation provisions;
- a single definition for CE marking;
- common rules of responsibility for those who affix the CE mark to their products;
- a proper information and market surveillance procedure as a prolongation of the GPSD system; and
- harmonised provisions for the future safeguard mechanisms, to complement those for market surveillance.

Report: within one year of the publication of the Decision, the Commission should present an in-depth analysis in the field of consumer safety markings, followed by legislative proposals if necessary.

It should be noted that this legislation is closely linked to that for market surveillance. See COD/2007/0029).

Common framework for the marketing of products

The Commission presents a Communication on the alignment of ten technical harmonisation directives to Decision No 768/2008/EC on a common framework for the marketing of products. It recalls that, since the 1970s, a large variety of goods have come to be regulated by EU legislation designed to ensure the protection of the consumer, the worker in the workplace, the environment, energy resources and so on in a uniform manner, thereby ensuring free movement throughout the Union. The adoption of the New Approach legislative technique in 1985, restricting legislative requirements to those that are essential and addressing detailed technical issues in harmonised European Standards, has contributed to the acceleration of the harmonisation process, enabling whole industrial sectors to benefit from free movement.

This initiative is an important step in the implementation of the legislative framework adopted as part of the goods package on 9 July 2008. The objective of the 2008 package was to boost the free movement of safe goods by reinforcing the effectiveness of EU product safety legislation, strengthening consumer protection and levelling the playing field for economic operators.

The New Legislative Framework (NLF) texts - Regulation (EC) No 765/2008 and Decision No 768/2008/EC - were adopted as part of the package (which also included a Communication on car registration and a proposal for a regulation on mutual recognition).

The two NLF texts constitute a major political breakthrough for the functioning of the internal market for goods, in that they not only establish an overarching and coherent approach to technical harmonisation policy in relation to product safety but also open the door to an effective market surveillance policy for all goods placed on the market, whether they originate in the EU or in third countries.

Following adoption of the NLF in July 2008, the Commission services screened product legislation to identify instruments due to be revised within the next 3-5 years (i.e. up to 2013) for sector-specific reasons (e.g. to clarify or expand their scope, to update safety requirements etc.). The Commission also looked for legislation that shared the structure and approach of the provisions of Decision No 768/2008/EC to form part of an exercise devoted solely to alignment with the Decision. This automatically limited the choice of directives to those adopted under the New Approach technique, as other legislation (in particular old or traditional approach directives) would require more in depth adaptation going beyond mere alignment. This process led the Commission to identify the following ten new approach directives for inclusion in this alignment package:

- Civil Explosives Directive: Directive 93/15/EEC on the harmonisation of the provisions relating to the placing on the market and supervision of explosives for civil use;
- Directive on equipment for use in explosive atmospheres (ATEX): Directive 94/9/EC on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres;
- Lifts Directive: Directive 95/16/EC on the approximation of the laws of the Member States relating to lifts;
- Pressure Equipment Directive: Directive 97/23/EC on the approximation of the laws of the Member States concerning pressure equipment;
- Measuring Instruments Directive: Directive 2004/22/EC on measuring instruments;
- Electromagnetic Compatibility Directive (EMC): Directive 2004/108/EC on the approximation of the laws of the Member States relating to electromagnetic compatibility;
- Low Voltage Directive (LVD): Directive 2006/95/EC on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits;
- Pyrotechnic Articles Directive: Directive 2007/23/EC on the placing on the market of pyrotechnic articles;
- Non-automatic Weighing Instruments Directive: Directive 2009/23/EC on non- automatic weighing instruments;
- Simple Pressure Vessels Directive: Directive 2009/105/EC relating to simple pressure vessels.

The Commission notes the following:

- the major common characteristic of these directives is that they have a similar structure: definitions, essential health and safety

requirements, references to harmonised European standards, requirements for manufacturers, traceability requirements and conformity assessment requirements (all have conformity assessment procedures, eight require the intervention of notified bodies) and safeguard mechanisms;

- some of the directives have cross sectoral relevance (in particular, low voltage, EMC, measuring instruments, equipment for use in explosive atmospheres and pressure equipment) thus reinforcing the expected benefits of alignment for economic operators and national authorities responsible for the surveillance of these markets;
- the sectors concerned are very important industrial sectors which are faced with severe international competition and will therefore benefit from simplification and the guarantee of a level playing field in the EU market. The report sets out the basic data for some of these sectors, including the figures on output and trade balance regarding equipment covered by the directives in question. These underline that enhancing legislative coherence and enabling effective market surveillance, in particular in relation to goods originating in third countries, will have very positive effects.

The main provisions: the proposals covered by this initiative are strictly limited in content to alignment with Decision No 768/2008/EC and the new terminology of the Lisbon Treaty (including the new provisions on comitology). More specifically, they will align definitions, traceability requirements, obligations of economic operators, criteria and procedures for the selection of conformity assessment bodies (notified bodies) and conformity assessment requirements.

The substance of the alignment of the ten directives can be summarised as follows:

(1) Measures intended to address the problem of non-compliance:

- obligations of importers and distributors to check that goods bear the CE marking are accompanied by the required documents and carry traceability information. Additional obligations are imposed on importers;
- obligations of manufacturers to provide instructions and safety information in a language easily understood by consumers and end-users, and to carry out sample testing and product monitoring;
- traceability requirements throughout the whole distribution chain: manufacturers and importers must put their names and addresses on products; every economic operator must be able to inform the authorities from whom he purchased a product and to whom he supplied it;
- reorganisation of safeguard clause procedure (market surveillance) to clarify how the relevant enforcement authorities are informed about dangerous goods and ensure that the same action is taken in relation to that product in all Member States.

(2) Measures intended to ensure the quality of work done by notified bodies:

- reinforcement of the notification requirements for notified bodies (including subcontractors and subsidiaries) such as impartiality, competence in carrying out their activity and the application of guidance developed by coordination groups;
- revised notification process: Member States notifying a body must include information on the evaluation of the competence of that body. Other Member States can object to the notification within a certain period;
- requirements for notifying authorities (i.e. the national authorities responsible for the assessment, notification and monitoring of notified bodies) such as objectivity and impartiality in carrying out their activity;
- information obligations: notified bodies must inform notifying authorities of refusals, restrictions, suspensions and withdrawals of certificates.

(3) Measures intended to ensure greater consistency among directives:

- alignment of commonly used definitions and terminology.
- alignment of the texts of the conformity assessment procedures.

It should be underlined that issues relating to the implementation of EU standardisation policy, which could have knock-on effects on the implementation of the directives covered here, are being dealt with in a separate initiative (the standardisation package).

The Commission has selected instruments for this package on the basis that the only amendments made to them relate to alignment with the provisions of the NLF. No changes are made to the substantive technical aspects of the particular sectoral legislation involved. Accordingly, the Commission calls upon the European Parliament and Council to treat the package as such in order to ensure the overall coherence implicit in the recast technique and to avoid splitting up debates into a collection of sectoral discussions.