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***I
REPORT

on the proposal for a regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products
(COM(2007)0037 – C6-0068/2007 – 2007/0029(COD))

Committee on the Internal Market and Consumer Protection

Rapporteur: André Brie

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty*
***I	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products
(COM(2007)0037 – C6-0068/2007 – 2007/0029(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2007)0037),

– having regard to Article 251(2) and Articles 95 and 133 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0068/2007),

– having regard to Rule 51 of its Rules of Procedure,

– having regard to the report of the Committee on the Internal Market and Consumer Protection and the opinions of the Committee on International Trade, the Committee on the Environment, Public Health and Food Safety and the Committee on Industry, Research and Energy (A6-0491/2007),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission	Amendments by Parliament
Amendment 1 Recital 1	
(1) For the purpose of ***strengthening the*** overall framework ensuring that products respect a high level of protection of public interests, such as health and safety, it is necessary to establish certain rules and principles in relation to accreditation and market surveillance, which are important aspects of that framework.	(1) For the purpose of ***establishing an*** overall framework ensuring that products respect a high level of protection of public interests, such as health and safety***, protection of consumers and of the environment***, it is necessary to establish certain rules and principles in relation to accreditation and market surveillance, which are important aspects of that framework. ***The overall framework for accreditation***

	and market surveillance established by this Regulation should not impact on the substantive rules of existing legislation setting out the provisions to be observed for the purpose of protecting the public interest in areas such as health, safety and protection of consumers and of the environment, but aims at enhancing their operation.

(This AM replaces AM 1 from the Draft Report)

Amendment 2
Recital 2

(2) This Regulation is to be seen as ***part of an overall framework ensuring a high level of safety of products as provided for in*** Decision ……. of the European Parliament and of the Council of ……. setting up a framework for the marketing of products.	(2) This Regulation is to be seen as ***complementary to*** Decision ……. of the European Parliament and of the Council of ……. setting up a framework for the marketing of products.

Amendment 3
Recital 3

(3) ***Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety and Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules already lay down a common and uniform regime on matters covered by this Regulation. In cases governed by food law and feed law the rules laid down in this Regulation should not therefore apply. However, given the specific nature of the accreditation obligations contained in Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products***	(3) ***It is very difficult to adopt Community legislation for every product which exists or which may be developed; there is a need for a broad-based, legislative framework of a horizontal nature to deal with such products, and also to cover lacunae, in particular pending revision of the existing specific legislation, and to complement provisions in existing or forthcoming specific legislation, in particular with a view to ensuring a high level of protection of health, safety, the environment and consumers, as required by Article 95 of the Treaty.***

and foodstuffs as traditional specialities guaranteed, Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs and [Council Regulation (EC) No […/…] of … on organic production and labelling of organic products], it is appropriate that the provisions of this Regulation should apply for the purposes of those accreditation obligations.

(This AM replaces AM 2 from the Draft Report)

Amendment 4
Recital 3 a (new)

(3a) The framework for market surveillance established hereunder should complement and strengthen existing provisions relating to market surveillance in other Community rules. However, in accordance with the principle of lex specialis, this Regulation should apply only in so far as there are no specific provisions with the same objective as those established hereby in other, existing or future, rules of Community law, such as Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety[1].

(1) OJ L 11, 15.1.2002, p. 4.

(This Compromise AM 1 replaces AMs 115 and 116)

Amendment 5
Recital 3 b (new)

(3b) However, in order to achieve a higher level of safety for consumer products, the market surveillance mechanisms provided for in Directive

	2001/95/EC should be reinforced as regards products presenting a serious risk, in accordance with the same principles as those established in this Regulation. Directive 2001/95/EC should therefore be amended accordingly.

Amendment 6
Recital 4

(4) Due to their specific nature, tobacco products under Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of laws, regulations and administrative provisions of the Member States concerning manufacture, presentation and sale of tobacco products should be excluded from this Regulation.	***deleted***

Justification

Cumbersome lists of exceptions that do not further understanding or principles of better regulation and may necessitate frequent revisions of the Regulation in future should be avoided.

Amendment 7
Recital 5

(5) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC, and Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, lay down a common regime for the products covered therein, which should not therefore be	***deleted***

subject to this Regulation.

Justification

See justification to recital 4.

Amendment 8
Recital 6 a (new)

	(6a) The establishment of a uniform national accreditation body shall be without prejudice to the allocation of functions within Member States.

Amendment 9
Recital 10

(10) Regulation (EC) No 761/2001 of the European Parliament and of the Council of 19 March 2001 allowing voluntary participation by organisations in a Community eco-management and audit schemes (EMAS) established a system for the accreditation of independent environmental verifiers and for the supervision of their activities. Since the rules covering that system differ from the provisions of this Regulation, cases governed by Regulation (EC) No 761/2001 should be excluded from the scope of this Regulation.	***deleted***

Justification

See justification to recital 4.

Amendment 10
Recital 14

(14) In those cases where it is not economically meaningful or sustainable for a Member State to establish a national accreditation body, that Member State should have ***the possibility of having***	(14) In those cases where it is not economically meaningful or sustainable for a Member State to establish a national accreditation body, that Member State should have recourse to the national

recourse to the national accreditation body of another Member State.	accreditation body of another Member State ***and should be encouraged to avail itself of that opportunity to the fullest extent possible***.

(This AM replaces AM 6 from the Draft Report)

Justification

Member States should be encouraged more strongly than in the proposal to use the services of the accreditation body of another Member State where relevant.

Amendment 11
Recital 15

(15) In order to avoid duplication of accreditation and to enhance acceptance and recognition of accreditation certificates as well as to perform effective monitoring of accredited conformity assessment bodies, the conformity assessment bodies should ***in principle*** request accreditation by the national accreditation body of the Member State in which they are established. Nevertheless, it is necessary to ensure that a conformity assessment body has the possibility to request accreditation in another Member State in cases where in its Member State there is no national accreditation body or where such body is not competent to provide the requested accreditation services. In these cases, appropriate co-operation and exchange of information between national accreditation bodies should be established.	(15) In order to avoid duplication of accreditation and to enhance acceptance and recognition of accreditation certificates as well as to perform effective monitoring of accredited conformity assessment bodies, the conformity assessment bodies should request accreditation by the national accreditation body of the Member State in which they are established. Nevertheless, it is necessary to ensure that a conformity assessment body has the possibility to request accreditation in another Member State in cases where in its Member State there is no national accreditation body or where such body is not competent to provide the requested accreditation services. In these cases, appropriate co-operation and exchange of information between national accreditation bodies should be established.

Justification

Deleted as unnecessary. The substantive rules (Art 6) contain certain exemptions and is proposed amended to make clear that a conformity assessment body is free to seek accreditation with any accreditation body for non compulsory assessment activities.

Amendment 12

Recital 16

(16) In order to ensure that national accreditation bodies fulfil the requirements and obligations under this Regulation, it is important that Member States support the proper functioning of the accreditation system, perform regular monitoring of their national accreditation bodies and take appropriate corrective measures where necessary.	(16) In order to ensure that national accreditation bodies fulfil the requirements and obligations under this Regulation, it is important that Member States support the proper functioning of the accreditation system, perform regular monitoring of their national accreditation bodies and take appropriate corrective measures ***within a reasonable timeframe*** where necessary.

Justification

See justification to Article 5(3).

Amendment 13
Recital 18

(18) ***The*** main mission ***of the European co-operation for Accreditation (EA)*** is to further a transparent and quality led system to evaluate the competence of conformity assessment bodies throughout Europe***. The EA*** is managing a peer evaluation system among national accreditation bodies from the Member States and other European countries. That system has proved to be efficient and to provide mutual confidence. Therefore, Member States should ensure that their national accreditation bodies seek ***or*** maintain membership in the EA.	(18) ***While this Regulation should provide for the recognition of another body in respect of certain functions in the area of accreditation, the European co-operation for Accreditation (EA), whose*** main mission is to further a transparent and quality led system to evaluate the competence of conformity assessment bodies throughout Europe, is managing a peer evaluation system among national accreditation bodies from the Member States and other European countries. That system has proved to be efficient and to provide mutual confidence. Therefore, ***the EA should be the body initially recognised under this Regulation and*** Member States should ensure that their national accreditation bodies seek ***and*** maintain membership in the EA ***for as long as it is so recognised***. ***At the same time, the possibility for a change in recognition of the relevant body should be provided for, in case there is a need for it in the future.***

(This AM replaces AM 9 from the Draft Report)

Justification

The EA is now in a position to provide services under the Regulation, and should be the body

initially recognised for that purpose, but other bodies may develop in future or the EA might change. The Regulation should be drafted to enable any suitable entity to perform the requisite functions. The proposal to explicitly mention the EA in the Regulation and grant it a form of permanent official standing is furthermore problematic as the EA is an organisation under private law. This reasoning does in no way question the competence of the EA, which it has sufficiently proved over many years.

Amendment 14
Recital 20

(20) The sectoral accreditation schemes should cover the fields of activity where general requirements for competence of conformity assessment bodies are not sufficient to ensure the necessary level of protection where specific detailed technology or health and safety related requirements are imposed. Given the fact that the EA has at its disposal a broad range of technical expertise, it should be requested to develop such schemes, especially for areas covered by Community legislation.	(20) The sectoral accreditation schemes should cover the fields of activity where general requirements for competence of conformity assessment bodies are not sufficient to ensure the necessary level of protection where specific detailed technology or health and safety related requirements are imposed. Given the fact that the EA has at its disposal a broad range of technical expertise, it should be requested***, as the body initially recognised hereunder,*** to develop such schemes, especially for areas covered by Community legislation.

Justification

See justification to recital 18.

Amendment 15
Recital 22

(***22) In certain sectors Community requirements already exist in order to ensure that market surveillance activities are carried out on the basis of common rules. To avoid any overlaps, those sectors should not be not subject to this Regulation. Hence, the following instruments should be excluded from the provisions on market surveillance but come under the scope of the provisions for control of products from third countries: Council Directive 70/156/EEC of 6***	***deleted***

February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers, Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Directive 97/68/EC of the European Parliament and of the Council of 16 December 1997 on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from the internal combustion engines to be installed in non-road mobile machinery, Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Directive 2002/88/EC of the European Parliament and of the Council of 9 December 2002 amending Directive 97/68/EC on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, Directive 2002/24/EC of the European Parliament and of the Council of 18 March 2002 relating to the type-approval of two or three-wheel motor vehicles and repealing Council Directive 92/61/EEC, Regulation (EC) No 1592/2002 of the European Parliament and of the Council of 15 July 2002 on common rules in the field of civil aviation and

establishing a European Aviation Safety Agency, Directive 2003/37/EC of the European Parliament and of the Council of 26 May 2003 on type-approval of agricultural or forestry tractors, their trailers and interchangeable towed machinery, together with their systems, components and separate technical units and repealing Directive 74/150/EEC, Directive 2004/26/EC of the European Parliament and of the Council of 21 April 2004 amending Directive 97/68/EC on the approximation of the laws of the Member States relating to measures against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

(This AM replaces AM 11 from the Draft Report)

Justification

See justification to Recital 4

Amendment 16
Recital 23

(23) Directive 2001/95/EC of the European Parliament and of the Council on general product safety has set up a market surveillance and administrative cooperation framework in respect of consumer products. The provisions of this	***deleted***

Regulation on market surveillance should not apply in relation to products, as defined in Article 2(a) of Directive 2001/95/EC, in so far as the health and safety of consumers is concerned.

Justification

The scope of the framework established by this Regulation for market surveillance should be as broad as possible and should subsume the GPSD. It is often unclear whether a product is a consumer product or not, and to not subsume the GPSD would risk creating confusion as to the rules that apply to a particular product. To include the GPSD in the framework established hereby represents a simplification of the overall market surveillance framework; to exclude it risks complication and fragmentation.

Amendment 17
Recital 23 a (new)

(23a) Appropriate independent certification, recognised by the competent authorities, may facilitate proof of compliance with the applicable product safety criteria.

Justification

This wording is identical with Recital 17 of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

Manufacturers do not always have the requisite specialist knowledge and, not least on cost grounds, choose to rely on the skills of independent certifiers.

Independent certifiers are familiar with the latest research and have the requisite know-how.

Amendment 18
Recital 24

(24) Cooperation of competent authorities at the national level and across borders in exchanging information, investigating infringements and taking action to bring about their cessation is essential to the protection of health and safety and to guaranteeing the smooth functioning of the internal market.	(24) Cooperation of competent authorities at the national level and across borders in exchanging information, investigating infringements and taking action to bring about their cessation***, even before the placing on the market of dangerous products, by reinforcing measures to identify them, mainly in seaports where 90% of imports into the European Union***

	are concentrated, is essential to the protection of health and safety and to guaranteeing the smooth functioning of the internal market. ***National consumer protection authorities should cooperate, at national level, with national market surveillance authorities and should exchange information with them relating to products which they suspect to present a risk.***

(This AM merges ITRE AM 2 and ENVI AM 2 (not yet translated so taken from AM document))

Justification

As individual consumers usually turn to the national consumer protection authorities in case of quality or safety problems, the relevant information should be forwarded to the market surveillance authorities for possible follow-up.

Amendment 19
Recital 28

(28) Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries lays down rules regarding the suspension of the release of products by customs authorities and provides for further proceedings including the involvement of market surveillance authorities. It is therefore appropriate that those provisions, including the involvement of market surveillance authorities, be integrated into this Regulation and have ***the same*** scope.	(28) Council Regulation (EEC) No 339/93 of 8 February 1993 on checks for conformity with the rules on product safety in the case of products imported from third countries lays down rules regarding the suspension of the release of products by customs authorities and provides for further proceedings including the involvement of market surveillance authorities. It is therefore appropriate that those provisions, including the involvement of market surveillance authorities, be integrated into this Regulation and have ***a similar*** scope.

(This AM replaces AM 15 from the Draft Report)

Amendment 20
Recital 28 a (new)

	(28a) Within one year after the publication of this Regulation in the

Official Journal of the European Union, the Commission shall present an in-depth analysis in the realm of consumer safety markings, if needed followed by legislative proposals.

Amendment 21
Recital 29

(29) Points of entry at the external borders are well placed to detect unsafe products even before they are placed on the market. An obligation for customs authorities to execute checks on an adequate scale can therefore contribute to a safer market place.	(29) Points of entry at the external borders are well placed to detect unsafe ***non-conforming*** products ***or products to which false or misleading CE markings have been affixed*** even before they are placed on the market. An obligation for customs authorities to execute checks on an adequate scale can therefore contribute to a safer market place. ***In order to increase the effectiveness of these checks, the customs authorities should get all necessary information about dangerous non-conforming products from the market surveillance authorities well in advance.***

Justification

The cooperation and exchange of information between customs and market surveillance authorities must be improved with a view to a more effective control at the Community borders. Market surveillance must be preventive, not reactive, and improved information is a necessary prerequisite for that. With regard to the obligations of the operators it has to be clear that all relevant economic operators are under an equal legal obligation for their equivalent role in placing a product on the European market.

Amendment 22
Recital 30 a (new)

(30a) It is necessary for Member States to provide for appropriate means of redress before the competent courts in respect of measures taken by the competent authorities which restrict the placing on the market of a product or require its withdrawal or recall.

Justification

If the authorities of a Member State have required an economic operator to recall a product but the action was found to be incorrect then the operator must be able to seek redress. This text is identical to Recital 37 of the General Product Safety Directive and, as such, is not a new or untried concept.

Amendment 23
Recital 30 b (new)

	(30b) Member States may find it useful to establish co-operation agreements with stakeholders, in particular with sectoral professional organisations, in order to take advantage of available market intelligence when establishing, implementing and updating market surveillance programmes.

Justification

Cooperation with stakeholders is already practiced in some Member States; the purpose of this amendment to encourage this good practice and to ensure that it is not prevented in a Member State due to unclear legislation.

Amendment 24
Recital 31

(31) *The* Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.	(31) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive ***and must be proportionally increased if the relevant economic operator has committed a similar infringement of the provisions of this Regulation in the past***.

Justification

It is one thing to breach the regulation just once, but another thing to breach it repeatedly. The penalty must be more severe in the latter case so that it is indeed dissuasive.

Amendment 25
Recital 32

(32) In order to achieve the objectives of this Regulation, it is necessary for the Community to contribute to the financing of activities required to implement the policies in the field of accreditation and market surveillance. Financing should be provided either in the form of grants without a call for proposals to the ***EA***, or in the form of grants with a call for proposals or by awarding contracts to ***the EA*** or ***to*** other bodies, depending on the nature of the activity to be financed and in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities, hereinafter "the Financial Regulation".	(32) In order to achieve the objectives of this Regulation, it is necessary for the Community to contribute to the financing of activities required to implement the policies in the field of accreditation and market surveillance. Financing should be provided either in the form of grants without a call for proposals to the ***body recognised under Article 12a***, or in the form of grants with a call for proposals or by awarding contracts to ***that*** or other bodies, depending on the nature of the activity to be financed and in accordance with Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities, hereinafter "the Financial Regulation".

Justification

See justification to Recital 18. The substitution of "EA" by "body recognised under Article 12a" should apply throughout the text and is not reflected in separate later amendments unless specifically required.

Amendment 26
Article 1, paragraph 1

1. ***This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing assessment of any substance, preparation or other product, whether or not such substance, preparation or product has undergone transformation, to be placed on the Community market.*** ***It also provides a framework for market surveillance and the control of products from third countries to ensure that substances, preparations and transformed products subject to Community legislation harmonising the conditions for the marketing of products, hereinafter "Community harmonisation legislation"*** respect a high level of protection of public	1. ***To ensure that products benefiting from the free movement of goods within the Community*** respect a high level of protection of public interests such as health and safety in general, health and safety at the workplace, protection of consumers ***and*** of the environment***, while ensuring that the free movement of products is not restricted beyond what is allowed under Community harmonisation legislation and any other relevant Community rules***, ***this Regulation provides a framework supporting specific rules of existing and future sectoral Community harmonisation legislation, without making any substantive changes to that legislation, in particular not to rules contained therein relating to protection of health and the environment and any***

interests such as health and safety in general, *of* health and safety at the workplace, protection of consumers***,*** of the environment, ***and of security***.	***specific rules on accreditation and market surveillance that may be contained therein. For these purposes, this Regulation lays down:*** ***(a) rules on the organisation and operation of accreditation of conformity assessment bodies;*** ***(b) a framework for market surveillance and for the control of products from third countries;*** ***(c) provisions relating to the Community CE mark and CE marking.***

(This AM replaces AMs 20, 21, 23 and 24 from the Draft Report)

Amendment 27
Article 1, paragraph 2

2. This Regulation shall not apply in cases governed by: ***(a) food law as defined in Article 3 of Regulation (EC) N° 178/2002 with the exception, as regards Chapter II, of Regulation (EC) N° 509/2006, 510/2006 and […/…] [on organic production and labelling of organic products];*** ***(b) feed law as defined in Article 3 of Regulation (EC) N° 882/2004;*** ***(c) Directive 2001/37/EC;*** ***(d) Directive 2002/98/EC;*** ***(e) Directive 2004/23/EC.***	***deleted***

Justification

The foreseen clause would disapply the Regulation from some important areas ruled by specific European legislation. As a matter of fact, accreditation is already largely utilized in most of the areas in question, and therefore the exclusions foreseen would be detrimental to the desirable achievement of quality objectives in those fields.

Amendment 28
Article 2, point -1 (new)

(-1) "products" shall mean any substance, preparation or other good, whether transformed or not;

(This AM replaces AM 25 from the Draft Report)

Amendment 29
Article 2, point 3

(3) "manufacturer" means any natural or legal person who designs or manufactures a product or who has such a product designed or manufactured, under his name or trademark;	(3) "manufacturer" means any natural or legal person who designs or manufactures a product or who has such a product designed or manufactured, under his name or trademark***, and who places it on the market***;

Justification

Bring the definition in consistency with the definitions of other market players.

Amendment 30
Article 2, point 5

(5) "distributor" means any natural or legal person in the supply chain, who makes a product available on the market;	(5) "distributor" means any natural or legal person in the supply chain***, other than the manufacturer or the importer***, who makes a product available on the market***;***

Justification

The distinction between economic operators who have similar roles in placing product on the market and those who are not making product available for the first time has to be clarified. The legal entity placing a product on the Community market should bear the responsibility that the product conforms to requirements. That is not the case of distributors.

Amendment 31
Article 2, point 9

(9) "harmonised standard" means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC in accordance with Article 6 of Directive *98/34/EC*;	(9) "harmonised standard" means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC ***on the basis of a remit issued by the Commission*** in accordance

with Article 6 of *that* Directive;

Amendment 32
Article 2, point 10

(10) "accreditation" means ***a third-party*** attestation***, related to a*** conformity assessment body***, conveying formal demonstration of its competence*** to carry out specific conformity assessment ***tasks***;	(10) "accreditation" means ***an*** attestation ***by a national accreditation body that a*** conformity assessment body ***meets the requirements (inter alia as to competence)*** to carry out ***the*** specific conformity assessment ***activities, set by harmonised standards and, where applicable, any additional requirements, including those set out in relevant sectoral schemes***;

Justification

The reference to "third party" is unnecessary as only a national accreditation body can provide accreditation under the Regulation. The scope of accreditation is defined by the standards that set the requirements for competence of conformity assessment bodies. If standards (harmonized or additional) are not referred to expressly the Regulation could apply to other schemes e.g. accreditation of journalists. The word "competence" should be interpreted in its wider meaning. The reference to "sectoral accreditation schemes" contemplates schemes referred to in Article 12(2).

Amendment 33
Article 2, point 13 a (new)

	(13a) "Community harmonisation legislation" means any Community legislation harmonising the conditions for the marketing of products;

Justification

This definition has been moved from Article 1 to collect all definitions in the same place.

Amendment 34
Article 2, point 13 b (new)

	(13b) "entering the Community market" means being presented for customs clearance;

Justification

To clarify the meaning of the expression "products entering the Community market" used in section 3 of Chapter III.

Amendment 35
Article 2, point 13 c (new)

(13c) "conformity assessment" means the demonstration that a product, process, system, person or body fulfils the specific requirements set out in the legislative instrument or instruments that apply to them;

Justification

The term conformity assessment should be defined, since this term is used extensively in the Regulation. The definition should be taken from ISO/IEC 17000:2004 'Conformity assessment – Vocabulary and general principles'.

Amendment 36
Article 2, point 13 d (new)

(13d) "conformity assessment body" means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

Amendment 37
Article 2, point 13 e (new)

(13e) "CE marking" means a marking which materializes the declaration of the manufacturer that the product is in conformity with all applicable requirements for its placing on the market;

Justification

The CE marking materializes the declaration of the manufacturer (or of his authorized representative) that the product is in conformity with all the applicable requirements. It does not attest the actual conformity of a product with the applicable requirements, which would be incorrect because in that case market surveillance - which of course covers also CE-marked products - would be superfluous for those products.

Amendment 38
Article 2, point 13 f (new)

(13f) "market surveillance" means the activities carried out and measures taken by public authorities to ensure that products are in compliance with legal requirements set out in the relevant Community legislation;

Amendment 39
Article 2, point 13 g (new)

(13g) "market surveillance authority" means the authority or authorities of each Member State responsible for carrying out market surveillance on its territory;

Justification

This definition has been moved from Article 15 to collect all definitions in the same place.

Amendment 40
Article 2, point 13 h (new)

(13h) "peer evaluation" means an assessment process between national accreditation bodies carried out against the requirements of this Regulation and additional sectoral technical specifications where applicable;

Amendment 41
Article 2, point 13 i (new)

(13i) "release for free circulation" means the procedure for conferring on non-Community goods the customs status of Community goods as laid down in the

Community Customs Code;

Amendment 42
Article 3, paragraph 1

1. Where accreditation is used on a compulsory or voluntary basis to assess the competence of conformity assessment bodies to carry out conformity assessment ***of any substance, preparation or other product, whether or not such substance, preparation or product has undergone transformation,*** this Chapter shall apply, irrespective of the legal status of the body performing the accreditation.	1. Where accreditation is used on a compulsory or voluntary basis to assess the competence of conformity assessment bodies to carry out conformity assessment this Chapter shall apply, irrespective of the legal status of the body performing the accreditation.

Justification

The definition of product is proposed included among the other definitions in Article 2.

(This AM replaces AM 32 from the Draft Report)

Amendment 43
Article 3, paragraph 2

2. This Chapter shall apply to accreditation referred to in Regulations (EC) Nos 509/2006 and 510/2006 and […/…] [on organic production and labelling of organic products].	***deleted***

Justification

The Regulations 509/2006 and 510/2006 are not to be excluded from the scope of this Regulation. Accreditation is already widely used for a variety of conformity assessment activities regarding a variety of food products. The scope of the accreditation framework should be as wide as possible to prevent the creation of several parallel systems, but it should be clearly linked to the existing framework.

Amendment 44
Article 3, paragraph 3

3. This chapter shall not apply in cases governed by Regulation (EC) No	***deleted***

761/2001.

Justification

The Regulation 761/2006 is not to be excluded from the scope of this Regulation. To exclude the use of accreditation for attesting the competence of EMAS verifiers is not justified as accreditation is already employed for such purpose in the vast majority of the Member States with clear benefits. The scope of the accreditation framework should be as wide as possible to prevent the creation of several parallel systems, but it should be clearly linked to the existing framework.

Amendment 45
Article 4, paragraph 2

2. Where a Member State considers it not economically meaningful or sustainable to have a national accreditation body or to provide certain accreditation services, it ***may*** have recourse to a national accreditation body of another Member State.	2. Where a Member State considers it not economically meaningful or sustainable to have a national accreditation body or to provide certain accreditation services, it ***should*** have recourse to a national accreditation body of another Member State.

Justification

If a Member State opts to not establish a national accreditation body, or to limit its duties, the Member State should as the main rule make use of an accreditation body of another Member State. While it is not proposed to make that obligatory, it should be expressed in stronger terms than simply a possibility for the Member State to do so.

Amendment 46
Article 4, paragraph 3, subparagraph 2 a (new)

	On the basis of the information referred to in subparagraphs 1 and 2, the Commission shall draw up and update the list of the national accreditation bodies operating in each Member State. That list shall be made publicly available by the Commission.

(This AM replaces AM 36 from the Draft Report)

Amendment 47
Article 4, paragraph 4

4. The national accreditation body shall ***be***	4. The national accreditation body shall ***act***

deemed to exercise public authority.	***as a*** public authority ***and in the public interest***.

Justification

To clarify the reference to exercise of public authority, which may have different meanings in different Member States, and to emphasise that the national accreditation bodies shall serve an important public interest.

Amendment 48
Article 4, paragraph 6

6. The national accreditation body shall operate on a non profit basis. It may not offer or provide any activities or services that conformity assessment bodies provide, ***nor may it*** provide consultancy services.	6. The national accreditation body shall operate on a non profit basis. It may not offer or provide any activities or services that conformity assessment bodies provide, provide ***commercial*** consultancy services***, own shares or otherwise have a financial or managerial interest in a conformity assessment body***.

Justification

Measures must be taken to ensure independence of both the national accreditation body and the conformity assessment bodies; and the list of these measures has to be completed with the one guaranteeing financial and managerial separation.

Amendment 49
Article 4, paragraph 8

8. The national accreditation body shall ***seek membership*** of ***European co-operation for Accreditation (EA)***.	8. The national accreditation body shall ***be a member*** of ***the body recognised under Article 12a***.

Justification

Voluntary membership in the recognised body is not sufficient because it would make the entire concept of European accreditation inconsistent. The change in Article 4(8) is in line with the general view on the desirability of identifying the EA as the one and only body to be granted special status under the Regulation expressed in the amendment to Recital 18.

Amendment 50
Article 4, paragraph 8 a (new)

	8a. National accreditation bodies shall establish and maintain appropriate structures to ensure the effective and

balanced involvement of all interested parties both within their organisations and the European accreditation network.

Justification

In order to balance the proposed non-competition status of accreditation and to ensure the safeguard of the required impartiality of national accreditation bodies, stakeholder interests should be adequately represented, both within the national accreditation bodies and the European accreditation network.

Amendment 51
Article 5, paragraph 1 a (new)

1a. Where a notification of a conformity assessment body is not based on an accreditation certificate, the notifying authority shall provide the Commission and the other Member States with all documentary evidence necessary for the verification of the competence of the conformity assessment body.

Justification

An important aim of the Regulation is to encourage the use of accreditation. Where a Member State nevertheless opts to not use accreditation, it should be obliged to demonstrate conclusively to the other Member States and the Commission that the competence of the conformity assessment body has been verified to the same level as if an accreditation body had been used. The text is carried over from the proposed Decision with some adjustments.

Amendment 52
Article 5, paragraph 3

3. Where the national accreditation body ascertains that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific conformity assessment activity or commits a serious breach of its obligations, the national accreditation body shall take all appropriate measures to restrict, suspend or withdraw its accreditation certificate.	3. Where the national accreditation body ascertains that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific conformity assessment activity or commits a serious breach of its obligations, the national accreditation body shall take all appropriate measures ***within a reasonable timeframe*** to restrict, suspend or withdraw its accreditation certificate.

Justification

National accreditation bodies shall take all appropriate measures within a reasonable timeframe to restrict, suspend or withdraw the accreditation certificate of a conformity assessment body in cases of incompetence of the latter. The evaluation of whether the measure has been taken with reasonable promptness would ultimately be for the courts but should depend on the seriousness of the problem in the individual case. A delay of even a short period could be deemed unreasonable if the circumstances and effects are sufficiently grave.

Amendment 53
Article 5, paragraph 4

4. Member States shall ***establish*** procedures for the resolution of appeals and complaints ***made against accreditation decisions, or the absence thereof***.	4. Member States shall ***ensure the establishment of*** procedures for the resolution of appeals ***made against accreditation decisions, or the absence thereof,*** and ***for the resolution of*** complaints.

Justification

In case national accreditation bodies fail to meet their obligations it has to be guaranteed that effective legal measures are available under national law so that the situation can be remedied.

Amendment 54
Article 5, paragraph 4 a (new)

	4a. Notwithstanding the provisions of this Regulation, in the area of medicinal products Member States shall have the right to impose additional requirements on notified bodies which they regard as essential to guarantee active, preventive and systematic market surveillance, and to achieve the active protection of patients, users and other third parties and compliance with the rules governing medicinal products laid down in Directive 93/42/EEC.

(This oral AM is based on AM 174)

Amendment 55
Article 5 a (new), title and paragraph 1

Article 5a
Principle of non-competition

1. National accreditation bodies shall not compete with conformity assessment bodies.

Amendment 56
Article 5 a (new), paragraph 2

2. National accreditation bodies shall not compete with other national accreditation bodies within the territory of the European Union with respect to accreditation for compulsory conformity assessment activities.

Amendment 57
Article 5 a (new), paragraph 3

3. National accreditation bodies, however, shall 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 the circumstances specified in Article 6(1) or if they are asked to do so by a national accreditation body under Article 6(3) in co-operation with the national accreditation body of that Member State.

Amendment 58
Article 6, paragraph 1, subparagraph 1

1. Where a conformity assessment body requests accreditation, it shall do so with the national accreditation body of the Member State in which it is established or with the national accreditation body to which that Member State has had recourse pursuant to Article 4(2).	1. Where a conformity assessment body requests accreditation ***for a compulsory conformity assessment activity***, it shall do so with the national accreditation body of the Member State in which it is established or with the national accreditation body to which that Member State has had recourse pursuant to Article 4(2).

Justification

European conformity assessment bodies have to compete with conformity assessment bodies from outside Europe. The cross-frontier accreditation policy for conformity assessment bodies from outside Europe is specified in Guidance by the International Accreditation Forum (IAF). The requirements for cross-frontier accreditation in the voluntary field should not be more restrictive than the policies by the IAF and by the International Laboratory Accreditation Co-operation (ILAC) to avoid unnecessary disadvantages (costs, bureaucracy) for the European bodies.

Amendment 59
Article 7, point 9 a (new)

(9a) it shall make it possible and guarantee 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.

Amendment 60
Article 8, paragraph 1, subparagraph 2

Member States ***may*** choose to accept successful peer evaluation under Article 9 as fulfilling the needs of the monitoring provided for in the first paragraph.	Member States ***shall*** choose to accept successful peer evaluation under Article 9 as fulfilling the needs of the monitoring provided for in the first paragraph.

Amendment 61
Article 8, paragraph 2 a (new)

2a. National accreditation bodies shall have in place appeal procedures to provide economic operators with a means of redress where they can demonstrate that an accredited body does not have the minimum required skills or competence, or that it is exhibiting bias.

Justification

The existing proposal provides for a procedure whereby Member States are required to monitor their national accreditation bodies at regular intervals. This protects the general public interest. However, since the actions of national accreditation bodies, and the bodies they accredit, have a direct impact on economic operators, the latter should have an explicit means of redress.

Amendment 62
Article 9, paragraph 1

1. National accreditation bodies shall ***operate a*** peer evaluation ***system and participate in it***.	1. National accreditation bodies shall ***subject themselves to*** peer evaluation ***as organised by the body recognised under Article 12a***.

Amendment 63
Article 9, paragraph 1 a (new)

	1a. Stakeholders shall have the right to participate in the system set up for the supervision of peer evaluation activities.

Justification

To be credibly independent the system should not be a closed loop among 'peers' accrediting themselves within a small 'club'. National authorities participating in peer assessment should not deprive themselves of the competence of the users of the system: the industry. The international scheme for the approval of electrical products according to IEC standards relies on peer assessment and is open to interested stakeholders at the management level: the same is also true in Europe within the association of the European Certification bodies active in the Low Voltage Directive area.

Amendment 64
Article 9, paragraph 2

2. Member States shall ensure that their national accreditation bodies regularly undergo peer evaluation.	2. Member States shall ensure that their national accreditation bodies regularly undergo peer evaluation***, as required by paragraph 1***.

Amendment 65
Article 9, paragraph 3

3. The peer evaluation shall be operated on the basis of sound and transparent evaluation criteria and procedures. Appropriate appeals procedures against decisions taken as a result of the evaluation shall be provided for.	3. The peer evaluation shall be operated on the basis of sound and transparent evaluation criteria and procedures***, especially concerning structural, human resource and process requirements, confidentiality and complaints***. Appropriate appeals procedures against decisions taken as a result of the evaluation shall be provided for.

Justification

To add certain elements as part of the obligatory basis of the peer evaluation. The reports on the peer evaluation should address these areas, as well any other relevant areas, under separate headings in a format enabling convenient comparison of all reports.

Amendment 66
Article 9, paragraph 4

4. The peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 7.	4. The peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 7. ***National accreditation bodies that have successfully undergone peer evaluation shall recognise the equivalence of each others' accreditations and the conformity assessment results issued by bodies accredited by them.***

Justification

Membership to the body recognized under Article 12a does not imply the obligation for national accreditation bodies to participate in the peer evaluation, which is the key instrument to achieve equivalence, transparency and consistency of accreditation practice. The peer evaluation system should be organised at European level and be operated according to harmonised rules.

Amendment 67
Article 9, paragraph 5

5. The results of the peer evaluation shall be communicated to all Member States and the Commission.	5. The ***final*** results of the peer evaluation shall be ***published and*** communicated to all Member States and the Commission.

Justification

The results of the evaluation must not only be made known to the Member States and the Commission but must also be accessible to all interested parties.

Amendment 68
Article 9, paragraph 6

6. The Commission shall oversee the rules and the proper functioning of the peer evaluation system.	6. The Commission shall***, in co-operation with the Member States,*** oversee the rules and the proper functioning of the peer evaluation system.

Amendment 69
Article 10, title

Presumption of conformity	Presumption of conformity ***for national accreditation bodies***

Justification

Compliance with the standard is to be demonstrated through the peer evaluation process established within EA. If the use of accreditation is to support efficiently the proper functioning of the internal market by increasing mutual confidence, then the accreditation bodies themselves need to be required to actively demonstrate that the confidence placed in them is justified.

Amendment 70
Article 10

National accreditation bodies that ***comply*** with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the Official Journal of the European Union, shall be presumed to fulfil the requirements set out in Article 7.	National accreditation bodies that ***demonstrate conformity*** with the criteria laid down in the relevant harmonised standard, the reference of which has been published in the Official Journal of the European Union, ***by successful participation in the peer evaluation system set out in Article 9,*** shall be presumed to fulfil the requirements set out in Article 7.

Justification

Compliance with the standard is to be demonstrated through the peer evaluation process established within the body recognized under Article 12a. If the use of accreditation is to support efficiently the proper functioning of the internal market by increasing mutual

confidence, then the accreditation bodies themselves need to be required to actively demonstrate that the confidence placed in them is justified.

Amendment 71
Article 11, paragraph 2

2. A national accreditation body shall inform the competent national authorities ***and*** the Commission of all conformity assessment activities in respect of which it operates accreditation in support of Community legislation and of any changes thereto.	2. A national accreditation body shall inform the competent national authorities***,*** the Commission ***and the body recognised under Article 12a of this Regulation*** of all conformity assessment activities in respect of which it operates accreditation in support of Community legislation and of any changes thereto.

Justification

The inclusion of "the body recognised under Article 12A of this regulation" into the information obligation for national accreditation bodies will increase the transparency among the various actors.

Amendment 72
Article 11, paragraph 3

3. A national accreditation body shall make publicly available information about the results of its peer evaluation, the conformity assessment activities in respect of which it operates accreditation and about any changes thereto.	3. A national accreditation body shall make ***regularly and*** publicly available information about the results of its peer evaluation, the conformity assessment activities in respect of which it operates accreditation and about any changes thereto.

Justification

The information about the results of the peer evaluation should be publicly available and on a regular basis.

Amendment 73
Article 12, paragraph 2

The Commission may also, following the procedure laid down *in* the first paragraph***,*** ***request the EA*** to develop sectoral accreditation schemes.	The Commission may also, following the procedure laid down *in* the first paragraph***:***
	(a) accept any such existing schemes that already lay down evaluation criteria and

procedures for peer evaluation;

(b) request the body recognised under Article 12a to lay down evaluation criteria and procedures for peer evaluation and to develop sectoral accreditation schemes.

Justification

The Regulation gives the body recognised under Article 12a a major role to ensure the homogeneity and further the quality of accreditation within Europe. Therefore the system of peer evaluation, under the responsibility of the body recognised under Article 12a, should also be under the control of the Member States and the Commission.

Amendment 74
Article 12, paragraph 3

Such schemes shall identify the sectoral technical specifications necessary to ensure the level of competence required by Community harmonisation legislation in fields with specific technology or health and safety related requirements.	Such schemes shall identify the sectoral technical specifications necessary to ensure the level of competence required by Community harmonisation legislation in fields with specific technology or health***,*** ***environment*** and safety related requirements.

Justification

The reference to the protection of the environment has been made already under previous articles not the least because cases of non-conformity with existing EU legislation in the environmental field also have to be dealt with.

Amendment 75
Article 12 a (new), title and paragraph 1

Article 12a

European accreditation infrastructure

1. The Commission shall, after consultation with the Member States, recognise a body which satisfies the requirements of the Annex to this Regulation.

Justification

The objective is to provide a set of basic requirements for the appointment of the recognised body, and for the framework agreement to be concluded with it, while ensuring that the

agreement can be terminated whether due to breach or without cause, in the latter case for example if an alternative body meeting the same requirements more effectively, or meeting higher requirements, has developed and therefore should be used instead, or simply for renegotiation.

Amendment 76
Article 12 a (new), paragraph 2

2. In order for a body to be recognised, it shall conclude a framework agreement with the Commission. That agreement shall contain, inter alia, the detailed tasks of the body, breach of which will entitle the Commission to terminate the agreement, funding provisions and provisions for the supervision of the recognised body, as well as other provisions customary for an agreement of its type. The Commission and the body concerned shall make the framework agreement public. Both the Commission and the body concerned shall be able to terminate the agreement without cause at the expiry of a reasonable notice period to be defined in the agreement.

Justification

See justification to Article 12 a (new), paragraph 1.

Amendment 77
Article 12 a (new), paragraph 3

3. The Commission shall communicate recognition under paragraph 1 to Member States and the national accreditation bodies.

Justification

See justification to Article 12 a (new), paragraph 1.

Amendment 78
Article 12 a (new), paragraph 4

4. The Commission may recognise only one such body at any given time.

Justification

See justification to Article 12 a (new), paragraph 1.

Amendment 79
Article 12 a (new), paragraph 5

5. The first body recognised under this Regulation shall be the European Co-operation for Accreditation, provided that it has concluded a framework agreement as aforesaid.

(This AM replaces AM 54 from the Draft Report)

Amendment 80
Article 13, paragraph 1 a (new)

1a. Each of the provisions of this Chapter shall apply in so far as there are no specific provisions with the same objective in rules of Community law, including Directive 2001/95/EC of the European Parliament and the Council of 3 December 2001 on general product safety.

(This Compromise AM merges AMs 196 and 197)

Amendment 81
Article 13, paragraph 2

2. Articles 14 to 23 shall not apply to products as defined in Article 2(a) of Directive 2001/95/EC in so far as the health or safety of consumers is concerned.	***deleted***

Justification

Article 13(2) should be deleted to minimise the risk of inconsistency as the borderline between products for consumer and professional use is blurred, and as the exclusion would mean an

unnecessary complication, lead to unclear procedures and responsibilities for the marketing of products. The framework provided by the Regulation should therefore apply also to the GPSD, where that Directive does not provide more specific rules, thus ensuring a high level of protection.

Amendment 82
Article 13, paragraph 3

3. Articles 14 to 23 shall not apply in cases governed by the following Community harmonisation legislation:	***deleted***
(a) Directive 70/156/EEC;	
(b) Directive 76/768/EEC;	
(c) Directive 90/385/EEC;	
(d) Directive 93/42/EEC;	
(e) Directive 97/68/EC;	
(f) Directive 98/79/EC;	
(g) Directive 2001/82/EC;	
(h) Directive 2001/83/EC;	
(i) Directive 2002/24/EC;	
(j) Directive 2002/88/EC;	
(k) Regulation (EC) N° 1592/2002;	
(l) Directive 2003/37/EC;	
(m) Directive 2004/26/EC;	
(n) Regulation (EC) N° 273/2004;	
(o) Regulation (EC) N° 726/2004;	

Justification

In the same way as the exclusion of the GPSD would jeopardise the establishment of a coherent framework for effective market surveillance, so would the far-reaching and sweeping exceptions of entire Directives under Article 13(3). As in the case of the GPSD, any specific rules in other legislation would apply instead of the more general rules of this Regulation, thus guaranteeing that the market surveillance measures will be both without gaps and adequate for the individual products.

Amendment 83
Article 13, paragraph 4

4. Articles 24 to 26 shall apply only in so far as other Community legislation does not contain specific provisions relating to the organisation of border controls on specific products.	***deleted***

Justification

Reworded and made into a new Article 13 paragraph 1a, above.

Amendment 84
Article 14

Member States shall organise and perform surveillance ***in order to ensure that products on the Community market, or entering that market, which are covered by Community harmonisation legislation, satisfy the provisions of the relevant Community harmonisation legislation and that they do not, under the condition that they are*** properly installed***,*** maintained ***and used***, compromise health or safety or ***other issues of public interest protection set out in the relevant Community harmonisation legislation***.	Member States shall organise and perform ***market*** surveillance ***as set out in this Chapter***. ***The objective of market surveillance is to 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***.

(This AM replaces AMs 61 and 65 from the Draft Report)

Amendment 85
Article 14, paragraph 1 a (new)

	1a. Member States shall not prohibit, restrict or impede the making available on the market within their territories of a product unless such prohibition, restriction or impediment is based on and complies with the requirements set out in this Regulation or Community harmonisation

legislation.

(This AM replaces AM 62 from the Draft Report)

Amendment 86
Article 14, paragraph 1 b (new)

1b. Member States shall ensure that their market surveillance covers the full range of products which are subject to legal requirements, irrespective of whether they are intended for consumers or likely to be used by consumers, or intended for professional use.

Justification

In order to create a maximum legal certainty, it needs to be specified that the market surveillance is undertaken on the full range of products which need to comply with legal requirements.

Amendment 87
Article 15, paragraph 1

Each Member State shall inform the Commission ***and*** the other Member States ***of the authorities competent to perform market surveillance on its territory, hereinafter "the market surveillance authorities"***.	***1.*** Each Member State shall inform the Commission ***of the national market surveillance authorities and their areas of competence. The Commission shall transmit this information to*** the other Member States.

(This AM replaces AM 66 from the Draft Report)

Amendment 88
Article 15, paragraph 1 a (new)

1a. Each Member State shall take the measures necessary to ensure that the public is aware of the existence, responsibilities and identity of the national market surveillance authority, as well as how that authority may be contacted.

Justification

See justification to Article 15

Amendment 89
Article 16, paragraph 1

1. Member States shall ensure communication and co-ordination between all the different market surveillance authorities.	1. Member States shall ensure communication and co-ordination between all the different market surveillance authorities ***within their jurisdiction***.

Justification

Clarification.

Amendment 90
Article 16, paragraph 2

2. Member States shall ***establish*** adequate procedures in order to *follow-up* complaints or reports on issues related to risks arising from products falling under Community harmonisation legislation, monitor accidents and damage to health which are suspected to have been caused by those products and follow up and update scientific and technical knowledge concerning safety issues.	2. Member States shall ***ensure that*** adequate procedures ***are established*** in order to *follow up* complaints or reports on issues related to risks arising from products falling under Community harmonisation legislation, monitor accidents and damage to health which are suspected to have been caused by products***, establish adequate procedures to verify that corrective actions have been effectively carried out*** and follow up and update scientific and technical knowledge concerning safety issues.

Justification

Market surveillance should include concrete follow-up of corrective actions. Concern has been expressed by various parties regarding the credibility of the CE marking. Such a credibility gap may stem from two points, firstly an inadequate process for catching those economic operators who purposefully flout Community legislation, and secondly an inadequate follow-up to ensure that, where a product has been found to be non-compliant, it is positively removed from the market. It is a matter for each Member State to verify that corrective actions have been effectively carried out.

Amendment 91
Article 16, paragraph 4

4. Member States shall ***establish, implement*** and periodically ***update*** market surveillance ***programmes***.	4. Member States shall ***ensure that market surveillance programmes are established, implemented*** and periodically ***updated. Each Member State shall draw up a global*** market surveillance ***programme within one year of the date of entry into force of this Regulation and communicate it to the other Member States and the Commission and make it available to the public on the internet. Subsequent updates of that programme shall be communicated and made public in the same manner. Member States may establish co-operation agreements with stakeholders, in particular with sectoral professional organizations, in order to take advantage of available market intelligence.***

(This AM merges AMs 211 and 212)

Amendment 92
Article 16, paragraph 5

5. Member States shall periodically review and assess the functioning of their surveillance activities.	5. Member States shall periodically review and assess the functioning of their surveillance activities. ***Such reviews and assessments shall occur no less frequently than every fourth year and the results thereof shall be communicated to the other Member States and the Commission and made available to the public on the internet.***

(This AM replaces AM 71 from the Draft Report)

Amendment 93
Article 17, paragraph 1, subparagraph 1

1. ***The*** market surveillance authorities shall perform appropriate checks on the characteristics of products on an adequate scale, through documentary, and, where	1. ***Taking into account established principles of risk assessment, complaints and other indications received, the*** market surveillance authorities shall perform

appropriate, physical and laboratory checks on the basis of representative samples.	appropriate checks on the characteristics of products on an adequate scale, through documentary, and, where appropriate, physical and laboratory checks on the basis of representative samples.

Justification

Where appropriate based on a risk assessment and indications of problems, and observing the principle of proportionality, market surveillance authorities should also be able to seize samples, in particular where the risk concerns sales of batches of often inexpensive components or consumer products, which are often rapidly sold-out in a distributor's promotional sale.

Amendment 94
Article 17, paragraph 1, subparagraphs 2 and 3

The authorities shall be entitled to require economic operators to make available such documentation and information as appear to them to be necessary for the purposes of ***Article 14.***	***Subject to the requirement of proportionality,*** the ***market surveillance*** authorities shall be entitled to require economic operators to make available such documentation and information as appear to them to be necessary for the purposes of ***carrying out their activities, including entering*** the premises of economic operators ***and taking the necessary representative samples of products***.
They shall also be entitled to enter the premises of *the* economic operators ***concerned where it appears to them to be necessary for the purposes of Article 14.***	

(This AM replaces AM 73 from the Draft Report)

Amendment 95
Article 17, paragraph 1, subparagraph 3 a (new)

	When market surveillance authorities perform checks as referred to in the first subparagraph, they shall recognise test reports showing conformity carried out by an accredited conformity assessment body within the Community as a valid indication of conformity.

Justification

For the sake of legal certainty, the test reports showing conformity carried out by an accredited notified body shall be recognised by the market surveillance authorities in all Member States.

Amendment 96
Article 17, paragraph 2, subparagraph 1

The market surveillance authorities shall ***take*** appropriate measures in order to alert *the* users *in* their territory *about* any product they have identified as presenting a risk.	The market surveillance authorities shall ***ensure that*** appropriate ***and proportionate*** measures ***are taken*** in order to alert users *within* their territory ***within an adequate timeframe*** *to* any product they have identified as presenting a ***serious*** risk.

(This AM replaces AM 74 from the Draft Report)

Amendment 97
Article 17, paragraph 2 a (new)

	2a. 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 at the address stated on the product in question or in the documentation accompanying the product.

Justification

It is important that the economic operator be informed if another Member State decides to withdraw one of its products. However, Member State authorities cannot be expected to contact the economic operator before sending information to authorities in another Member State, as this would slow the procedure considerably.

Amendment 98
Article 17, paragraph 3

3. The market surveillance authorities shall carry out their duties with due independence ***and*** observe confidentiality ***and professional secrecy***.	3. The market surveillance authorities shall carry out their duties with due independence ***from political and commercial pressure. They shall*** observe confidentiality ***where necessary in order to protect information appropriately identified by the economic operator concerned as a commercial secret or to preserve personal data, subject always to the requirement that information is made***

public under this Regulation in order to protect the interests of users in the Community.

Justification

The market surveillance activities should operate only for the purpose set out in the proposed new paragraph 5 of Article 14 and should thus be independent from both commercial and political pressure. In the balance to be struck between observance of confidentiality and the need to inform the public of serious risks, confidentiality should be limited to the minimum information strictly needed to be kept confidential, such as information shown to be a commercial secret and not necessary to make public in order to provide proper information on the risk.

Amendment 99
Article 18

Member States shall ensure that products which present a serious risk, including a serious risk the effects of which are not immediate, ***requiring*** a rapid intervention are recalled or withdrawn or that they are prohibited from being made available on ***the*** market and that the Commission is ***without delay*** informed in accordance with Article 20.	Member States shall ensure that products which present a serious risk, including a serious risk the effects of which are not immediate, ***and require*** a rapid intervention***,*** are recalled or withdrawn*,* or that they are prohibited from being made available on ***their*** market and that the Commission is informed ***without delay*** in accordance with Article 20.

(This AM replaces AM 76 from the Draft Report)

Amendment 100
Article 18, paragraph 1 a (new)

1a. 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 risk and the likelihood of it occurring. The risk assessment shall take all relevant data into account including, where available, data on risks that have materialised with respect to the product. Account shall also be taken of any measures that may have been taken by the economic operator concerned to alleviate the risk. 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.

(This AM replaces AM 77 from the Draft Report)

Amendment 101
Article 19, paragraph 1

1. Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the making available of a product, to withdraw it from the market or recall it, states the exact grounds on which it is based.	1. Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the making available of a product, to withdraw it from the market or recall it, ***is proportionate and*** states the exact grounds on which it is based.

Justification

In order to ensure that measures are respected by economic operators and the system functions more smoothly, the measures must be proportionate and should not exceed what is appropriate in each case.

Amendment 102
Article 19, paragraph 3

3. Prior to the adoption of a measure as referred to in paragraph 1, the economic operator concerned*,* shall be given the opportunity to put forward his viewpoint, unless such consultation is not possible because of the urgency of the measure to be taken***, as justified by health or safety requirements or other public interests covered by the relevant Community harmonisation legislation***.	3. Prior to the adoption of a measure as referred to in paragraph 1, the economic operator concerned shall be given the opportunity to put forward his viewpoint, unless such consultation is not possible because of the urgency of the measure to be taken***, as justified by health or safety requirements or other grounds relating to the public interest covered by relevant Community harmonisation legislation***. ***If action has been taken without the operator being heard, he shall be given the opportunity to be heard as soon as possible and the action taken shall be reviewed promptly thereafter.***

Justification

This amendment is in line with the proposed broadening of the scope for market surveillance. The addition expresses the general rule in case of ex parte interim measures.

Amendment 103
Article 19, paragraph 3 a (new)

3a. Any measure referred to in paragraph 1 shall be promptly withdrawn or modified to be made less restrictive upon the economic operator demonstrating that he has taken effective action for the removal of the serious risk.

Justification

Article 19(1) contains a number of possible market interventions that could be taken by authorities and the economic consequences resulting from each of these will have varying consequences for economic operators. In line with the general provisions of Community law, the level of market intervention should be proportionate to the level of risk for the public. Provisions with similar effect are already contained within the General Product Safety Directive.

Amendment 104
Article 21, title

Information support system	***General information*** support system

(This AM replaces AM 82 from the Draft Report)

Amendment 105
Article 21, paragraph 1

1. The Commission shall develop and maintain a general archiving and exchange of information system on issues relating to market surveillance activities.	1. The Commission shall develop and maintain a general archiving and exchange of information system on issues relating to market surveillance activities ***and programmes***. ***The system shall appropriately reflect notifications and information transmitted under the Community Rapid Information System.***

(This AM replaces AM 83 from the Draft Report)

Amendment 106
Article 21, paragraph 2, subparagraph 2

The safeguard of confidentiality ***and professional secrecy*** with regard to the information content shall be ensured. The protection of ***professional secrecy*** shall not prevent the dissemination to the market surveillance authorities of information relevant for ensuring the effectiveness of market surveillance activities.	***Without prejudice to subparagraph 2 of Article 17(3), the*** safeguard of confidentiality with regard to the information content shall be ensured. The protection of ***confidentiality*** shall not prevent the dissemination to the market surveillance authorities of information relevant for ensuring the effectiveness of market surveillance activities.

Justification

See justification to Article 21, paragraph 2, first subparagraph

Amendment 107
Article 22, paragraph 2 a (new)

	2a. The Commission shall collect and organise such data on national market surveillance measures as will enable it to fulfil its obligations.

(This AM replaces AM 87 from the Draft Report)

Amendment 108
Article 22, paragraph 2 b (new)

	2b. Before the reporting Member State notifies other Member States and the Commission of its findings and actions, it shall contact the economic operator at the address provided on or accompanying the product (if any). Where the reaction of the economic operator is supplied within a period of twenty-eight days, it shall be included with the report from the Member State. The requirement to include the reaction of the economic operator shall not apply if the reporting Member State has grounds for believing that such a delay would present a significant risk to public health and safety.

Justification

Economic operators should generally be given the opportunity to respond to the view of

authorities, especially when the subject of compliance is to be raised to other Member States, thereby significantly increasing the consequences on their business.

Amendment 109
Article 22, paragraph 2 c (new)

2c. 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 at the address stated on the product in question or in the documentation accompanying the product.

Justification

It is important that the economic operator be informed if another Member State decides to withdraw one of its products. However, Member State authorities cannot be expected to contact the economic operator before sending information to authorities in another Member State as this would slow the procedure considerably.

Amendment 110
Article 23, paragraph 1

1. The Commission shall draw-up and coordinate market surveillance initiatives for which expertise and cooperation of two or more Member States are required in order to share resources and expertise.	1. The Commission shall draw-up and coordinate market surveillance initiatives for which *the* expertise and cooperation of two or more Member States are required in order to share resources and expertise***, including also initiatives for cooperation with third countries***.

Justification

Market surveillance should be effective for all products placed on the EU market regardless of where they are manufactured or how they are distributed. Therefore common initiatives with third countries and an improved co-operation with their respective authorities would first contribute to a better understanding of the complex EU rules and regulations, and furthermore it would encourage these authorities to take measures for the prevention of illegal exports into the EU of non compliant products.

Amendment 111
Article 23, paragraph 2, point (b a) (new)

(ba) develop appropriate programmes for the cooperation with third countries relating to exchange of information and technical support, to promote and assess European systems and activities relating to conformity assessment, market surveillance and accreditation;

Justification

See justification to Article 23, paragraph 1

Amendment 112
Article 23, paragraph 2, point (b b) (new)

(bb) produce an annual report on the enforcement of Community harmonisation legislation;

Justification

It is important to improve information on the implementation of this regulation, which will benefit all economic operators.

Amendment 113
Article 23, paragraph 2, point (b c) (new)

(bc) set up a common, public database, accessible to the Member States' public administrations and economic operators, listing all cases where a product was found to present a serious risk to health and safety or was in breach of Community harmonisation legislation;

Justification

The information dissemination concerning the implementation of the proposed regulation needs to be significantly improved. In this specific case, the common database would enable economic operators in good faith to avoid to enter into business with no reliable counterparts, both from outside and inside the Community.

Amendment 114
Article 23, paragraph 2, point (b d) (new)

	(bd) develop, organise and set up programmes and exchanges of experience, information and best practice, programmes and actions for common projects, information campaigns, joint visit programmes and the sharing of resources in cooperation with third countries accordingly.

Justification

A big number of non-conform products reaching the EC internal market are produced in third countries (e. g. China: 47%). This is very often rooted in inadequate information and training. Therefore common programs and exchanges should be developed and set up in cooperation with these countries accordingly to those in the EC.

Amendment 115
Article 23, paragraph 3

3. Member States shall ensure that their national authorities participate in the activities referred to in paragraph 2, where appropriate.	3. Member States shall ensure that their national authorities participate ***fully*** in the activities referred to in paragraph 2, where appropriate.

Justification

There must be full cooperation between the national authorities in order to ensure that the system is effective, and Member States should not be left a margin of discretion as regards their participation.

Amendment 116
SECTION 2 A (NEW)

	SECTION 2a
	CONFORMITY OF PRODUCTS - CE MARKING

Justification

In order to more effectively address the CE marking, certain fundamental provisions of the proposed Decision are proposed amended and incorporated into the Regulation.

Amendment 117
Article 23 a (new), paragraph 1

Article 23a

General principles of the CE marking

1. The CE mark shall only be affixed by the manufacturer or his authorised representative. The mark may only be affixed where the conditions set out in the relevant Community legislation providing for CE marking have been fulfilled. By affixing or having affixed the CE mark, the manufacturer takes over responsibility for the conformity of the product with the requirements laid down in the relevant Community legislation.

(This AM replaces AM 95 from the Draft Report)

Amendment 118
Article 23 a (new), paragraph 2

2. The CE marking shall be the only marking which attests conformity of the product with the applicable requirements of the relevant Community legislation providing for its affixation. Member States shall refrain from introducing into their national regulations any reference to a conformity marking other than the CE marking in connection with conformity to the provisions contained in the legislation on CE marking.

Amendment 119
Article 23 a (new), paragraph 3

3. Member States shall ensure correct implementation of the regime governing the CE marking and take legal action in the case of improper use. 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.

Justification

See justification to Article 23 b (new), paragraph 1.

Amendment 120
Article 24, paragraph 1

1. Member States shall ensure that their ***customs*** authorities ***perform or have performed*** appropriate checks on the characteristics of a product on an adequate scale before *it* is released for free circulation.	1. Member States shall 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. Member States shall also ensure the effective cooperation between customs and market surveillance authorities, inter alia to carry out*** appropriate checks on the characteristics of a product on an adequate scale, ***in accordance with the principles set out in Article 17(1),*** before *that product* is released for free circulation.

(This AM replaces AM 102 from the Draft Report)

Amendment 121
Article 24, paragraph 1 a (new)

	1a. 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, which shall include the sharing of information relevant to their functions.

Justification

This amendment authorises and requires the flow of information between the authorities in those Member States where more than one kind of authority is involved.

Amendment 122
Article 24, paragraph 2, introductory part

2. ***The customs*** authorities ***shall*** suspend	2. ***Member States shall ensure that the***

release ***of a product*** for free circulation when, in carrying out the checks referred to in paragraph 1***, they make either of the following findings***:	***relevant*** authorities suspend release for free circulation ***within the Community market*** when ***either of the following findings are made during*** the checks referred to in paragraph 1:

Justification

This amendment is consequential to an amendment to 24.1 which makes explicit Member States' freedom to deliver on their common EU obligations in a manner of their choosing.

Amendment 123
Article 24, paragraph 2, point (a)

(a) the product displays characteristics which give cause to believe that the product, under the condition that it is properly installed, maintained and used, presents a serious risk to health ***or*** safety or to any other issue of public interest protection as referred to in ***the second subparagraph of*** Article 1 ***paragraph 1***;	(a) the product displays characteristics which give cause to believe that the product, under the condition that it is properly installed, maintained and used, presents a serious risk to health***,*** safety***, protection of the environment*** or to any other issue of public interest protection as referred to in Article 1;

(This AM replaces AM 104 from the Draft Report)

Amendment 124
Article 24, paragraph 2, point b

(b) the product is not accompanied by the documentation required by the relevant Community harmonisation legislation or is not marked in accordance with such legislation.	(b) the product is not accompanied by the ***written or electronic*** documentation required by the relevant Community harmonisation legislation or is not marked in accordance with such legislation.

Justification

This amendment adds the term "written or electronic documentation" to remove any ambiguity in the interpretation of "documentation".

Amendment 125
Article 24, paragraph 2, point b a (new)

	(ba) the product is affixed with a false or misleading CE marking.

Justification

National customs authorities must be in a position to suspend the circulation of any product on the market if it is affixed with a false or misleading CE marking.

Amendment 126
Article 25, paragraph 1

1. A product the release of which has been suspended by the customs authorities pursuant to Article 24 shall be released if, within ***three*** working days of the suspension of release, the customs authorities have not been notified of any action taken by the market surveillance authorities and provided that all the other requirements and formalities pertaining to such release have been met.	1. A product the release of which has been suspended by the customs authorities pursuant to Article 24 shall be released if, within ***five*** working days of the suspension of release, the customs authorities have not been notified of any action taken by the market surveillance authorities and provided that all the other requirements and formalities pertaining to such release have been met.

Justification

Article 25 gives three days to (internal) MSA for action; otherwise the product is to be released for free circulation. Three days is barely enough to simply exchange mails between two public administrations and public safety has not to suffer from administrative delays, in case of dangerous goods.

Amendment 127
Article 26, paragraph 2, subparagraph 1

2. Where the market surveillance authorities find that the product concerned does not comply with the Community harmonisation legislation, they shall take appropriate action which may***, if necessary,*** include prohibiting the product from being placed on the market.	2. Where the market surveillance authorities find that the product concerned does not comply with the Community harmonisation legislation, they shall take appropriate action, which may include prohibiting the product from being placed on the market.

Justification

Deletion as unnecessary.

Amendment 128

Article 26, paragraph 2, subparagraph 2

In cases where placing on the market is prohibited, they shall ***ask*** the customs authorities to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document: 'Product not in conformity - release for free circulation not authorized – Regulation (EC) No …/..',	***Where*** placing on the market is prohibited, they shall ***require*** the customs authorities ***not to release it for free circulation and*** to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document: 'Product not in conformity - release for free circulation not authorized – Regulation (EC) No …/..',

Justification

The obligation not to release goods should be explicit.

Amendment 129
Article 26, paragraph 4

4. ***Market surveillance*** authorities may destroy products presenting a serious risk where they deem it necessary and proportionate.	4***. Member States'*** authorities may destroy ***or otherwise render inoperable*** products presenting a serious risk where they deem it necessary and proportionate.

(This is AM 253 but now it does not introduce a new paragraph; it changes paragraph 4 instead)

Amendment 130
Article 26, paragraph 4 a (new)

	4a. Market surveillance authorities shall provide authorities in charge of external border controls with information on product categories in which a serious risk or non-compliance within the meaning of paragraphs 1 and 2 has been identified.

Amendment 131
Article 32, paragraph 2

2. The Commission shall evaluate the relevance of the conformity assessment, accreditation and market surveillance activities receiving Community financing in the light of the requirements of Community	2. The Commission shall evaluate the relevance of the conformity assessment, accreditation and market surveillance activities receiving Community financing in the light of the requirements of Community

policies and legislation and inform the European Parliament and the Council about the outcome of such activities at least every ***five*** years.	policies and legislation and inform the European Parliament and the Council about the outcome of such activities at least every ***three*** years.

Justification

The five year period proposed by the executive Commission is too long and needs to be shortened.

Amendment 132
Article 34

In order to facilitate the implementation of this Regulation, the Commission shall draw up guidelines.	In order to facilitate the implementation of this Regulation, the Commission shall draw up guidelines ***in consultation with stakeholders***.

Justification

Stakeholders should be consulted by the Commission when setting up implementation guidelines.

Amendment 133
Article 35 a (new)

	Article 35a ***Review clause***
	Not later than …[1] , the Commission shall submit to the European Parliament and to the Council a report on the application of this 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, in the interests of better regulation and simplification. The report shall include an evaluation of the extension of the scope of Chapter III of

this Regulation to all products.

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[1] Five years from the date of entry into force of this Regulation.

Amendment 134
Article 36

The Member States shall lay down the rules on penalties, which may include criminal sanctions, for serious infringements, applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by […] at the latest and shall notify it without delay of any subsequent amendment affecting them.	The Member States shall lay down the rules on penalties, which may include criminal sanctions, for serious infringements, applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive ***and must be proportionally increased if the relevant economic operator has committed a similar infringement of the provisions of this Regulation in the past***. The Member States shall notify those provisions to the Commission by […] at the latest and shall notify it without delay of any subsequent amendment affecting them.

Justification

See justification to Amendment 134.

Amendment 135
Article 36 a (new)

Article 36a

Amendment to Directive 2001/95/EC

In Article 8 of Directive 2001/95/EC, paragraph 3 shall be replaced by the following:

"3. In the case of products posing a serious risk, the competent authorities shall take with due dispatch the appropriate measures referred to in paragraph 1(b) to (f). The existence of a serious risk shall be determined by the Member States, assessing each individual

	case on its merits, taking into account the guidelines referred to in point 8 of Annex II."

Amendment 136
Article 37, paragraph 1

Regulation (EEC) No 339/93 is repealed with effect from ***two years after*** the date of entry into force of this Regulation.	Regulation (EEC) No 339/93 is repealed with effect from the date of entry into force of this Regulation.

Amendment 137
Article 38, paragraph 2

Chapter III shall apply with effect from two years after the date of entry into force of this Regulation.	***deleted***

Amendment 138
Annex (new)

	Annex
	Requirements for recognition under Article 12a.
	1. A body recognised under Article 12a ("the body") shall be established within the European Community.
	2. Under the body's constitution, national accreditation bodies from within the Community shall be entitled to be members, provided that they pay the requisite membership fees and comply with the rules and objectives of the body, as set out herein and as agreed with the Commission in the framework agreement.
	3. The body shall consult all stakeholders in the preparation of decisions that will affect them.
	4. The body shall provide its members with peer evaluation services satisfying the requirements of Article 9.

5. The body's procedures shall enable the conclusion of multilateral agreements that ensure that where a national accreditation body successfully completes periodical peer evaluation in respect of the accreditation services it provides, those services shall be recognised by other national accreditation bodies.

6. The body shall carry out the tasks requested by the Commission under Article 12.

(This AM replaces AM 110 from the Draft Report)

EXPLANATORY STATEMENT

The Rapporteur welcomes the proposal for a Regulation on the accreditation and market surveillance of products in the Community, and the accompanying proposal for a Decision on a common framework for the marketing of products.

Creating an internal market for goods is one of the European Community's objectives. The internal market is an area without internal borders in which the free movement of goods, persons, services and capital is guaranteed under the EC Treaty. The purpose of the proposal is to provide a common framework for the existing infrastructures for accreditation for the control of conformity assessment bodies, and market surveillance for the control of products and economic operators.

The main objective is to safeguard the free movement of goods in a harmonised context. Attaching central importance to the free movement of goods as one of the pillars of the internal market will only contribute to growth and competitiveness if the necessary consumer confidence exists. Removal of barriers for economic operators and creation of favourable economic conditions for companies must always reflect a high level of consumer protection. High consumer health and safety standards and environmental protection are central concerns in any EU policy.

Though the Rapporteur welcomes the proposals, he is of the opinion that there is room for further improvement. He therefore proposes amendments along the following lines:

Subject matter and scope

The Rapporteur is concerned about the limited scope of the Regulation as to the product sectors covered. The proposal offers an opportunity to establish a broader framework for both accreditation and market surveillance. That opportunity should be seized in order to minimise regulatory fragmentation, as well as in the interest of simplification and better regulation.

The many and broad exclusions cover whole pieces of legislation, not just those parts that may be relevant. The exclusions risk turning the Regulation into the exception instead of the framework intended. To get rid of the exclusions avoids the need to revise the Regulation as and when new legislation is enacted. Maintaining the exclusions opens the door to requests for even more exclusions, adding to the problem. Demands for exclusions could possibly be motivated more by various sector specific interests than by a concern to establish a coherent framework.

Favouring a broad scope of application the Rapporteur therefore proposes to remove all the exclusions.

Instead, the general principle that more specific rules have precedence over more general rules is restated. This is a general and well-established principle of law found in many other pieces of Community legislation, including in the Directive 2001/95/EC on General Product Safety (GPSD).

Some definitions, such as “products”, “Community harmonisation legislation”, “entering the Community market”, “conformity assessment”, and “CE marking” have been introduced, whereby coherence of the definitions in the Regulation and the Decision must be ensured.

Accreditation and conformity assessment

Accreditation has not hitherto been regulated at Community level, although it has been and is practised in all Member States. As a result Member States have developed different (and divergent) systems and requirements. The proposal sets out a comprehensive framework for accreditation and lays down at Community level the principles for its work and organisation.

The Rapporteur strongly supports the idea to leave accreditation as a national responsibility, whereby national accreditation bodies have to act as public authorities and in the public interest. Consequently competition between accreditation bodies is excluded in the compulsory area.

With regard to the scope of accreditation the Rapporteur is of the opinion that it should be as wide as possible to prevent the creation of several systems. As a result the confidence in accreditation would be strengthened and confusion among economic operators avoided.

Regarding operation of accreditation, certain rights of the respective authorities have been strengthened in order to maintain high accreditation standards.

Role of European cooperation for accreditation (EA)

The Rapporteur is of the opinion that to enshrine the European co-operation for accreditation (EA) in the Regulation is problematic in so far as, firstly, the EA is an entity under private law, secondly it has not been decided yet formally whether the EA will be the organisation in question or for how long, and thirdly in case of possible changes to the corporate structure of the EA, such as a change of name or if it was to be put into liquidation or merge. The Rapporteur does not at all question the competence of the EA, which it has sufficiently proved over many years, but he believes that the Regulation should refer to a body to be recognised upon meeting certain criteria.

As a consequence the Commission would have to recognise a body which satisfies the requirements of Annex A after consultation with the Member States, and come to a framework agreement to contains, inter alia, provisions for the supervision of the body.

Market surveillance and customs authorities

The general comments under subject matter and scope above apply with particular force to market surveillance. The Rapporteur sees no good reason to establish a framework for market surveillance that is riddled with exclusions. A framework for market surveillance should by its very nature be broad.

For example, the GPSD should be included in the framework as the borderline between products for consumer use and for professional use is blurred, as the exclusion would mean

unnecessary complication, and as it may lead to unclear procedures and responsibilities. The

Also the exclusion of 15 entire Directives and Regulations under Article 13(3) would contradict the establishment of an efficient market surveillance based on EU-wide rules.

However, it would have to be guaranteed that the market surveillance measures will be adequate for individual products, and the respective specific regulations and practices be maintained. This is achieved by the general principle that specific rules applying to different sectors have precedence over the more general rules of the framework provided for hereby.

The Rapporteur strengthens the provisions for the obligations of the Member States as regards the establishment, implementation and periodical update of their market surveillance programmes. Review and assessment procedures are reinforced. Communication between the Member States and the Commission, and information to the public, is emphasised.

The Rapporteur proposes focussing the market surveillance effort on those products representing a serious risk. Provisions regarding products presenting a serious risk have been amended and clarified especially as regards the risk assessment.

In order to increase the effectiveness of market surveillance across the EU the Rapporteur believes that common initiatives with third countries and an improved co-operation with their respective authorities would contribute to a better understanding of the complex EU rules and regulations, and also encourage third country authorities to take measures for the prevention of illegal exports into the EU.

Regarding control of products entering the Community market the Rapporteur is of the opinion that co-ordination and exchange of information between customs and market surveillance authorities have to be strengthened. The volume of third country products entering the Community market is constantly growing, and simultaneously the significance of the controls of the customs authorities is increasing. In order to improve the effectiveness of the customs authorities they should receive the necessary information about dangerous products from the respective market surveillance authorities well in advance. The Regulation will lead to a further increase of market surveillance activities, and in the interest of fair competition and, not least, consumers the approach of market surveillance should be preventive instead of reactive.

CE marking

The Rapporteur is of the opinion that the CE marking needs better protection. Provisions (inspired by the proposed Decision) dealing with the CE marking are therefore introduced. As the meaning of the CE marking is not clearly understood, an increasing number of products bearing the CE marking do not comply with the relevant legislation. It is thus a shared interest of manufacturers, traders and consumers to have clear rules on the CE marking. For the market surveillance authorities the appropriately applied CE marking constitutes a very useful instrument for their effective market surveillance activities.

14.9.2007

OPINION OF THE COMMITTEE ON INTERNATIONAL TRADE

for the Committee on Internal Market and Consumer Protection

on the proposal for a regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (COM(2007)0037 – C6-0068/2007 – 2007/0029(COD))

Draftsman: Helmuth Markov

SHORT JUSTIFICATION

The Committee on International Trade welcomes the proposals of the Commission aiming at creating a stricter and more comprehensive Community surveillance on marketing of products.

The draftsperson is in particular of the opinion that the proposed regulation may represent an important step forward in the creation of a safer and well functioning single market.

He has taken note of the fact that there is still a certain risk of distortion to competition due to differing practices in the designation of conformity assessment bodies by national authorities and unequal treatment in the case of non-complying or dangerous products on the market, through very different national market surveillance infrastructures, rules and means.

He also agrees with the Commission's conclusions according to which past abusive practices have resulted in a certain lack of trust in conformity marking and that coherence in the implementation and enforcement of the current rules could certainly be improved. Previous experience has shown that abusive practices often involve imported goods which may easily escape from the system of verifications manned by the Community and the competent national authorities.

The CE marking is often considered as the proof that an item is intrinsically safe because it respects the stringent Community rules defending the fundamental right of consumers and citizens to have access only to safe products. This is unfortunately not always true. Since the CE marking is in most cases affixed under the responsibility of the manufacturer, there is no real certainty that this marking is faithfully reflecting the conformity of the product to the Community legislation. This is even more evident when considering that technical standards

and verifications in third countries may be less severe than those applied in the European Union.

Under these conditions, there is no doubt that the system based on the "EC declaration of conformity" (which is largely self-managed by producers inside and outside the Community) needs to be enforced by a serious surveillance system and by equally credible sanctions. The Community public interest cannot accept that basic rights of the citizens are sacrificed to the interests of powerful multinational groups.

In this respect, the national customs authorities play a vital role in ensuring that unsafe products are not placed on the market. A better coordination and a wider circulation of information is likely to increase the efficacy of the action of national customs authorities and ensure that fraudulent practices aiming at circumventing the foreign producers' and importers' legal obligations are properly tackled.

It should also be advisable if, in accordance to article 16.3 of the Decision, the national customs authorities would be authorised to suspend the release of a product for free circulation in case it affixes markings, signs and inscriptions which are false or likely to mislead third parties as to the meaning or form of the CE marking.

The draftsperson is of the opinion that the destruction of imported products which are found to be dangerous for public health or not complying with Community laws is a proportionate response which would provide an efficient deterrent against imports of products for which the entry into the market has been denied. This remedy should also put an end to the unacceptable practice according to which products which are dangerous or not complying with conformity marking are often re-exported and subsequently enter the Community market at other points of entry.

Surveillance would become effective only if penalties applicable to infringements are effective, proportionate and dissuasive. Legislation at Community level addressing this issue, though suitable, is probably premature. The draftsperson would however recommend that a common framework according to which similar penalties shall be applied in the whole Community is put in place. These rules should also be implemented in a consistent manner which would avoid serious breaches in the Community's surveillance system. The draftsperson also recommends that more serious penalties are applied when an economic operator is found responsible for repeated violations of the Community harmonisation legislation.

The proposed Regulation could also be improved as far as the communication is concerned. To this extent, the draftsperson has proposed the following improvements:

a) the annual publication by the European Commission, in cooperation with Member States, of a report on the enforcement of the Community harmonisation legislation;

b) the set up of a common and public database, accessible to the Member States' public administrations and economic operators, listing all cases where a product was found to present a serious risk to health and safety or was in breach of Community harmonisation legislation.

AMENDMENTS

The Committee on International Trade calls on the Committee on Internal Market and Consumer Protection, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 Recital 29	
(29) Points of entry at the external borders are well placed to detect unsafe products even before they are placed on the market. An obligation for customs authorities to execute checks on an adequate scale can therefore contribute to a safer market place.	(29) Points of entry at the external borders are well placed to detect unsafe products ***or products affixed with markings, signs or inscriptions which are false or likely to mislead third parties as to the meaning or form of the CE marking*** even before they are placed on the market. An obligation for customs authorities to execute checks on an adequate scale can therefore contribute to a safer market place.
Justification	
There is the clear need that customs authorities will be also in charge of verifying whether products entering the Community are affixing false or misleading CE markings.	
Amendment 2 Recital 31	
(31) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.	(31) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive. ***They should be proportionally increased if the liable economic operator has, in the past, been found liable for similar infringements of the provisions of this Regulation.***

[1] Not yet published in OJ.

Justification

Recidivist economic operators should in principle be submitted to more severe and dissuasive penalties than those applied to economic operators which have been found in breach with this regulation only once. This is a plain legal principle which should be applied also in the case in point.

Amendment 3
Article 6, paragraph 1, point (c a) (new)

	(ca) where the body to be accredited forms a part of a subsidiary of an organisation established in another Member State, it may request accreditation from either the local or the parent organisation's national accreditation body.

Justification

In cases where conformity assessment bodies, test and calibration laboratories etc. form part of a larger cross-border organisation they should be allowed to be accredited either in the MS they are based in or in the MS their parent organisation is established in.

Amendment 4
Article 9, paragraph 5

5. The results of the peer evaluation shall be communicated to all Member States and the Commission.	5. The ***final*** results of the peer evaluation shall be ***made public and*** communicated to all Member States and the Commission.

Justification

The results of the peer evaluation are of direct interest not only to the Member States and the Commission but also to the customers and other stakeholders of accreditation.

Amendment 5
Article 17, paragraph 2, subparagraph 1

2. The market surveillance authorities shall take appropriate measures in order to alert the users in their territory about any product they have identified as presenting a risk.	2. The market surveillance authorities shall take appropriate ***and proportionate*** measures in order to alert the users in their territory about any product they have identified as presenting a risk.

Justification

The legal text needs to clearly state that measures taken in response to a demonstrated lack of

conformity must be proportionate.

Amendment 6
Article 19, paragraph 1

1. Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the making available of a product, to withdraw it from the market or recall it, states the exact grounds on which it is based.	1. Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the making available of a product, to withdraw it from the market or recall it, ***is proportionate and*** states the exact grounds on which it is based.

Justification

The legal text needs to clearly state that measures taken in response to a demonstrated lack of conformity must be proportionate.

Amendment 7
Article 23, paragraph 2, point (b a) (new)

	(ba) produce an annual report on the enforcement of Community harmonisation legislation;

Justification

The information dissemination concerning the implementation of the proposed regulation needs to be significantly improved.

Amendment 8
Article 23, paragraph 2, point (b b) (new)

	(bb) set up a common, public database, accessible to the Member States' public administrations and economic operators, listing all cases where a product was found to present a serious risk to health and safety or was in breach of Community harmonisation legislation;

Justification

The information dissemination concerning the implementation of the proposed regulation needs to be significantly improved. In this specific case, the common database would enable economic operators in good faith to avoid to enter into business with no reliable counterparts, both from outside and inside the Community.

Amendment 9
Article 23, paragraph 2, point (b c) (new)

(bc) develop, organise and set up such programmes and exchanges of experience, information and best practice, programmes and actions for common projects, information campaigns, joint visit programmes and the sharing of resources in cooperation with third countries accordingly.

Justification

A big number of non-conform products reaching the EC internal market are produced in third countries (e. g. China: 47%). This is very often rooted in inadequate information and training. Therefore common programs and exchanges should be developed and set up in cooperation with these countries accordingly to those in the EC.

Amendment 10
Article 23, paragraph 3

3. Member States shall ensure that their national authorities participate in the activities referred to in paragraph 2***, where appropriate.***	3. Member States shall ensure that their national authorities ***fully*** participate in the activities referred to in paragraph 2.

Justification

For a better functioning system, cooperation between national authorities needs to be maximised and not left to the discretional appreciation of single Member States.

Amendment 11
Article 24, paragraph 1 a (new)

1a. Member States shall confer greater powers on their customs authorities and provide them with the resources they need in order to accomplish their tasks, including the destruction of products not conforming to Community legislation.

Justification

National customs authorities have a vital role to play in preventing products being marketed in the Union when they do not conform to Community legislation. To enable them to carry out their activities to the best possible effect, they must be given greater powers, extending to the

destruction of products not in conformity, including products bearing marks likely to mislead consumers, especially as to the meaning and form of the CE mark.

Amendment 12
Article 24, paragraph 2, point (b a) (new)

(ba) the product is affixed with markings, signs or inscriptions which are false or likely to mislead third parties as to the meaning or form of the CE marking, or both.

(See art. 16.3 of the Decision)

Justification

The national customs authorities should be authorised to suspend the release of a product for free circulation also when it affixes markings, signs and inscriptions which are false or likely to mislead third parties as to the meaning or form of the CE marking.

Amendment 13
Article 26 a (new)

Article 26a

General principles governing the CE marking

1. The CE marking may be affixed only by the manufacturer or its agent. By affixing the CE marking the manufacturer assumes responsibility for the product's conformity to the requirements of Decision …/… of the European Parliament and of the Council of ... [on a common framework for the marketing of products].

2. The CE marking is the only marking certifying that the product conforms to the relevant requirements. Member States shall refrain from referring in their national legislation, and shall remove any existing references, to a conformity mark other than the CE marking in connection with full conformity to the provisions of Community legislation on the CE marking.

3. No marks, signs, or inscriptions may be affixed to a product if they are likely to cause confusion as to the meaning or the

"CE" graphic symbol by which the marking is denoted. Any other marking may be affixed to the product, provided that it does not detract from the visibility, legibility, or meaning of the CE marking.

Justification

Products bearing the CE mark are considered safe because they have been manufactured in accordance with Community legislation. It is consequently in the interest of producers, dealers, and consumers alike to have clear rules on CE marking. The rules governing the CE mark therefore need to be directly applicable and hence laid down in the text of the regulation. Naturally, this does not in any way lessen the need to ensure that inclusion of the above article in the regulation will be compatible with the existing Community directives.

Amendment 14
Article 26 b (new)

Article 26b
Rules and conditions for affixing the CE marking

1. The CE marking shall take the form of the initials "CE" as illustrated below:

2. If the size of the CE marking is reduced or enlarged, the proportions shown in the scale drawing reproduced in paragraph 1 must remain unaltered.

3. Where the specific legislation gives no indication of the exact size, the CE marking must be no smaller than 5 mm.

4. The CE marking shall be affixed visibly, legibly, and indelibly to the product or its data plate. Where this is impossible or not warranted on account of the nature of the product, the CE marking shall be affixed to the product packaging or to the accompanying documents, if these are provided for by law.

5. The CE marking shall be affixed to the product before the latter is placed on the market. It may be followed by a pictogram or any other mark denoting a particular

	risk or use. ***6. The CE marking shall be followed by the identification number of the conformity assessment body and/or of any body involved at the production checking stage. The identification number of such a body must be affixed either by the body itself or, acting on its instructions, by the manufacturer or its agent established within the Community.*** ***7. Member States shall ensure that the rules governing the CE marking are properly enforced, and shall take legal proceedings in cases of misuse. They shall establish penalties, including criminal penalties for serious infringements, which must be proportionate to the seriousness of the infringements and constitute an effective deterrent to improper use.***

Justification

Products bearing the CE mark are considered safe because they have been manufactured in accordance with Community legislation. It is consequently in the interest of producers, dealers, and consumers alike to have clear rules on CE marking. The rules governing the CE mark therefore need to be directly applicable and hence laid down in the text of the regulation. Naturally, this does not in any way lessen the need to ensure that inclusion of the above article in the regulation will be compatible with the existing Community directives.

Amendment 15
Article 32, paragraph 2

2. The Commission shall evaluate the relevance of the conformity assessment, accreditation and market surveillance activities receiving Community financing in the light of the requirements of Community policies and legislation and inform the European Parliament and the Council about the outcome of such activities at least every ***five*** years.	2. The Commission shall evaluate the relevance of the conformity assessment, accreditation and market surveillance activities receiving Community financing in the light of the requirements of Community policies and legislation and inform the European Parliament and the Council about the outcome of such activities at least every ***three*** years.

Justification

The five year period proposed by the executive Commission is too long and needs to be shortened.

Amendment 16
Article 36

The Member States shall lay down the rules on penalties, which may include criminal sanctions, for serious infringements, applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by […] at the latest and shall notify it without delay of any subsequent amendment affecting them.	The Member States shall lay down the rules on penalties, which may include criminal sanctions, for serious infringements, applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. ***Those penalties shall be proportionally increased if the economic operator has, in the past, been found liable for having placed on the market products in breach of the provisions of this Regulation.*** The Member States shall notify those provisions to the Commission by […] at the latest and shall notify it without delay of any subsequent amendment affecting them.

Justification

Recidivist economic operators should in principle be submitted to more severe and dissuasive penalties than those applied to economic operators which have been found in breach with this regulation only once. This is a plain legal principle which should be applied also in the case in point.

PROCEDURE

Title	Accreditation and market surveillance relating to the marketing of products
References	COM(2007)0037 - C6-0068/2007 - 2007/0029(COD)
Committee responsible	IMCO
Opinion by Date announced in plenary	INTA 13.3.2007
Draftsman Date appointed	Helmuth Markov 21.3.2007
Discussed in committee	7.5.2007 27.6.2007
Date adopted	12.9.2007
Result of final vote	+: 29 –: 1 0: 0
Members present for the final vote	Kader Arif, Graham Booth, Daniel Caspary, Françoise Castex, Glyn Ford, Eduard Raul Hellvig, Jacky Henin, Syed Kamall, Sajjad Karim, Alain Lipietz, Marusya Ivanova Lyubcheva, Helmuth Markov, Cristiana Muscardini, Vural Öger, Georgios Papastamkos, Godelieve Quisthoudt-Rowohl, Tokia Saïfi, Peter Šťastný, Robert Sturdy, Gianluca Susta, Daniel Varela Suanzes-Carpegna, Corien Wortmann-Kool, Zbigniew Zaleski
Substitutes present for the final vote	Harlem Désir, Vasco Graça Moura, Małgorzata Handzlik, Pia Elda Locatelli, Eugenijus Maldeikis, Javier Moreno Sánchez, Jan Marinus Wiersma

23.11.2007

OPINION OF THE COMMITTEE ON THE ENVIRONMENT, PUBLIC HEALTH AND FOOD SAFETY

for the Committee on the Internal Market and Consumer Protection

on the proposal for a regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (KOM(2007)0037 – C6-0068/2007 – 2007/0029(COD))

Draftsman: Peter Liese

SHORT JUSTIFICATION

In recent years the European Union has adopted numerous rules placing specific requirements on manufacturers of products. These focus primarily on consumer safety, protection against harmful effects on health and, most recently, increasingly on the environmental properties of products, in particular through the Energy-Using Products Directive. The rules are being adopted on the basis of the 'New Approach', under which responsibility for complying with the rules lies first and foremost with manufacturers themselves, who confirm that the rules have been complied with by affixing the CE mark. Above all, the rules entail little red tape or expense for manufacturers. However, they can lead to problems where individual manufacturers or groups of manufacturers affix the CE mark without complying with the rules. That can put consumers at risk and result in damage to the environment. Moreover, it can put honest manufacturers, who comply with the rules and bear the costs of compliance, at a competitive disadvantage in relation to their competitors who enjoy an unfair advantage. Parliament has therefore already called on a number of occasions, for example when the Energy-Using Products Directive was adopted, for stronger market surveillance. The Commission has now put forward a proposal addressing this issue. However, the proposal does not go far enough, given that, for example, it provides for a transitional period of two years. During those two years, consumers and the environment will continue to be exposed unnecessarily to products that have not undergone checks. Your draftsman is therefore proposing that the period in question be reduced to one month, in order to enable the benefits of improved market surveillance to take effect as quickly as possible. Your draftsman is also proposing that reference to compliance with environmental rules be made throughout the text. Other amendments relate to checks to be performed following a ban. Frequently, bans on marketing of products are imposed, but checks to ensure that the ban is being complied with are not carried out. A further amendment relates to the speed with which products are sold. Specifically in the case of seasonal or sales items it is necessary to seize defective products within days, sometimes within hours, as they would otherwise be sold out. It is important, furthermore, for Member States to ensure that there are sufficient staff to perform the relevant

tasks.

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 Recital 1	
(1) For the purpose of strengthening the overall framework ensuring that products respect a high level of protection of public interests, such as health and safety, it is necessary to establish certain rules and principles in relation to accreditation and market surveillance, which are important aspects of that framework.	(1) For the purpose of strengthening the overall framework ensuring that products respect a high level of protection of public interests, such as health and safety ***or the environment***, it is necessary to establish certain rules and principles in relation to accreditation and market surveillance, which are important aspects of that framework.
Justification	
In line with Article 1 paragraph 1 on 'subject matter and scope', the draftsman suggests introducing a clear reference to the protection of the environment. It is important to make sure that all cases of non-conformity to EU legislation, including especially in the environment field, should be adequately dealt with.	
Amendment 2 Recital 24	
(24) Cooperation of competent authorities at the national level and across borders in exchanging information, investigating infringements and taking action to bring about their cessation is essential to the protection of health and safety and to guaranteeing the smooth functioning of the internal market.	(24) Cooperation of competent authorities at the national level and across borders in exchanging information, investigating infringements and taking action to bring about their cessation***, even before the placing on the market of the dangerous products by reinforcing measures to identify them mainly in the seaports where***

[1] Not yet published in OJ.

	90% of imports into the European Union are concentrated, is essential to the protection of health and safety and to guaranteeing the smooth functioning of the internal market.

Amendment 3
Recital 30 a (new)

	(30a) It is necessary for Member States to provide for appropriate means of redress before the competent courts in respect of measures taken by the competent authorities which restrict the placing on the market of a product or require its withdrawal or recall.

Justification

If a Member State asked a manufacturer to recall a product but the action was found to be incorrect, the economic operator needs to obtain redress from Member States who initiated the action.

This text is identical to Recital 37 of the General Product Safety Directive and, as such, is not a new or untried concept.

Amendment 4
Article 2, point 5

(5) “distributor” means any natural or legal person in the supply chain, who makes a product available on the market;	(5) “distributor” means any natural or legal person in the supply chain, who makes a product available***, but does not place it*** on the market;

Justification

The distinction between economic operators who have similar roles in placing a product on the market and those who are not making a product available for the first time has to be clarified.

The legal entity placing a product on the EU market should bear the responsibility that the product is properly intended and manufactured for the EU market according to our Regulations. It is not the case of distributors.

Amendment 5
Article 2, point 11

(11) “national accreditation body” means the ***sole*** authoritative ***body*** in a Member State that ***performs*** accreditation with authority derived from government;	(11) “national accreditation body” means the authoritative ***body or bodies*** in a Member State that ***perform*** accreditation with authority derived from government;

Justification

Follow-up amendment to the amendment to Article 4(1).

The requirement that there be a single national accreditation body contravenes the subsidiarity principle and the obligation on the bodies of the European Communities not to encroach upon the basic structure of the constitution of the Member States or to undermine their fundamental - in this case federal - structures. In order to safeguard federalism in the Member States it is therefore necessary to permit them to set up a second accreditation body.

Amendment 6
Article 2, point 13 a (new)

	(13a) “entering the Community market” means being presented for customs clearance.

Justification

The distinction between economic operators who have similar roles in placing a product on the market and those who are not making a product available for the first time has to be clarified.

The legal entity placing a product on the EU market should bear the responsibility that the product is properly intended and manufactured for the EU market according to our Regulations. It is not the case of distributors.

Amendment 7
Article 2, point 13 b (new)

	(13b) “conformity assessment body” means a body that performs conformity assessment services (generally laboratories, inspection bodies, and certification bodies).

Justification

The distinction between economic operators who have similar roles in placing a product on

the market and those who are not making a product available for the first time has to be clarified.

The legal entity placing a product on the EU market should bear the responsibility that the product is properly intended and manufactured for the EU market according to our Regulations. It is not the case of distributors.

Amendment 8
Article 2, point 13 c (new)

(13c) "conformity assessment" means the demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

Justification

The distinction between economic operators who have similar roles in placing a product on the market and those who are not making a product available for the first time has to be clarified.

The legal entity placing a product on the EU market should bear the responsibility that the product is properly intended and manufactured for the EU market according to our Regulations. It is not the case of distributors

Amendment 9
Article 4, paragraph 1, subparagraph 1 a (new)

In Member States with a federal structure, a second accreditation body may be established in order to safeguard federal powers. In such cases, the two accreditation bodies are called upon to work together in mutual trust and cooperation.

Justification

The requirement that there be a single national accreditation body contravenes the subsidiarity principle and the obligation on the bodies of the European Communities not to encroach upon the basic structure of the constitution of the Member States or to undermine their fundamental - in this case federal - structures. In order to safeguard federalism in the Member States it is therefore necessary to permit them to set up a second accreditation body.

Amendment 10
Article 4, paragraph 6

6. The national accreditation body shall operate on a non profit basis. It may not offer or provide any activities or services that conformity assessment bodies provide, nor may it provide consultancy services.	6. The national accreditation body shall operate on a non profit basis. It may not offer or provide any activities or services that conformity assessment bodies provide, nor may it provide consultancy services***, nor may it own shares in the conformity assessment bodies***.

Justification

In order for the accreditation body to be fully independent of all conformity assessment bodies it is responsible for (some of which may act as Notified Bodies) it is necessary to ensure not only functional barriers within one company, but also true independence so as to avoid any possible concerns regarding conflict or confusion of interest: thus it is necessary to ensure financial separation.

Amendment 11
Article 5, paragraph 2

2. The national accreditation ***body*** shall monitor any conformity assessment body to which ***it has*** issued an accreditation certificate.	2. The national accreditation ***bodies*** shall monitor any conformity assessment body to which ***they have*** issued an accreditation certificate.

Justification

Follow-up amendment to the amendment to Article 4(1).

The requirement that there be a single national accreditation body contravenes the subsidiarity principle and the obligation on the bodies of the European Communities not to encroach upon the basic structure of the constitution of the Member States or to undermine their fundamental - in this case federal - structures. In order to safeguard federalism in the Member States it is therefore necessary to permit them to set up a second accreditation body.

Amendment 12
Article 5, paragraph 3

3. Where the national accreditation ***body ascertains*** that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific conformity assessment activity or commits a serious breach of its obligations, the national accreditation ***body*** shall take all appropriate measures to restrict, suspend or withdraw ***its***	3. Where the national accreditation ***bodies ascertain*** that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific conformity assessment activity or commits a serious breach of its obligations, the national accreditation ***bodies*** shall take all appropriate measures to restrict, suspend or withdraw ***their***

accreditation certificate.	accreditation certificate.

Justification

Follow-up amendment to the amendment to Article 4(1).

The requirement that there be a single national accreditation body contravenes the subsidiarity principle and the obligation on the bodies of the European Communities not to encroach upon the basic structure of the constitution of the Member States or to undermine their fundamental - in this case federal - structures. In order to safeguard federalism in the Member States it is therefore necessary to permit them to set up a second accreditation body.

Amendment 13
Article 6, paragraph 1, subparagraph 1

1. Where a conformity assessment body requests accreditation, it shall do so with the national accreditation ***body*** of the Member State in which it is established or with the national accreditation ***body*** to which that Member State has had recourse pursuant to Article 4(2).	1. Where a conformity assessment body requests accreditation, it shall do so with the national accreditation ***bodies*** of the Member State in which it is established or with the national accreditation ***bodies*** to which that Member State has had recourse pursuant to Article 4(2).

Justification

Follow-up amendment to the amendment to Article 4(1).

The requirement that there be a single national accreditation body contravenes the subsidiarity principle and the obligation on the bodies of the European Communities not to encroach upon the basic structure of the constitution of the Member States or to undermine their fundamental - in this case federal - structures. In order to safeguard federalism in the Member States it is therefore necessary to permit them to set up a second accreditation body.

Amendment 14
Article 6, paragraph 1, subparagraph 2, point (a)

(a) where the Member State in which it is established has decided not to establish ***a*** national accreditation ***body*** and has not had recourse to ***a*** national accreditation ***body*** of another Member State pursuant to Article 4(2).	(a) where the Member State in which it is established has decided not to establish national accreditation ***bodies*** and has not had recourse to national accreditation ***bodies*** of another Member State pursuant to Article 4(2).

Justification

Follow-up amendment to the amendment to Article 4(1).

The requirement that there be a single national accreditation body contravenes the subsidiarity principle and the obligation on the bodies of the European Communities not to encroach upon the basic structure of the constitution of the Member States or to undermine their fundamental - in this case federal - structures. In order to safeguard federalism in the Member States it is therefore necessary to permit them to set up a second accreditation body.

Amendment 15
Article 8, paragraph 2 a (new)

	2a. National accreditation bodies shall have appeal procedures to provide economic operators with a means of redress where they can demonstrate that an accredited body does not have the minimum required skills or competence.

Justification

The existing proposal provides for a procedure whereby Member States are required to monitor their national accreditation bodies at regular intervals and thus the general public interest is protected. However, the actions of national accreditation bodies, and the bodies they accredit, have a direct impact on economic operators and so they too should have an explicit means of redress.

Amendment 16
Article 16, paragraph 1

1. Member States shall ensure communication and co-ordination between all the different market surveillance authorities.	1. Member States shall ensure communication and co-ordination between all the different market surveillance authorities ***within their jurisdiction***.

Justification

Market surveillance should also ensure a concrete follow-up of corrective actions on the market. Concern has been expressed in the Parliament's Working Document regarding the credibility of the CE marking. We do not believe that any such credibility gap stems from two points, firstly an inadequate process for catching those economic operators who deliberately flout Community legislation, and secondly an inadequate process to follow-up to ensure that, where a product has been found by a Court to be non-compliant, then it is positively removed from the market. Hence, market surveillance procedures should also ensure a concrete follow-up of corrective actions on the market place. As market surveillance is organised at Member State level in accordance with the principle of subsidiarity, this Regulation should require each Member State to verify that corrective actions have been effectively carried out.

Amendment 17
Article 16, paragraph 2, subparagraph 1 a (new)

Member States shall establish adequate procedures in order to verify that corrective actions have been effectively carried out.

Justification

See justification under amendment 3.

Amendment 18
Article 16, paragraph 4

4. Member States shall establish, implement and periodically update market surveillance programmes.	4. Member States shall establish, implement and periodically update market surveillance programmes. ***Member States may establish co-operation agreements with stakeholders, in particular with sectoral professional organisations, in order to take advantage of available market intelligence.***

Justification

See justification under amendment 3.

Amendment 19
Article 16, paragraph 5

5. Member States shall periodically review and assess the functioning of their surveillance activities.	5. Member States shall periodically review and assess the functioning of their surveillance activities ***and report publicly thereon***.

Justification

See justification under amendment 3.

Amendment 20
Article 17, paragraph 1, subparagraph 1 a (new)

.	***The authorities shall be entitled to seize samples of a product which they expect to***

be rapidly sold out.

Justification

Market surveillance speed should be adapted to the speed of sales of batches of often inexpensive components or consumer products: these are often rapidly sold out in a distributor's promotional sale. Experience shows that once products are placed on the market, delays between complaints and action by market surveillance authorities often lead to the situation where authorities are not in a position to carry out checks, as the products have already been sold. This is particularly the case for promotional or seasonal sales of consumer products, such as Christmas lighting. It happens also for small electrical components such as electrical controls, switchgears or small measuring instruments. Therefore, when customs authorities have a serious reason to believe that the imported product may not be in compliance with all EU requirements, they should be entitled to seize samples of the product in order to speed up the control by market surveillance authorities and ensure possible legal action against the importer or the manufacturer's authorised representative in case of characterised default of compliance with EU legislation.

Amendment 21
Article 19, paragraph 1

1. Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the making available of a product, to withdraw it from the market or recall it, states the exact grounds on which it is based.	1. Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation ***and the principle of proportionality,*** to prohibit or restrict the making available of a product, to withdraw it from the market or recall it, states the exact grounds on which it is based.

Justification

Article 19(1) contains a number of possible market interventions that could be taken by authorities and the economic consequences resulting from each of these will have varying consequences for economic operators. In line with the general provisions of Community law, the level of market intervention should be proportionate to the level of risk for the public. Provisions with similar effect are already contained within the General Product Safety Directive.

Amendment 22
Article 24, paragraph 1, subparagraph 1 a (new)

Member States shall ensure that their customs authorities have the necessary powers and resources in order to properly perform their tasks.

Justification

For the sake of consistency and efficiency of the overall framework for the marketing of goods, the draftsman suggests the introduction of a similar provision for customs controls as for market surveillance authorities under Article 16(3).

Amendment 23
Article 34

In order to facilitate the implementation of this Regulation, the Commission shall draw up guidelines.	In order to facilitate the implementation of this Regulation, the Commission shall draw up guidelines ***in consultation with stakeholders***.

Justification

Stakeholders should be consulted by the Commission when setting up implementation guidelines.

Amendment 24
Article 35, paragraph 2

2. Where in a Member State accreditation is not operated by a single national accreditation body and that Member State intends to continue to operate accreditation, it shall make the necessary structural adaptations in order to establish a ***single*** national accreditation body by 1 January ***2010*** at the latest.	2. Where in a Member State accreditation is not operated by a single national accreditation body and that Member State intends to continue to operate accreditation, it shall make the necessary structural adaptations in order to establish a national accreditation body ***or a second national accreditation body pursuant to the second subparagraph of Article 4(1)*** by 1 January ***2014*** at the latest.

Justification

Follow-up amendment to the amendment to Article 4(1).

In addition, the transitional period for the legal and administrative implementing measures required must be extended. Particularly in countries with complex accreditation systems, these changes cannot be made by 2010 and the transitional period should therefore be extended to 2014.

Amendment 25
Article 38, paragraph 2

Chapter III shall apply with effect from ***two years*** after the date of entry into force of this Regulation.	Chapter III shall apply with effect from ***one month*** after the date of entry into force of this Regulation.

Justification

An additional two years' delay until market surveillance can operate under the urgently needed efficient conditions is not acceptable. Manufacturers who do respect European legislation and standards currently face heavy threats from unfair competitors.

PROCEDURE

Title	Accreditation and market surveillance relating to the marketing of products
References	COM(2007)0037 - C6-0068/2007 - 2007/0029(COD)
Committee responsible	IMCO
Opinion by Date announced in plenary	ENVI 13.3.2007
Draftsman Date appointed	Peter Liese 10.5.2007
Discussed in committee	26.6.2007 8.10.2007
Date adopted	22.11.2007
Result of final vote	+: 31 –: 6 0: 0
Members present for the final vote	Pilar Ayuso, Johannes Blokland, Frieda Brepoels, Dorette Corbey, Chris Davies, Avril Doyle, Mojca Drčar Murko, Edite Estrela, Jill Evans, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Marie Anne Isler Béguin, Caroline Jackson, Dan Jørgensen, Marie-Noëlle Lienemann, Peter Liese, Alexandru-Ioan Morţun, Roberto Musacchio, Riitta Myller, Miroslav Ouzký, Frédérique Ries, Guido Sacconi, Karin Scheele, Carl Schlyter, Richard Seeber, Bogusław Sonik, Antonios Trakatellis, Thomas Ulmer, Anja Weisgerber, Glenis Willmott
Substitutes present for the final vote	Alfonso Andria, Kathalijne Maria Buitenweg, Duarte Freitas, Milan Gaľa, Alojz Peterle

5.10.2007

OPINION OF THE COMMITTEE ON INDUSTRY, RESEARCH AND ENERGY

for the Committee on the Internal Market and Consumer Protection

on the proposal for a regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products (COM(2007)0037 – C6-0068/2007 – 2007/0029(COD))

Draftsman: John Purvis

SHORT JUSTIFICATION

The draftsman welcomes the proposal for a regulation on the accreditation and market surveillance of products in the Community, and the accompanying proposal for a decision on a common framework for the marketing of products. These are designed to facilitate the operation of the internal market of goods whilst ensuring that the products entered and circulated in the internal market are safe.

The Regulation builds upon systems already existing in Member States; introduces strengthened rules on market surveillance to filter unsafe products, including imports; and strengthens the role of accreditation for conformity assessment bodies thus enhancing confidence in product conformity assessment.

Though the draftsman, as stated above, welcomes the proposals, he is of the opinion that there is room for further improvement and therefore proposes amendments along the following lines:

- Some definitions, such as "making available on the market" and "entering the Community market" must be clarified; new definitions on "conformity assessment"; "conformity assessment body" have to be introduced; coherence of definitions in the Regulation and the Decision must be ensured. Article 2 of the Regulation is therefore amended accordingly.

- Concerning the institutional side: the rules of cross-border accreditation should be simplified, while at the same time ensuring that increased cross-border competition does not result in lower accreditation standards; national consumer protection organizations should be involved in the cooperation among competent national authorities; customs authorities, which are the first line of defence with imports, have

to be reinforced and equipped with adequate resources. Articles 6 and 24 of the Regulation are therefore amended this way.

- Provisions of the existing directives concerning identification numbers and lists of notified bodies have been updated in order to give immediate legal certainty to the current practical application of the notification procedure.

- As far as procedures are concerned: certain rights of the competent authorities (e.g. the right to take samples of products even before receiving complaints) have to be reinforced; in order to avoid unnecessary red tape burdens, other factors such as the size of the company, the relative complexity of the technology used, and whether or not a product is a result of unit or series production should be taken into account when carrying out conformity procedures. Articles 2, 7, and 17 of the Regulation are amended in this way. Also, the economic impact should be considered before authorities decide to recall a product - any action taken should be proportionate to the level of risk. Economic operators should also have the right to respond to such a decision, and appeal if necessary. Therefore Articles 2 and 19 have been amended. Article 16 has been amended to call on Member States to ensure there are procedures to verify that corrective actions are actually carried out.

- Recital 30a and Article 34 of the Regulation, as well as Article 14 of the Decision are amended to ensure more involvement of stakeholders and professional organizations.

- In order to avoid having "double standards" (i.e. a set of requirements introduced by Directive 2001/95/EC on general product safety (GPSD), and another set introduced by the present proposal) and to ensure the higher level of protection introduced by this proposal, the exemption stipulated in Article 13 (2) of the Regulation should be deleted. Also, exceptions listed in Article 1 of the Decision should be deleted as this is a *sui generis* decision directed towards the legislator and therefore not directly applicable.

- The CE marking needs better protection. Its meaning of conformity with EU regulatory standards is not always clearly understood. As a result, an increasing number of products bearing the CE marking do not in fact comply with the relevant legislation. It is a shared interest of manufacturers, traders and consumers to have clear rules on the CE marking. In order to have these rules applied straight away and not to make them subject to future national legislation, Articles 16-17 of the Decision should be placed in the Regulation.
- Article 4 and 16 have been amended to emphasise the importance of transparency in decision-making and the independence of market surveillance authorities.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Internal Market and Consumer Protection, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament

Amendment 1
Recital 23

(23) Directive 2001/95/EC of the European Parliament and of the Council on general product safety has set up a market surveillance and administrative cooperation framework in respect of consumer products. The provisions of this Regulation on market surveillance should not apply in relation to products, as defined in Article 2(a) of Directive 2001/95/EC, in so far as the health and safety of consumers is concerned.	***deleted***

Justification

In order to avoid having "double standards" (i.e. a set of requirements introduced by Directive 2001/95/EC (General Product Safety Directive), and another set introduced by the present proposal) and to ensure the higher level of protection introduced by this proposal, this exemption should be deleted. The borderline between products for consumer use and for professional use is blurred, and such distinction could lead to unclear procedures and responsibilities. Therefore Article 13 paragraph 2 and the corresponding Recital have to be deleted.

Amendment 2
Recital 24

(24) Cooperation of competent authorities at the national level and across borders in exchanging information, investigating infringements and taking action to bring about their cessation is essential to the protection of health and safety and to guaranteeing the smooth functioning of the internal market.	(24) Cooperation of competent authorities at the national level and across borders in exchanging information, investigating infringements and taking action to bring about their cessation is essential to the protection of health and safety and to guaranteeing the smooth functioning of the internal market. ***National consumer protection authorities should cooperate, at national level, with national market surveillance authorities and should exchange information with them relating to products which they suspect to present a***

[1] Not yet published in OJ.

risk.

Justification

As individual consumers usually turn to the national consumer protection authorities in case of quality or safety problems, the relevant information should be forwarded to the market surveillance authorities for possible follow-up.

Amendment 3
Recital 30 a (new)

(30a) Member States may find it useful to establish co-operation agreements with stakeholders, in particular with sectoral professional organisations, in order to take advantage of available market intelligence when establishing, implementing and updating market surveillance programmes.

Justification

Cooperation with stakeholders is already practiced in some Member States; the purpose of this amendment to encourage this good practice and to ensure that it is not prevented in a Member State due to unclear legislation.

Amendment 4
Recital 30 b (new)

(30b) Member States should ensure adequate appeal procedures in respect of measures taken by competent authorities which restrict the placing on the market of products or require their withdrawal or recall.

Justification

If a Member State asks a manufacturer to recall a product, which is later found to be compliant, the economic operator should have access to appeal from the Member State(s) who made the demand. This text is based on Recital 37 of the General Product Safety Directive and, as such, is not a new or untried concept.

Amendment 5
Recital 36 a (new)

(36a) The CE marking, evidencing the conformity of a product, is the visible consequence of a complete assessment process designed to verify conformity in a broad sense. General principles governing the use of the CE marking and rules as to its affixing, which should apply in the application of Community legislation harmonising the use of that marking, should therefore be laid down in this Regulation.

Justification

The CE marking needs better protection. As the meaning of the CE marking is not clearly understood, an increasing number of products bearing the CE marking do not comply with the relevant legislation. It is therefore a shared interest of manufacturers, traders and consumers to have clear rules on the CE marking. In order to have these rules applied straight away and not to make them subject to future legislation, Articles 16 &17 of the Decision (COM(2007)053) should be included in this Regulation, as well as the corresponding recitals.

Amendment 6
Recital 36 b (new)

(36b) It is essential to make clear to both manufacturers and users that by affixing the CE marking to a product the manufacturer thereof declares that the product is in conformity with all applicable requirements and that he accepts full liability for it.

Justification

The CE marking needs better protection. As the meaning of the CE marking is not clearly understood, an increasing number of products bearing the CE marking do not comply with the relevant legislation. It is therefore a shared interest of manufacturers, traders and consumers to have clear rules on the CE marking. In order to have these rules applied straight away and not to make them subject to future legislation, Articles 16 &17 of the Decision (COM(2007)053) should be included in this Regulation, as well as the corresponding recitals.

Amendment 7
Recital 36 c (new)

(36c) The legal protection offered by the CE marking, which derives from its registration as a Community collective marking, enables public authorities to ensure proper enforcement and to prosecute infringements.

Justification

The CE marking needs better protection. As the meaning of the CE marking is not clearly understood, an increasing number of products bearing the CE marking do not comply with the relevant legislation. It is therefore a shared interest of manufacturers, traders and consumers to have clear rules on the CE marking. In order to have these rules applied straight away and not to make them subject to future legislation, Articles 16 &17 of the Decision (COM(2007)053) should be included in this Regulation, as well as the corresponding recitals.

Amendment 8
Article 2, point 1

(1) "making available on the market" means any supply of a product for distribution***,*** consumption ***or use*** on the Community market in the course of a commercial activity, whether in return for payment or free of charge;	(1) "making available on the market" means any supply of a product for distribution ***or*** consumption on the Community market in the course of a commercial activity, whether in return for payment or free of charge***, but excluding products assembled for personal use in the furtherance of a professional activity and the incorporation of parts into a final product that is to be made available on the market and where there is no immediate risk to health and safety***;

Justification

This clarification will reduce excessive administrative and financial burdens for craftsmen and SMEs (when assembling products for their own use or manufacturing products to be integrated in a final work). This addition is also in line with an existing provision of Guidance Paper M (May 2005) of the Construction Product Directive (89/106/EEC) dealing with conformity.

Amendment 9
Article 2, point 2 a (new)

(2a) "entering the Community market" means being presented for customs clearance at a Community border;

Justification

This definition would clarify the meaning of the expression "products entering the Community market" used in Chapter III , Section 3 of the Regulation. There is a difference between economic operators who place a product on the market for the first time, and thus bear the responsibility of ensuring it is compliant with EU legislation, and distributors who distribute products already being sold on the Community market. This term is used in Article 24, so a definition is useful for reference.

Amendment 10
Article 2, point 3

(3) "manufacturer" means a natural or legal person who designs or manufactures a product or who has such a product designed or manufactured, under his name or trademark;	(3) "manufacturer" means a natural or legal person who designs or manufactures a product or who has such a product designed or manufactured, under his name or trademark***, and who places it on the market***;

Justification

Bring the definition in consistency with the definitions of other market players and with the provisions of proposed Article 7(1) and(7) (linked with Amendments 2 and 3).

Amendment 11
Article 2, point 11 a (new)

	(11a) "conformity assessment" means ascertaining whether specified requirements relating to a product, process, system, person or body are fulfilled.

Justification

The term "conformity assessment body" should be added, since this term is used extensively in the Regulation. The definition is taken from ISO/IEC 17000:2004 'Conformity assessment – Vocabulary and general principles'.

Amendment 12
Article 2, point 11 b (new)

	(11b) "conformity assessment body" means a body that performs conformity assessment activities;

Justification

The term 'conformity assessment' should be defined, as it is used several times in the regulation. There is no need to give examples of what conformity assessment bodies might be. The definition is taken from ISO/IEC 17000:2004 'Conformity assessment – Vocabulary and general principles'.

Amendment 13
Article 4, paragraph 6

6. The national accreditation body shall operate on a non profit basis. It may not offer or provide any activities or services that conformity assessment bodies provide, nor may it provide consultancy services.	6. The national accreditation body shall operate on a non profit basis. It may not offer or provide any activities or services that conformity assessment bodies provide, nor may it provide consultancy services***, nor may it own shares in a conformity assessment body***.

Justification

Measures must be taken to ensure independence of both the national accreditation body and the conformity assessment bodies; and the list of these measures has to be completed with the one guaranteeing financial separation.

Amendment 14
Article 7, point 9 a (new)

	(9a) it shall ensure that conformity assessment bodies carry out conformity assessments in a proportionate manner, avoiding unnecessary burdens for economic operators and in particular taking into consideration the size of the applicant economic operator, the complexity of any technology used in the product concerned and whether or not the product is a result of unit or series production.

Justification

In order to avoid unnecessary burden, other factors such as the size of the company, the relative complexity of the technology used, and the serial character of production should be taken into account when carrying out conformity procedures. The corresponding provision of the proposal for the Decision (COM(2007)0053 - Article 22, paragraph 4, subparagraph 4a

new) on a common framework for the marketing of products is amended accordingly.

Amendment 15
Article 8, paragraph 2 a (new)

2a. Member States shall ensure that adequate appeal procedures are available against decisions made by national accreditation bodies and conformity assessment bodies.

Justification

The existing proposal provides for a procedure whereby Member States are required to monitor their national accreditation bodies at regular intervals and thus the general public interest is protected. However, the actions of national accreditation bodies, and the bodies they accredit, have a direct impact on economic operators and so they too should have an explicit means of appeal.

Amendment 16
Article 13, paragraph 2

2. Articles 14 to 23 shall not apply to products as defined in Article 2(a) of Directive 2001/95/EC in so far as the health or safety of consumers is concerned.	***deleted***

Justification

In order to avoid having "double standards" (i.e. a set of requirements introduced by Directive 2001/95/EC, and another set introduced by the present proposal) and to ensure the higher level of protection as guaranteed by this proposal, Articles 14 to 23 of the proposal should also apply to products defined in Article 2(a) of Directive 2001/95/EC. Therefore Article 13 (2) of the proposal and the corresponding recital have to be deleted.

Amendment 17
Article 16, paragraph 1

1. Member States shall ensure communication and co-ordination between all the different market surveillance authorities.	1. Member States shall ensure communication and co-ordination between all the different market surveillance authorities ***under their jurisdiction***.

Justification

Emphasis should be placed on the need for cooperation between different competent authorities in a Member State (e.g. different regional bodies, different government ministries). Clarification that Article 16 refers to cooperation between different authorities within Member States. Article 22 deals with cross-border cooperation.

Amendment 18
Article 16, paragraph 2

2. Member States shall establish adequate procedures in order to follow-up complaints or reports on issues related to risks arising from products falling under Community harmonisation legislation, monitor accidents and damage to health which are suspected to have been caused by those products and follow up and update scientific and technical knowledge concerning safety issues.	2. Member States shall establish adequate procedures in order to follow-up complaints or reports on issues related to risks arising from products falling under Community harmonisation legislation, monitor accidents and damage to health which are suspected to have been caused by those products and follow up and update scientific and technical knowledge concerning safety issues. ***Member States shall establish adequate procedures in order to verify that corrective actions have been effectively carried out.***

Justification

Market surveillance should also ensure follow-up for corrective actions in order to catch economic operators who deliberately do not comply with Community legislation, and to ensure that when a product has been found non-compliant, it is actually removed from the market.

Amendment 19
Article 16, paragraph 5

5. Member States shall periodically review and assess the functioning of their surveillance activities.	5. Member States shall periodically review and assess the functioning of their surveillance activities ***and shall make publicly available reports thereon***.

Justification

For the sake of transparency the results of the review and assessment of the surveillance activities should be available for the public.

Amendment 20

Article 17, paragraph 1, subparagraph 3

They shall also be entitled to enter the premises of the economic operators concerned where it appears to them to be necessary for the purposes of Article 14.	They shall also be entitled to enter the premises of the economic operators concerned ***and take samples of products*** where it appears to them to be necessary for the purposes of Article 14**.**

Justification

Some inexpensive components or consumer products can often be rapidly sold-out in a distributor's promotional sale before any complaints reach authorities, authorising them to react. For authorities to be able to perform their function effectively there must be a measure that entitles them to take a sample of the products from any economic operator for the purposes of assessing conformity without waiting for an official complaint to be made.

Amendment 21
Article 17, paragraph 2 a (new)

	2a. 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 at the address stated on the product in question or in the documentation accompanying the product.

Justification

It is important that the economic operator be informed if another Member State decides to withdraw one of its products. However, Member State authorities cannot be expected to contact the economic operator before sending information to authorities in another Member State, as this would slow the procedure considerably.

Amendment 22
Article 19, paragraph 1

1. Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the making available of a product, to withdraw it from the market or recall it, states the exact grounds on which it is based.	1. Member States shall ensure that any measure taken, pursuant to the relevant Community harmonisation legislation, to prohibit or restrict the making available of a product, to withdraw it from the market or recall it, states the exact grounds on which it is based***, and is proportionate to the degree***

of risk to the public.

Justification

Market intervention measures have different impact on the economic operators; therefore these measures should be chosen carefully and should be proportionate to the level of risk for the public. Similar provisions are already included in the General Product Safety Directive.

Amendment 23
Article 22, paragraph 2 a (new)

2a. 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 or in the documentation accompanying the product. The economic operator shall be permitted a reasonable period in which to respond, which shall be twenty-eight days where there is no immediate risk to the health and safety of the public.

Justification

Economic operators should be given the opportunity to react on the position of relevant authorities, in particular when other Member States are also involved thus, the procedure may have a significant impact on their business. The proposed period of 28 days provides with a reasonable balance between the needs of the enforcement bodies and the economic operators. The same deadline is already applied in e.g. the UK implementation of the Directive on the restriction of the use of hazardous substances in electrical and electronic equipment and experience has shown that it is appropriate.

Amendment 24
Article 24, paragraph 1 a (new)

1a. Member States shall confer greater powers on their customs authorities and provide them with the resources they need in order to accomplish their tasks, including the destruction of products not conforming to Community legislation.

Justification

National customs authorities have a vital role to play in preventing products being marketed in the Union when they do not conform to Community legislation. To enable them to carry out their activities to the best possible effect, they must be given greater powers, extending to the destruction of products not in conformity, including products bearing marks likely to mislead consumers, especially as to the meaning and form of the CE mark.

Amendment 25
Article 25, paragraph 1

1. A product the release of which has been suspended by the customs authorities pursuant to Article 24 shall be released if, within ***three*** working days of the suspension of release, the customs authorities have not been notified of any action taken by the market surveillance authorities and provided that all the other requirements and formalities pertaining to such release have been met.	1. A product, the release of which has been suspended by the customs authorities pursuant to Article 24, shall be released if, within ***five*** working days of the suspension of release, the customs authorities have not been notified of any action taken by the market surveillance authorities and provided that all the other requirements and formalities pertaining to such release have been met.

Justification

The deadline of three days is barely enough to simply exchange mails between the public administrations concerned; therefore, as public safety should not suffer from administrative delays, the deadline should be extended.

Amendment 26
Article 26, paragraph 2

2. Where the market surveillance authorities find that the product concerned does not comply with the Community harmonisation legislation, they shall take appropriate action which may***, if necessary,*** include prohibiting the product from being placed on the market.	2. Where the market surveillance authorities find that the product concerned does not comply with the Community harmonisation legislation, they shall take appropriate action which may include prohibiting the product from being placed on the market.
In cases where placing on the market is prohibited, they shall ***ask*** the customs authorities to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document:	Where placing on the market is prohibited, they shall ***instruct*** the customs authorities ***not to release the product concerned for free circulation and*** to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document:
‘Product not in conformity - release for free	‘Product not in conformity - release for free

circulation not authorized – Regulation (EC) No …/..',	circulation not authorized – Regulation (EC) No …/..',

Justification

Explicit instructions from the market surveillance authorities and explicit action by the customs authorities are needed to prevent the free circulation of non-compliant products. It is unlikely, but not impossible, that an unauthorized product will be released for free-circulation in the absence of such explicit action.

Amendment 27
Chapter III, Section 3 a (new), Title (after Article 26)

SECTION 3A

CONFORMITY OF PRODUCTS - CE MARKING

Justification

The CE marking needs better protection. As the meaning of the CE marking is not clearly understood, an increasing number of products bearing the CE marking do not comply with the relevant legislation. It is therefore a shared interest of manufacturers, traders and consumers to have clear rules on the CE marking. In order to have these rules applied straight away and not to make them subject to future legislation, Articles 16-17 of the Decision should be transferred into the Regulation.

Amendment 28
Article 26 a (new)

Article 26a

General principles of the CE marking

1. The CE marking shall be affixed only by the manufacturer or his authorised representative.

By affixing or having affixed the CE marking the manufacturer shall assume responsibility for the conformity of the product with the requirements laid down in Decision No .../… of the European Parliament and of the Council of ... [on a common framework for the marketing of products][1].

2. The CE marking shall be the only marking which attests the conformity of the product with applicable requirements. Member States shall not introduce into their national law and shall withdraw any reference to a conformity marking other than the CE marking in connection with conformity to the provisions contained in Community legislation relating to the CE marking.

3. The affixing on products of markings, signs and inscriptions which are likely to be misleading as to the meaning or form of the CE marking shall be prohibited. Other markings that do not impair the visibility, legibility and meaning of the CE marking may be affixed.

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[1] OJ L...

Justification

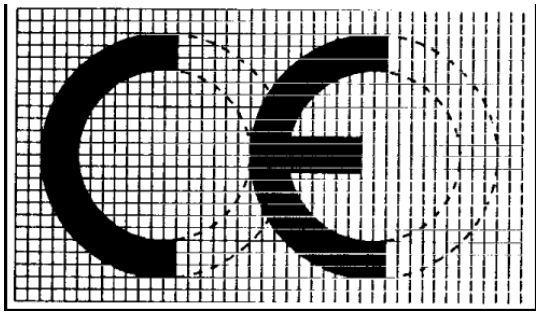
The CE marking needs better protection. As the meaning of the CE marking is not clearly understood, an increasing number of products bearing the CE marking do not comply with the relevant legislation. It is therefore a shared interest of manufacturers, traders and consumers to have clear rules on the CE marking. In order to have these rules applied straight away and not to make them subject to future legislation, Articles 16-17 of the Decision should be transferred into the Regulation.

Amendment 29
Article 26 b (new)

Article 26b

Rules and conditions for the affixing of the CE marking

1. The CE marking shall consist of the initials "CE" taking the following form:



2. If the CE marking is reduced or enlarged the proportions given in the graduated drawing in paragraph 1 must be respected.

3. Where specific legislation does not impose specific dimensions, the CE marking shall have a height of at least 5 mm.

4. The CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where this is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents, where the legislation concerned provides for such documents.

5. The CE marking shall be affixed before the product is placed on the market. It may be followed by a pictogram or any other marking indicating a special risk or use.

6. The CE marking shall be followed by the identification number of the conformity assessment body and/or any other body involved in the production control phase.

The identification number of such body shall be affixed by the body itself or under its instructions, by the manufacturer or his authorised representative established within the Community.

7. Member States shall ensure correct implementation of the regime governing the CE marking, and take legal action in case of improper use. Member States shall also put in place penalties, which may include criminal sanctions for serious infringements, that must be proportionate to the seriousness of the offence and

constitute an effective deterrent against improper use.

Justification

The CE marking needs better protection. As the meaning of the CE marking is not clearly understood, an increasing number of products bearing the CE marking do not comply with the relevant legislation. It is therefore a shared interest of manufacturers, traders and consumers to have clear rules on the CE marking. In order to have these rules applied straight away and not to make them subject to future legislation, Articles 16-17 of the Decision should be transferred into the Regulation.

Amendment 30
Final provisions, Title

FINAL PROVISIONS	***AMENDING AND*** FINAL PROVISIONS

Justification

Including provisions on the notified bodies and their identification numbers into the Regulation will give immediate legal certainty to the current practical application of the notification procedure. This requires specific amending text to the existing Directives therefore the title has to be amended.

Amendment 31
Article 33 a (new) (after "Final provisions")

Article 33a

Article 9 (1), second sentence, of Directive 87/404/EEC; Article 9 (2), second sentence, of Directive 88/378/EEC; Article 9 (1) of Directive 89/686/EEC; Article 9 (1), second sentence, of Directive 90/384/EEC; Article 11 (1), second subparagraph, of Directive 90/385/EEC; Article 9 (1), second subparagraph, of Directive 90/396/EEC; Article 8 (1), second and third subparagraphs, of Directive 92/42/EEC; Article 6 (2), second subparagraph, of Directive 93/15/EEC; Article 16 (1), second subparagraph, of Directive 93/42/EEC; Article 9 (1), second subparagraph, of Directive 94/9/EC; Article 9 (1), second subparagraph, of Directive 94/25/EC; Article 9 (1), second subparagraph, of Directive 95/16/EC; Article 20 (1), second

subparagraph, of Directive 96/48/EC; Article 12 (1), second subparagraph, of Directive 97/23/EC; Article 9 (1), second subparagraph, of Directive 98/37/EC; Article 15 (1), second subparagraph, of Directive 98/79/EC; Article 8 (1), second subparagraph, of Directive 99/36/EC; Article 15 (4) of Directive 2000/14/EC; Article 11 (4) of Directive 2004/22/EC; and Article 12 (3) of Directive 2004/108/EC are replaced by the following:

"The Commission shall assign an identification number to a notified body. It shall assign a single such number even where the body is notified under several Community acts. The Commission shall make publicly available the list of the bodies including the identification numbers that have been allocated to them and the activities for which they have been notified. The Commission shall ensure that this list is kept up to date."

Justification

Including provisions on the notified bodies and their identification numbers into the Regulation will give immediate legal certainty to the current practical application of the notification procedure. This requires specific amending text to the existing Directives.

Amendment 32
Article 33 b (new)

Article 33b

1. Article 10(3) of Directive 89/106/EEC is replaced by the following:

"The list of approval bodies which are competent to issue European technical approvals, as well as any amendments to that list, shall be made publicly available.".

2. Article 18(1), second subparagraph, of Directive 89/106/EEC is replaced by the following:

"The Commission shall assign an identification number to a notified body. It shall assign a single such number even

where the body is notified under several Community acts. The Commission shall make publicly available the list of the bodies including the identification numbers that have been allocated to them and the activities and products for which they have been notified. The Commission shall ensure that this list is kept up to date.".

3. Article 13(1), second subparagraph, of Directive 97/23/EC is replaced by the following:

"The Commission shall make publicly available a list of recognised organisations with the tasks for which they have been recognised. The Commission shall ensure that this list is kept up to date.".

4. Article 11(3) of Directive 99/5/EC is replaced by the following:

"The Commission shall assign an identification number to a notified body. It shall assign a single such number even where the body is notified under several Community acts. The Commission shall make publicly available the list of the bodies including the identification numbers that have been allocated to them and the activities for which they have been notified. The Commission shall also make available a list of surveillance authorities. Member States shall provide the Commission with all information necessary to keep these lists up to date.".

5. Article 9(1), third subparagraph, of Directive 99/36/EC is replaced by the following:

"The Commission shall make publicly available the list of the approved bodies including the identification numbers that have been allocated to them and the activities for which they have been notified. The Commission shall ensure that this list is kept up to date.".

6. In Article 16(1) of Directive 2000/9/EC, in Article 20(1) of Directive 2001/16/EC and in Article 8(1) of Regulation (EC) No

	552/2004, the words "The Commission shall publish in the Official Journal of the European Union" are replaced by the words "The Commission shall make publicly available".

Justification

Including provisions on the notified bodies and their identification numbers into the Regulation will give immediate legal certainty to the current practical application of the notification procedure. This requires specific amending text to the existing Directives.

Amendment 33
Article 34

In order to facilitate the implementation of this Regulation, the Commission shall draw up guidelines.	In order to facilitate the implementation of this Regulation, the Commission shall draw up guidelines ***after consultation with relevant stakeholders***.

Justification

Stakeholders should be consulted by the Commission when setting up implementation guidelines.

PROCEDURE

Title	Accreditation and market surveillance relating to the marketing of products
References	COM(2007)0037 - C6-0068/2007 - 2007/0029(COD)
Committee responsible	IMCO
Opinion by Date announced in plenary	ITRE 13.3.2007
Draftsman Date appointed	John Purvis 12.4.2007
Discussed in committee	26.6.2007
Date adopted	2.10.2007
Result of final vote	+: 44 –: 0 0: 2
Members present for the final vote	Jan Březina, Philippe Busquin, Jerzy Buzek, Jorgo Chatzimarkakis, Silvia Ciornei, Pilar del Castillo Vera, Lena Ek, Nicole Fontaine, Adam Gierek, Umberto Guidoni, András Gyürk, Fiona Hall, David Hammerstein, Rebecca Harms, Mary Honeyball, Ján Hudacký, Romana Jordan Cizelj, Anne Laperrouze, Pia Elda Locatelli, Eluned Morgan, Angelika Niebler, Reino Paasilinna, Miloslav Ransdorf, Vladimír Remek, Mechtild Rothe, Paul Rübig, Andres Tarand, Radu Ţîrle, Patrizia Toia, Claude Turmes, Nikolaos Vakalis, Alejo Vidal-Quadras, Dominique Vlasto
Substitutes present for the final vote	Alexander Alvaro, Pilar Ayuso, Ivo Belet, Manuel António dos Santos, Avril Doyle, Robert Goebbels, Françoise Grossetête, Erika Mann, John Purvis, Bernhard Rapkay, Silvia-Adriana Ţicău, Vladimir Urutchev, Lambert van Nistelrooij

PROCEDURE

Title	Accreditation and market surveillance relating to the marketing of products			
References	COM(2007)0037 - C6-0068/2007 - 2007/0029(COD)			
Date submitted to Parliament	14.2.2007			
Committee responsible Date announced in plenary	IMCO 13.3.2007			
Committee(s) asked for opinion(s) Date announced in plenary	INTA 13.3.2007	ENVI 13.3.2007	ITRE 13.3.2007	JURI 13.3.2007
Not delivering opinions Date of decision	JURI 18.6.2007			
Rapporteur(s) Date appointed	André Brie 20.3.2007			
Discussed in committee	7.5.2007	27.6.2007	16.7.2007	12.9.2007
	2.10.2007	5.11.2007	21.11.2007	
Date adopted	27.11.2007			
Result of final vote	+: 39 –: 0 0: 0			
Members present for the final vote	Charlotte Cederschiöld, Gabriela Creţu, Mia De Vits, Janelly Fourtou, Vicente Miguel Garcés Ramón, Evelyne Gebhardt, Malcolm Harbour, Anna Hedh, Iliana Malinova Iotova, Pierre Jonckheer, Kurt Lechner, Lasse Lehtinen, Toine Manders, Arlene McCarthy, Nickolay Mladenov, Catherine Neris, Bill Newton Dunn, Zita Pleštinská, Zuzana Roithová, Heide Rühle, Leopold Józef Rutowicz, Christel Schaldemose, Andreas Schwab, Alexander Stubb, Eva-Britt Svensson, Marianne Thyssen, Horia-Victor Toma, Jacques Toubon			
Substitutes present for the final vote	Emmanouil Angelakas, André Brie, Wolfgang Bulfon, Colm Burke, Giovanna Corda, András Gyürk, Filip Kaczmarek, Manuel Medina Ortega, Ieke van den Burg, Anja Weisgerber			
Substitutes under Rule 178(2) present for the final vote	Ingo Friedrich, Toomas Savi, Samuli Pohjamo			