

EUROPEAN PARLIAMENT

2004



2009

Committee on the Internal Market and Consumer Protection

PROVISIONAL
2007/0029(COD)

29.6.2007

*****I**

DRAFT 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)¹,
 - 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 the Environment, Public Health and Food Safety, the Committee on International Trade and the Committee on Industry, Research and Energy (A6-0000/2007),
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 strengthening the overall framework ensuring that products respect a high level of protection of public interests, such as health and safety ***or the protection 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***

¹ Not yet published in OJ.

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

Justification

A clear reference should be made to the protection of the environment. Cases of non conformity with existing EU legislation in the environmental field should be dealt with. EU legislation in the environmental field as become very complex, and therefore conformity assessment procedures in this area are a also cost factor for EU manufacturers. The framework provisions set out herein do not change existing, specific legislation, and if there for example are more precise rules in such legislation relating to market surveillance they will have preference over the general rules herein.

Amendment 2

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 and foodstuffs as traditional specialities guaranteed, Council Regulation (EC) No

(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. No specific product area should therefore be excluded from the scope of this Regulation. However, in accordance with the principle that more specific provisions take precedence over more general, this Regulation shall 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.

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.

Justification

The scope of the Regulation should be broadened to enable it to fulfil its function as a framework and cover existing or future gaps. More specific rules will have precedence over more general rules hereof, so there will be no lessening of substantive standards. This is not a new concept - the language above is borrowed from recital 5 and Article 1(2) of the Directive on general product safety. The principle also avoids cumbersome lists of exceptions that do not further understanding or principles of better regulation and may necessitate frequent revisions of the Regulation in future.

Amendment 3

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

See justification to recital 3.

Amendment 4

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 *deleted*

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 subject to this Regulation.

Justification

See justification to recital 3.

Amendment 5
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 3.

Amendment 6
Recital 14

(14) In those cases where it is not economically meaningful or sustainable for a Member State to establish a national

(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*** recourse to the national accreditation body of another Member State.

accreditation body, that Member State should have recourse to the national accreditation body of another Member State.

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 7
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 8
Recital 16

(16) In order to ensure that national accreditation bodies fulfil the requirements

(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.

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 9 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 the Regulation should provide for the recognition of another body for certain functions to be provided hereunder, 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 hereunder 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.***

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 10
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 11
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 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***

(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 ***lacunae***, those sectors should ***however also*** be subject to ***the overall framework established by*** this Regulation. ***To the extent they contain more specific provisions than those established by the Regulation, those more specific provisions will prevail.***

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.

Justification

See justification to recital 3.

Amendment 12
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

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 13

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. ***The Member States should promote cooperation and exchange of information between national consumer organisations and market surveillance authorities.***

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 14

Recital 27

(27) Community legislation harmonising the conditions for the marketing of products provides for specific procedures establishing whether a national measure restricting the free movement of a product is justified or not (safeguard clause procedures). Those procedures apply subsequently to a rapid exchange of information on products presenting a serious risk.

(27) Community legislation harmonising the conditions for the marketing of products provides for specific procedures establishing whether a national measure restricting the free movement of a product is justified or not (safeguard clause procedures). Those procedures apply subsequently to a rapid exchange of information on products presenting a serious risk. ***As the market surveillance framework established by this Regulations covers also products not falling under the harmonised area, a general safeguard clause procedure should be established. It should apply in those cases where the Community harmonisation legislation***

does not contain a safeguard procedure or that procedure does not apply.

Justification

A general safeguard procedure is required as a consequence of the broadening of the scope of the market surveillance to cover all products.

Amendment 15

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 the same scope. ***All operators that place products on the Community market shall be subject to the same obligations regardless of whether they are manufacturers, authorised representatives or importers.***

Justification

There should be an even playing field between operators regardless of their type.

Amendment 16

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 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 products from the market surveillance authorities well in advance.

Justification

See justification to Article 24.

Amendment 17

Recital 30

(30) Experience has shown that products which are not released are often re-exported and subsequently enter the Community market at other points of entry, thus negating the customs authorities' efforts. Market surveillance authorities should therefore be given the means to proceed with the destruction of products if they deem it appropriate. ***deleted***

Justification

The Community Customs Code already allows for destruction of goods. To add the same possibility in the Regulation is unnecessary and also disproportionate as the reason given for it is lack of cooperation between customs authorities in the EU, a problem to be addressed by requirements for enhanced cooperation in the Regulation and which should not be managed by possibly facilitating destruction of goods.

Amendment 18

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 19

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 20

Article 1, paragraph 1, subparagraph 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.

1. This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing assessment of any product to be placed on the Community market.

Justification

"Products" are proposed to be defined in Article 2, amongst the other definitions used in the Regulation.

Amendment 21

Article 1, paragraph 1, subparagraph 2

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 interests such as health and safety in general, of health and safety at the workplace, protection of consumers, of the environment, and of security.

It also provides a framework for market surveillance, ***including a Community safeguard procedure***, and ***for*** the control of products from third countries, to ensure that ***products benefiting from the free movement of goods within the Community, whether such products are*** subject to Community harmonisation legislation ***or not***, respect a high level of protection of public interests such as health and safety in general, of health and safety at the workplace, protection of consumers, of the environment, and of security, ***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.***

Justification

A broad market surveillance framework requires a correspondingly broad safeguard procedure, to enable the Commission to react at least in severe cases of unwarranted action against the free movement of products regardless of whether they are covered by harmonisation legislation or not, thus creating the foundation of a uniform system but without impinging on the competence of the Court. The community safeguard clause proposed here is intended to be less stringent than the safeguard clauses in individual directives. The latter would continue to apply in their specific areas.

Amendment 22

Article 1, paragraph 2

2. This Regulation shall not apply in cases governed by: ***deleted***

(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.

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 23

Article 1, paragraph 2 a (new)

2a. It also contains provisions relating to the Community CE mark.

Justification

The meaning of "CE marking" is proposed defined in Article 2, and a new Section 4 would contain certain basic provisions for the CE marking inspired by the corresponding provisions of the proposed Decision on a common framework for the marketing of products, but amended inter alia with the aim of strengthening the mark. This would make those basic provisions applicable immediately upon the Regulation coming into force.

Amendment 24

Article 1, paragraph 2 b (new)

2b. This Regulation also provides a framework supporting the 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 specific rules on accreditation and market surveillance that may be contained therein.

Justification

The framework provisions of this Regulation should apply as broadly as possible and therefore a number of the proposed exemptions from its applicability are proposed deleted. More specific provisions contained in other Community legislation on the issues covered herein will prevail over the provisions hereof. This concept is not new and is reflected e.g. in Article 1(2) of the GPSD.

Amendment 25 Article 2, point -1 (new)

(-1) "products" shall mean any substances, preparations and other moveable goods, whether transformed or not;

Justification

The reference to "moveable goods" provides a scope equal to that of the Articles of the Treaty on the free movement of goods

Amendment 26 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 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 27 Article 2, point 13 a (new)

(13a) "Community harmonisation legislation" shall mean 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 28
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 29
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 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 30
Article 2, point 13 d (new)

(13d) “CE marking” means a marking which materializes the declaration of the manufacturer (or of his authorized representative) that the product is in conformity with all applicable requirements for its placing on the EU 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 31
Article 2, point 13 e (new)

(13e) "market surveillance authority" means the authority/-ies 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 32
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 of any product, 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.

Amendment 33
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 proposed to not 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 34 Article 3, paragraph 3

3. This chapter shall not apply in cases ~~governed by Regulation (EC) No 761/2001.~~ deleted

Justification

The Regulation 761/2006 is proposed to not 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 35 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 36 Article 4, paragraph 3, subparagraph 2 a (new)

On the basis of the information referred to in the previous subparagraphs, the Commission shall draw up and update the list of the national accreditation bodies operating for each Member State. That list shall be published in the Official Journal of the European Union, C series.

Justification

To ensure transparency of the identities of the national accreditation bodies from the entry into force of this Regulation.

Amendment 37
Article 4, paragraph 4

4. The national accreditation body shall **be deemed to exercise** public authority.

4. The national accreditation body shall **act 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 38
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 39

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 European co-operation for Accreditation (EA).

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 40

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 conformity assessment body's competence.

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 41

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 42 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 43 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 44
Article 9, paragraph 1a (new)

1a. Stakeholders shall have the right to participate in the system set up for the supervision of the 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 45
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 46
Article 11, paragraph 2

2. A national accreditation body shall

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.

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 47

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 48

Article 12, paragraph 2

The Commission may also, following the procedure laid down the first paragraph, **request the EA** to develop sectoral accreditation schemes.

The Commission may also, following the procedure laid down 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 49 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 ***or other public interest protection***.

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 50 Article 12 a (new), paragraph 1

Article 12a

European accreditation infrastructure

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

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 51
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 duties of the body, the breach of which will entitle the Commission to terminate the agreement for cause, funding provisions, 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 shall make the framework agreement public. Both the Commission and the body 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 52
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 53
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 54

Article 12 a (new), paragraph 5

5. On the entry into force of this Chapter, European Co-operation for Accreditation shall be the recognised body, provided that it has concluded a framework agreement as aforesaid.

Justification

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

Amendment 55

Article 13, paragraph 1

1. This Chapter shall apply ***to substances, preparations and transformed products, hereinafter “products”, covered by Community harmonisation legislation.***

1. This Chapter shall apply to ***all*** products.

Justification

To provide a coherent and unified framework for market surveillance regardless of whether a particular product happens to fully or partially fall under the harmonised area, the provisions on market surveillance must apply to all products.

Amendment 56

Article 13, paragraph 1 a (new)

1a. The provisions of this Chapter shall apply without prejudice to provisions contained in existing more specific Community legislation on the issues covered herein.

Justification

This provision sets out the basic principle of the precedence of more specific legislation over more general, such as the framework established hereby. This legal principle is not new. It is confirmed in other Community legislation, such as the GPSD. It also provides for regulatory

simplification in that there would be no list of exemptions that would have to be updated from time to time. It also means that in those few cases where a genuine uncertainty as to the applicable rule may arise, the decision is ultimately taken by a neutral body (court), not by interested parties.

Amendment 57
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 58
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 59

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 60

Article 14, title

General requirements

General requirements **and principles**

Amendment 61

Article 14, paragraph 1

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

1. Member States shall organise and perform surveillance in order to ensure that products on the Community market, or entering that market, satisfy the provisions of **any** relevant Community **rules, including Community harmonisation legislation**, and that they do not, under the condition that they are properly installed,

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**.

maintained and used, compromise health or safety or other issues of public interest protection set out in the relevant Community **rules**.

Justification

This is in line with the objective of providing a coherent, uniform framework for market surveillance regardless of the type of product. The reference to Community rules covers all applicable rules, whether of the Treaty or in secondary legislation, including the proposed regulation on the application of certain national technical rules to products lawfully marketed in another Member State (the Stubb report).

Amendment 62
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 which complies with all the applicable Community rules, unless such prohibition, restriction or impediment is based on and complies with the requirements set out herein or other applicable Community rules.

Justification

To elaborate the fact that market surveillance is subject to the Community rules applicable to the free movement of goods, and itself a rule-bound activity.

Amendment 63
Article 14, paragraph 1 b (new)

1b. Market surveillance shall operate from the placing of a product on the market to its final use or consumption. It shall take due account of the principle of proportionality, of the risk assessed, of the presumption of conformity for products bearing the relevant conformity marking and accompanied by the relevant declaration of conformity and/or documentation, and shall give priority to

the fields and sectors where the potential risk is the highest and to cases which are of individual interest further to accidents, complaints or other relevant indications.

Justification

This provision aims at setting out certain fundamental principles and methods for market surveillance, and to emphasise that the surveillance covers the entire life of a product and must be directed on those areas where there are concrete indications of problems, while taking into account inter alia the need to act in a manner proportionate to the risk.

Amendment 64

Article 14, paragraph 1 c (new)

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

Justification

This aims at establishing an obligation on the Member States, enforceable by infringement action by the Commission, to actually perform market surveillance across the whole spectrum of products.

Amendment 65

Article 14, paragraph 1 d (new)

1d. The object of market surveillance is to ensure that products which are liable to compromise the health or safety of person, the protection of the environment or other relevant issues of public interest protection are withdrawn, prohibited or restricted from being made available on the market subject to the conditions set out herein and that the public, the Commission and the other Member States are appropriately informed.

Justification

To restate the fundamental goal of market surveillance, including providing information to the public on dangerous products and actions taken.

Amendment 66
Article 15

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"***.

Each Member State shall inform the Commission ***of their market surveillance authorities and their areas of competence. The Commission shall transmit the information*** to the other Member States.

Justification

The proposed changes aim at clarification, as well as ensuring public awareness of the market surveillance authorities. As the information to be provided by the Member States should include the competence of the respective market surveillance authorities, it is appropriate to pass the information via the Commission to enable it to check for completeness and consistency. The definition of "market surveillance authority" has been included in Article 2.

Amendment 67
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 it may be contacted.

Justification

See justification to Article 15

Amendment 68
Article 16, paragraph 1

1. Member States shall ensure communication and co-ordination between

1. Member States shall ensure communication and co-ordination between

all the different market surveillance authorities.

all the different market surveillance authorities *within its jurisdiction*.

Justification

Clarification.

Amendment 69
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, 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 70
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 from this Regulation entering into force and communicate it to the other Member States, the Commission and the public. Subsequent updates of**

that programme shall be communicated in the same manner.

Justification

The preparation and publication by each Member State of comprehensive market surveillance programmes will facilitate coordinated, risk-based market surveillance, increase awareness by the public and enable comment from those concerned.

Amendment 71
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 of the reviews and assessments shall be communicated to the other Member States, the Commission and the public.***

Justification

Market surveillance programmes risk being of little use unless regularly assessed and reviewed in the light of experience gained, and such reviews should of course be made public.

Amendment 72
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 appropriate, physical and laboratory checks on the basis of representative samples.

1. ***Taking into account established principles of risk assessment, complaints and other indications received the*** market surveillance authorities shall perform 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 73
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**.

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**.

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 **hereof**, to enter the premises of the economic operators **and to take samples of products**.

Justification

See justification to Article 17, paragraph 1.

Amendment 74
Article 17, paragraph 2

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.

They shall co-operate with economic operators on actions which could prevent or reduce risks caused by products made available by them.

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

They shall co-operate with economic operators on actions which could prevent or reduce **serious** risks caused by products made available by them.

Justification

Many products represent a simple risk. If that risk is of a standard nature, known and accepted, as for example with many tools and household items, it makes little sense to oblige the authorities to inform of it. To avoid dissipation of resources the market surveillance should focus on those products representing a serious risk, which could include a product of a type normally presenting only a simple risk if the individual product also carries an unexpected risk, e.g. due to a construction error. Information on serious risks should be provided promptly.

Amendment 75
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 to protect information appropriately identified by the economic operator concerned as a commercial secret or to preserve personal data, subject always to the information required to be made public hereunder 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 76
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 **to an interest defined in applicable Community rules**, 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 the market and that the Commission is informed **without delay** in accordance with Article 20.

Justification

See justification to Article 18, paragraph 1 a (new).

Amendment 77

Article 18, paragraph 1 a (new)

1a. The decision as to whether 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. A product shall not be deemed to represent a serious risk for the sole reason that there may be a substitutable product representing a lesser risk in the same respect.

Justification

While it may not be feasible to define the concept of serious risk, some guidance on how to assess whether a product represents such a risk can nevertheless be provided, to further uniform application. In case of products representing a simple risk, e.g. technological development may lead to a newer product representing a lesser risk. That in itself should not mean that the older, possibly traditional, product is deemed to represent a serious risk.

Amendment 78

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 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

This amendment is in line with the proposed broadening of the scope for market surveillance.

Amendment 79

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. ***If action has been taken without hearing the operator, he shall be given the opportunity to be heard as soon as practicable and the action taken 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 80 Article 19, paragraph 3 a (new)

3a. Any measure as referred to in paragraph 1 shall be withdrawn or modified to be made less restrictive promptly upon the economic operator demonstrating that he has taken action effective 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 81 Article 20, paragraph 1

1. Where a Member State takes measures under Article 18 and considers that the reasons which prompted the measures or the effects of the measures taken go

1. Where a Member State takes ***or intends to take*** measures under Article 18 and considers that the reasons which prompted the measures or the effects of the measures

beyond its territory, it shall, immediately, notify the Commission, in accordance with paragraph 4, of the measures taken or those it intends to take. It shall also inform the Commission without delay of modification or withdrawal of any such measure.

taken go beyond its territory, it shall, immediately, notify the Commission, in accordance with paragraph 4, of the measures taken or those it intends to take. It shall also inform the Commission without delay of modification or withdrawal of any such measure. ***The Commission shall transmit this information to the other Member States.***

Justification

The Commission should be involved in the chain of information to enable it to perform an initial vetting of the information for possible clarification purposes before transmission to the other Member States. There is of course nothing to prevent the Member State concerned to simultaneously disseminate the information directly to the other member States.

Amendment 82
Article 21, title

Information support system

General Information support system
(ICSMS)

Justification

The ICSMS is an information exchange system currently in use in a number of Member States and which has proved its effectiveness. Its use should therefore be generalised. In future, a merger of the ICSMS and Rapex should be envisaged.

Amendment 83
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.***

Justification

Compare the amendment to Article 16(4), emphasising the need for market surveillance programmes to be established.

Amendment 84
Article 21, paragraph 2, subparagraph 1

2. For the purposes of paragraph 1, Member States and the Commission shall provide information at their disposal on products presenting a risk, in particular, identification of risks, results of testing carried out, provisional restrictive measures taken, contacts with the economic operators concerned, and justification for action or lack thereof.

2. For the purposes of paragraph 1, Member States and the Commission shall provide information at their disposal on products presenting a **serious** risk, in particular, identification of risks, results of testing carried out, provisional restrictive measures taken, contacts with the economic operators concerned, and justification for action or lack thereof.

Justification

Changes as a consequence of the focus on serious risks, and to reiterate the principle that timely and useful dissemination of information on products representing a serious risk takes precedence to the extent necessary over aspects of confidentiality.

Amendment 85

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 paragraph 3 of Article 17 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 86

Article 22, paragraph 1

1. Member States shall ensure efficient co-operation and exchange of information on all issues relating to products presenting a risk between their market surveillance authorities and those of the other Member States and between their own authorities and the Commission and the relevant Community Agencies.

1. Member States shall ensure efficient co-operation and exchange of information on all issues relating to products presenting a **serious** risk between their market surveillance authorities and those of the other Member States and between their own authorities and the Commission and the relevant Community Agencies.

Justification

A change as a consequence of the focus on serious risks.

Amendment 87
Article 22, paragraph 2 a (new)

2a. The Commission shall collect and organise such data on national market surveillance measures that will enable it to fulfil its obligations under Article 24.

Justification

A change to ensure that the Commission will be in a position to operate the proposed general safeguard clause proposed in Article 24.

Amendment 88
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 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 89
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

the European systems and activities relating to conformity assessment, market surveillance and accreditation.

Justification

See justification to Article 23, paragraph 1

Amendment 90
SECTION 2 A (NEW)

***SECTION 2a
SAFEGUARD PROCEDURE***

Justification

To reflect the addition of a new, limited safeguard procedure to balance the enhanced and broadened market surveillance.

Amendment 91
Article 23 a (new), paragraph 1

Article 23a

Community safeguard procedure

1. Where objections are raised against a national measure of a Member State under Article 18 or where the Commission considers the national measure to be contrary to Community law, and the Commission finds the matter sufficiently important based on its frequency, economic importance, effects on intra-Community trade, effects on individual economic operators or users, including consumers, or other criteria deemed relevant by the Commission, it shall without delay enter into consultation with the parties concerned and shall proceed to the evaluation of the national measure. On the basis of the results of that evaluation, the Commission shall take a decision, indicating whether the measure is justified or not. The

Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator(s), and publish the decision on its website.

Justification

This proposed addition represents a general safeguard clause of similar but less stringent structure as the safeguard clauses found in the individual new approach directives. It is intended to balance the proposed broadened market surveillance, without requiring the Commission to investigate each and every possible misuse. In cases of suspected systematic abuse of sufficient severity it should enable a prompter resolution to cases of infringement of the principle of free movement of goods than forcing each individual operator to take the Member State concerned to court.

Amendment 92

Article 23 a (new), paragraph 2

2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the product is withdrawn from their markets. Member States shall inform the Commission thereof. If the national measure is considered unjustified, all Member States concerned shall withdraw the measure.

Justification

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

Amendment 93

Article 23 a (new), paragraph 3

3. Where the national measure is considered to be justified and, where applicable, a non-compliance of the product is attributed to shortcomings in the harmonised standards as referred to in Article [35(5) (b)], the Commission or the Member State shall bring the matter before the Standing Committee set up under Article 5 of Directive 98/34/EC.

Justification

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

Amendment 94
SECTION 2 B (NEW)

SECTION 2b
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 95
Article 23 b (new), paragraph 1

Article 23b

General principles of the CE marking

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

Justification

This Article aims at both clarifying the effect of the CE marking for the free movement of the products concerned and at enhancing the protection of the CE mark. 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.

For the market surveillance authorities the appropriately applied CE marking constitutes a very useful instrument for their effective market surveillance activities.

Amendment 96
Article 23 b (new), paragraph 2

2. The CE marking is the only marking which attests conformity of the product with the applicable requirements of the relevant Community legislation providing for its affixation and a product bearing the CE marking is therefore presumed to not represent a serious risk. The specific safeguard provisions set out in the relevant Community harmonisation legislation applies to a product that has the CE mark affixed. A Member State other than the member State where the product was initially placed on the market may not require a product bearing the CE mark to be subject to additional testing, certification, marking or any other similar measure.

Justification

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

Amendment 97
Article 23 b (new), paragraph 3

3. No reference in national legislation to a conformity marking other than the CE marking, in relation to conformity to the provisions contained in the relevant Community legislation providing for CE marking, shall be applicable against any economic operator.

Justification

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

Amendment 98
Article 23 b (new), paragraph 4

4. The affixing on a product of markings, signs and inscriptions that are likely to

mislead third parties as to the meaning or form of the CE marking, or both, is prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking are not thereby impaired.

Justification

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

Amendment 99
Article 23 b (new), paragraph 5

5. 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 100
Article 23 c (new), paragraph 1

Article 23c

Certain rules and conditions for the affixing of the CE marking

1. Regardless of provisions to the contrary in individual Community legislation providing for the affixation of the CE marking, it shall be the choice of the manufacturer to affix the CE marking or to have it affixed.

Justification

With the proposed broadened market surveillance and the complementary general safeguard clause, and considering the problems with competing marks and also those operators who may produce for only the local market, the CE marking could be made voluntary. It should however be his choice. The text proposed to achieve this may have to be made more specific. To make the marking voluntary may also well strengthen it against other marks, if it proves to be demanded by users as opposed to being forced on operators.

Amendment 101 Article 23 c (new), paragraph 2

2. Article 23b paragraph 2 does not apply to a product to which the CE mark is not affixed.

Justification

See justification to Article 23 c (new), paragraph 1. If an operator opts to not affix the CE mark, while entitled to do so, he would forego the specific benefits following from the marking.

Amendment 102 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 customs authorities ***have the necessary powers and resources in order to properly perform their tasks. Member States shall also ensure an effective cooperation between customs and market surveillance authorities, inter alia to realise*** appropriate checks on the characteristics of a product on an adequate scale, ***in accordance with the principles set out in paragraph 1 of Article 17,*** before it is ***placed on the market. All operators that place products on the Community market shall be subject to the same obligations regardless of whether they are manufacturers, authorised representatives or importers.***

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 103

Article 24, paragraph 2, subparagraph 1, introductory part

2. The customs authorities shall suspend 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:

2. The customs authorities shall suspend release of a product **to be placed on the market** when, in carrying out the checks referred to in paragraph 1, they make either of the following findings:

Justification

See justification to Article 24, paragraph 1.

Amendment 104

Article 24, paragraph 2, subparagraph 1, 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 the second subparagraph of Article 1 paragraph 1;

Justification

See justification to Article 24, paragraph 1.

Amendment 105

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,

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.

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 106

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 107

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 ask 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 108
Article 26, paragraph 4

4. Market surveillance authorities may ~~destroy products presenting a serious risk where they deem it necessary and proportionate.~~ deleted

Justification

The Community Customs Code already provides for destruction of goods. To introduce the same possibility here would not only appear unnecessary but might cause confusion, and would also appear disproportionate, as the problem sought resolved (see Recital 30 of the proposal) is an internal Community problem of deficient cooperation. In addition, a right to destroy for the reasons advanced by the Commission should, were it retained, be balanced by potentially complicated provisions allowing the operator to protect his goods e.g. by posting a guarantee.

Amendment 109
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 110
Annex A (new)

Annex A

Requirements for the body to be recognised under Article 12a.

1. The body to be recognised under Article 12a, hereafter “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 review services which satisfy the requirements of Article 9.

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

6. The body shall co-operate with requests from the Commission arising under Article 12.

Justification

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

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 broad 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.

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 contain, inter alia, provisions for the supervision of the body.

The Rapporteur will pursue discussions with the Commission regarding the proposed Community financing of the body, including on the legal basis invoked.

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 only covers some products, and with uncertainty as to precisely what those products may be. A framework for market surveillance should by its very nature cover the entire market.

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 Regulation should simply subsume the GPSD and that way a high level of protection will be ensured.

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.

The Rapporteur introduces an additional section on a simple safeguard procedure, inspired by the proposed Decision. With the scope of market surveillance extended to all products, a similarly broad safeguard procedure is necessary to enable the Commission to take action against systemic unwarranted action against products. This creates the basis for a uniform Community-wide system without gaps. The safeguard clause proposed is intended to be less stringent than those in the individual New Approach directives (which would continue to apply in their areas as being more specific rules). Both the market surveillance framework and the safeguard clause would thus include all products, including those covered by mutual recognition.

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.

The Rapporteur also proposes that the CE marking becomes voluntary. The marking has a specific function in the context of market surveillance, but if an individual operator does not want to affix the mark to products that could legally be marked, he should be free to not avail himself of the benefit of the mark. The requirements apply regardless of the marking itself. Making the CE marking voluntary should reduce friction with other marks and could lead to simplification for smaller operators. It might strengthen the mark if it turns out to be demanded by the users.