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Committee on Industry, Research and Energy

2007/0029(COD)

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OPINION

of the Committee on Industry, Research and Energy

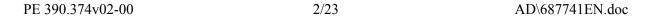
for the Committee on the Internal Market and Consumer Protection

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

Draftsman: John Purvis

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SHORT JUSTIFICATION

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

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

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

- Some definitions, such as "making available on the market" and "entering the Community market" must be clarified; new definitions on "conformity assessment"; "conformity assessment body" have to be introduced; coherence of definitions in the Regulation and the Decision must be ensured. Article 2 of the Regulation is therefore amended accordingly.
- Concerning the institutional side: the rules of cross-border accreditation should be simplified, while at the same time ensuring that increased cross-border competition does not result in lower accreditation standards; national consumer protection organizations should be involved in the cooperation among competent national authorities; customs authorities, which are the first line of defence with imports, have to be reinforced and equipped with adequate resources. Articles 6 and 24 of the Regulation are therefore amended this way.
- Provisions of the existing directives concerning identification numbers and lists of notified bodies have been updated in order to give immediate legal certainty to the current practical application of the notification procedure.
- As far as procedures are concerned: certain rights of the competent authorities (e.g. the right to take samples of products even before receiving complaints) have to be reinforced; in order to avoid unnecessary red tape burdens, other factors such as the size of the company, the relative complexity of the technology used, and whether or not a product is a result of unit or series production should be taken into account when carrying out conformity procedures. Articles 2, 7, and 17 of the Regulation are amended in this way. Also, the economic impact should be considered before authorities decide to recall a product any action taken should be proportionate to the level of risk. Economic operators should also have the right to respond to such a decision, and appeal if necessary. Therefore Articles 2 and 19 have been amended. Article 16 has been amended to call on Member States to ensure there are procedures to verify that corrective actions are actually carried out.

- Recital 30a and Article 34 of the Regulation, as well as Article 14 of the Decision are amended to ensure more involvement of stakeholders and professional organizations.
- In order to avoid having "double standards" (i.e. a set of requirements introduced by Directive 2001/95/EC on general product safety (GPSD), and another set introduced by the present proposal) and to ensure the higher level of protection introduced by this proposal, the exemption stipulated in Article 13 (2) of the Regulation should be deleted. Also, exceptions listed in Article 1 of the Decision should be deleted as this is a *sui generis* decision directed towards the legislator and therefore not directly applicable.
- The CE marking needs better protection. Its meaning of conformity with EU regulatory standards is not always clearly understood. As a result, an increasing number of products bearing the CE marking do not in fact comply with the relevant legislation. It is a shared interest of manufacturers, traders and consumers to have clear rules on the CE marking. In order to have these rules applied straight away and not to make them subject to future national legislation, Articles 16-17 of the Decision should be placed in the Regulation.
- Article 4 and 16 have been amended to emphasise the importance of transparency in decision-making and the independence of market surveillance authorities.

AMENDMENTS

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

Text proposed by the Commission¹

Amendments by Parliament

Amendment 1 Recital 23

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

deleted

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¹ Not yet published in OJ.

so far as the health and safety of consumers is concerned.

Justification

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

Amendment 2 Recital 24

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

Justification

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

Amendment 3 Recital 30 a (new)

(30a) Member States may find it useful to establish co-operation agreements with stakeholders, in particular with sectoral professional organisations, in order to take advantage of available market intelligence

when establishing, implementing and updating market surveillance programmes.

Justification

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

Amendment 4 Recital 30 b (new)

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

Justification

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

Amendment 5 Recital 36 a (new)

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

Justification

The CE marking needs better protection. As the meaning of the CE marking is not clearly understood, an increasing number of products bearing the CE marking do not comply with

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the relevant legislation. It is therefore a shared interest of manufacturers, traders and consumers to have clear rules on the CE marking. In order to have these rules applied straight away and not to make them subject to future legislation, Articles 16 &17 of the Decision (COM(2007)053) should be included in this Regulation, as well as the corresponding recitals.

Amendment 6 Recital 36 b (new)

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

Justification

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

Amendment 7 Recital 36 c (new)

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

Justification

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

Amendment 8 Article 2, point 1

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

Justification

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

Amendment 9 Article 2, point 2 a (new)

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

Justification

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

Amendment 10 Article 2, point 3

- (3) "manufacturer" means a natural or legal person who designs or manufactures a
- (3) "manufacturer" means a natural or legal person who designs or manufactures a

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product or who has such a product designed or manufactured, under his name or trademark; product or who has such a product designed or manufactured, under his name or trademark, and who places it on the market;

Justification

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

Amendment 11 Article 2, point 11 a (new)

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

Justification

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

Amendment 12 Article 2, point 11 b (new)

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

Justification

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

Amendment 13 Article 4, paragraph 6

- 6. The national accreditation body shall operate on a non profit basis. It may not offer or provide any activities or services
- 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.

that conformity assessment bodies provide, nor may it provide consultancy services, nor may it own shares in a conformity assessment body.

Justification

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

Amendment 14 Article 7, point 9 a (new)

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

Justification

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

Amendment 15 Article 8, paragraph 2 a (new)

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

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Justification

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

Amendment 16 Article 13, paragraph 2

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

deleted

Justification

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

Amendment 17 Article 16, paragraph 1

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

Justification

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

Amendment 18 Article 16, paragraph 2

- 2. Member States shall establish adequate procedures in order to follow-up complaints
- 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.

or reports on issues related to risks arising from products falling under Community harmonisation legislation, monitor accidents and damage to health which are suspected to have been caused by those products and follow up and update scientific and technical knowledge concerning safety issues.

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

Justification

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

Amendment 19 Article 16, paragraph 5

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

Justification

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

Amendment 20 Article 17, paragraph 1, subparagraph 3

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

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

Justification

Some inexpensive components or consumer products can often be rapidly sold-out in a distributor's promotional sale before any complaints reach authorities, authorising them to react. For authorities to be able to perform their function effectively there must be a measure

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that entitles them to take a sample of the products from any economic operator for the purposes of assessing conformity without waiting for an official complaint to be made.

Amendment 21 Article 17, paragraph 2 a (new)

2a. Where the market surveillance authorities of one Member State wish to withdraw a product manufactured in another Member State, they shall advise the economic operator concerned at the address stated on the product in question or in the documentation accompanying the product.

Justification

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

Amendment 22 Article 19, paragraph 1

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

Justification

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

Amendment 23 Article 22, paragraph 2 a (new)

2a. Where the market surveillance

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

Justification

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

Amendment 24 Article 24, paragraph 1 a (new)

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

Justification

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

Amendment 25 Article 25, paragraph 1

- 1. A product the release of which has been suspended by the customs authorities
- 1. A product, the release of which has been suspended by the customs authorities

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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

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

Justification

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

Amendment 26 Article 26, paragraph 2

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

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 .../..',

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.

Where placing on the market is prohibited, they shall *instruct* the customs authorities *not to release the product concerned for free circulation and* to include the following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document:

'Product not in conformity - release for free circulation not authorized – Regulation (EC) No .../..',

Justification

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

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

SECTION 3A

CONFORMITY OF PRODUCTS - CE MARKING

Justification

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

Amendment 28 Article 26 a (new)

Article 26a

General principles of the CE marking

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

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

- 2. The CE marking shall be the only marking which attests the conformity of the product with applicable requirements. Member States shall not introduce into their national law and shall withdraw any reference to a conformity marking other than the CE marking in connection with conformity to the provisions contained in Community legislation relating to the CE marking.
- 3. The affixing on products of markings, signs and inscriptions which are likely to be misleading as to the meaning or form of the CE marking shall be prohibited. Other markings that do not impair the visibility,

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legibility and meaning	of	the	CE	marking	g
may be affixed.					

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¹ O.J	<i>I</i>		

Justification

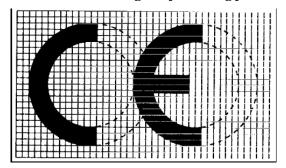
The CE marking needs better protection. As the meaning of the CE marking is not clearly understood, an increasing number of products bearing the CE marking do not comply with the relevant legislation. It is therefore a shared interest of manufacturers, traders and consumers to have clear rules on the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

Amendment 29 Article 26 b (new)

Article 26b

Rules and conditions for the affixing of the CE marking

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



- 2. If the CE marking is reduced or enlarged the proportions given in the graduated drawing in paragraph 1 must be respected.
- 3. Where specific legislation does not impose specific dimensions, the CE marking shall have a height of at least 5 mm
- 4. The CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where this is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents, where

the legislation concerned provides for such documents.

- 5. The CE marking shall be affixed before the product is placed on the market. It may be followed by a pictogram or any other marking indicating a special risk or use.
- 6. The CE marking shall be followed by the identification number of the conformity assessment body and/or any other body involved in the production control phase.

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

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

Justification

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

Amendment 30 Final provisions, Title

FINAL PROVISIONS

AMENDING AND FINAL PROVISIONS

Justification

Including provisions on the notified bodies and their identification numbers into the Regulation will give immediate legal certainty to the current practical application of the

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notification procedure. This requires specific amending text to the existing Directives therefore the title has to be amended.

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

Article 33a

Article 9 (1), second sentence, of Directive 87/404/EEC; Article 9 (2), second sentence, of Directive 88/378/EEC; Article 9 (1) of Directive 89/686/EEC; Article 9 (1), second sentence, of Directive 90/384/EEC; Article 11 (1), second subparagraph, of Directive 90/385/EEC; Article 9 (1), second subparagraph, of Directive 90/396/EEC; Article 8 (1), second and third subparagraphs, of Directive 92/42/EEC; Article 6 (2), second subparagraph, of Directive 93/15/EEC; Article 16 (1), second subparagraph, of Directive 93/42/EEC; Article 9 (1), second subparagraph, of Directive 94/9/EC; Article 9 (1), second subparagraph, of Directive 94/25/EC; Article 9 (1), second subparagraph, of Directive 95/16/EC; Article 20 (1), second subparagraph, of Directive 96/48/EC; Article 12 (1), second subparagraph, of Directive 97/23/EC; Article 9 (1), second subparagraph, of Directive 98/37/EC; Article 15 (1), second subparagraph, of Directive 98/79/EC; Article 8 (1), second subparagraph, of Directive 99/36/EC; *Article 15 (4) of Directive 2000/14/EC;* Article 11 (4) of Directive 2004/22/EC; and Article 12 (3) of Directive 2004/108/EC are replaced by the following:

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

is kept up to date."

Justification

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

Amendment 32 Article 33 b (new)

Article 33b

- 1. Article 10(3) of Directive 89/106/EEC is replaced by the following:
- "The list of approval bodies which are competent to issue European technical approvals, as well as any amendments to that list, shall be made publicly available.".
- 2. Article 18(1), second subparagraph, of Directive 89/106/EEC is replaced by the following:
- "The Commission shall assign an identification number to a notified body. It shall assign a single such number even where the body is notified under several Community acts. The Commission shall make publicly available the list of the bodies including the identification numbers that have been allocated to them and the activities and products for which they have been notified. The Commission shall ensure that this list is kept up to date.".
- 3. Article 13(1), second subparagraph, of Directive 97/23/EC is replaced by the following:
- "The Commission shall make publicly available a list of recognised organisations with the tasks for which they have been recognised. The Commission shall ensure that this list is kept up to date.".
- 4. Article 11(3) of Directive 99/5/EC is replaced by the following:
- "The Commission shall assign an identification number to a notified body. It

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

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

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

6. In Article 16(1) of Directive 2000/9/EC, in Article 20(1) of Directive 2001/16/EC and in Article 8(1) of Regulation (EC) No 552/2004, the words "The Commission shall publish in the Official Journal of the European Union" are replaced by the words "The Commission shall make publicly available.".

Justification

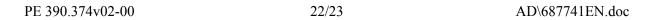
Including provisions on the notified bodies and their identification numbers into the Regulation will give immediate legal certainty to the current practical application of the notification procedure. This requires specific amending text to the existing Directives.

Amendment 33 Article 34

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



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



PROCEDURE

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