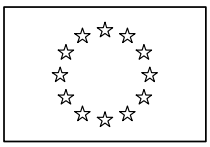

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.2.2007
COM(2007) 37 final

2007/0029 (COD)

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

{SEC(2007) 173}
{SEC(2007) 174}

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- Grounds for and objectives of the proposal

Free movement of goods, a central pillar of the Single Market, is a major driver for competitiveness and economic growth in the EU. Moreover, Community technical legislation ensuring the free circulation of products has contributed considerably to the completion and operation of the Single Market. It provides for high levels of protection to be respected and generally also provides economic operators with the means to demonstrate conformity, thus ensuring free circulation through trust in the products..

Experience in the implementation of all this legislation has shown, however:

– a certain risk of distortion to competition because of differing practices in the designation of conformity assessment bodies by national authorities and unequal treatment in the case of non complying or dangerous products on the market, through very different national market surveillance infrastructures, rules and means.

– a certain lack of trust in conformity marking.

– a certain lack of coherence in its implementation and enforcement.

The proposals, following the Council's Resolution of 10 November 2003, have the objective 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, by reinforcing and extending what exists and not weakening existing instruments such as the General Product Safety Directive which is very successful and effective. Secondly they set out agreed references for the organisation of the revision of existing product related Community harmonisation legislation, where necessary and for the development of future product related legislation.

- General context

The present proposals are very much within the framework of the overall Commission policy to promote simplification and better regulation as widely as possible. Originally the Council, in its Resolution of 10 November 2003, invited the Commission to review only the "new approach" directives. However faced with the possibility of bringing together harmonised instruments that could apply regardless of the legislative technique used (old/new approach legislation) the option followed has been to put forward proposals that can apply in as many sectors as possible within a coherent and transparent, harmonised manner, with standardised instruments. This covers in particular such issues as definitions such as placing on the market etc, the obligations for economic operators, the evaluation of the competence of conformity assessment bodies, conformity assessment procedures, control of products from third countries or conformity marking issues.

It also covers the issues relating to market surveillance in general. It is possible to put into place an overall policy and infrastructures throughout the Community without having to do so sector by sector and especially by building on the experience of the General Product Directive

for consumer products, whose principles and mechanisms can be extended to the surveillance of all products, whether consumer products or products for professional use.

- Existing provisions in the area of the proposal

The Council Resolution of 7 May 1985 relating the new approach to technical harmonisation and standardisation is the founding document in this area, whilst Council Decision 93/465 of 22 July 1993 sets out the basic rules for CE marking and for the application of the harmonised conformity assessment procedures. These texts have been complemented by different resolutions on standardization as well as by Directive 98/34 recognising the role of the European standardization organizations and the priority for European standards, not to mention the 25 "new approach directives relating to different product sectors.

Directive 2001/95/EC of the European Parliament and of the Council on general product safety provides a market surveillance infrastructure and information exchange system for the non harmonised areas and sets obligations for economic operators and national authorities in relation to consumer products.

- Consistency with the other policies and objectives of the Union

These proposals are central to the completion of the Single market for products, and contribute to other policies such as in particular, protection of the consumer, of workers and of the environment. They are integral to the overall policies of the Commission within the Lisbon agenda on the chapters better regulation, simplification and market surveillance.

- Consistency with the other policies and objectives of the Union

These proposals are central to the completion of the Single market for products, and contribute to other policies such as in particular, protection of the consumer, of workers and of the environment. They are integral to the overall policies of the Commission within the Lisbon agenda on the chapters' better regulation, simplification and market surveillance.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- Consultation of interested parties

Consultation methods, main sectors targeted and general profile of respondents

The content of the proposals was put together following 20 working documents which were widely circulated to all the major stakeholders. This brought some 250 contributions.

In 2006 an internet consultation via Your Voice in Europe (IPM) provoked 280 answers which mainly confirmed the results of the first consultations.

The Commission drew up 4 fact finding questionnaires dedicated to different stakeholder groups. The questionnaire for companies was used by the Euro Info Centre network to carry out a business panel operation (i.e. face to face interviews with 800 SMEs).

Summary of responses and how they have been taken into account

The contributions received confirm that the proposals should build on what exists as opposed

to creating a new system. Thus the existing accreditation system requires a legal base as opposed to being replaced by another system. They reaffirm it as a public authority activity and that, as such, should be free of commercial competition. The conformity assessment body system requires stricter selection criteria and harmonised national selection processes. Support was given to the harmonised definitions and the obligations set out for the economic operators. It was confirmed that a systematic requirement for authorised representatives did not solve the problem of traceability. Practically all contributions supported a Community market surveillance system with information and cooperation system between national authorities in extension to the mechanisms of the GPSD and without creating new tools. The option of abandoning the CE marking was contested and clarifying its meaning and protecting it legally were supported..

An open consultation was conducted over the internet from 01/06/2006 to 26/07/2006. The Commission received 280 responses. The results are available on http://ec.europa.eu/enterprise/newapproach/review_en.htm.

- Collection and use of expertise

Scientific/expertise domains concerned

Professionals in the fields of Conformity assessment, accreditation, market surveillance, standardisation and technical harmonisation were involved as well as experts from trade, consumer protection and other associations.

Methodology used

The experts were consulted on the working documents, participated in meetings and were the addressees of the questionnaires.

Main organisations/experts consulted

The national experts responsible for standardization and horizontal issues have been consulted as have been those responsible for the implementation of Community legislation. The experts in the field of accreditation and conformity assessment have also been consulted as have professional trade and consumer associations.

Summary of advice received and used

The vast majority of experts have expressed agreement with the contents of the proposals which were drawn up on the basis of their contributions.

Means used to make the expert advice publicly available

The option of placing their contributions on the new approach website with the results of the consultations is being examined.

- Impact assessment

Basically there are three general options:

(1) The first option consists in keeping the current situation unchanged. Products covered by Community harmonisation legislation would be marketed under the conditions

created by the existing legal framework and the non-legislative measures currently in place.

(2) The second option comprises non-regulatory measures which could be taken without a need to change the existing or introducing new legislation. There are however two limitations to the potential scope of this option:

(a) Problems originating in the existing legal provisions can only be eliminated through a change in the legislation.

(b) The Commission has made extensive use of non-regulatory instruments. In the area of market surveillance and evaluation/monitoring of notified bodies they have so far been insufficient to address effectively the problems related to the uneven level of enforcement by national authorities.

(3) The third option comprises measures requiring the intervention of the Community legislator accompanied by the reinforcement of non regulated instruments.

The only option which answers the feedback from all the stakeholders and which provides the solutions to the problems exposed is option 3.

The Commission carried out an impact assessment listed in the Work Programme, whose report is accessible on http://ec.europa.eu/enterprise/newapproach/review_en.htm.

3. LEGAL ELEMENTS OF THE PROPOSAL

- Summary of the proposed action

The proposals complete the different existing legislative tools by putting forward reinforced Community policies on market surveillance and accreditation; to bring coherence to existing sectoral instruments and to examine how these horizontal instruments can be applied to all sectors regardless of whether they are "old" or "new" approach.

The proposals consist in: a regulation for the introduction of accreditation and reinforcement market surveillance, and a sui generis decision to set the framework for future legislation.

The regulation should:

– organise accreditation at the national and European levels; irrespective of the different sectors of activity in which accreditation is used. The proposal insists on the public authority nature of accreditation in order for it to be the last level of public authority control, and sets the framework for the recognition of the existing organisation European co-operation for Accreditation (EA) so as to ensure the proper functioning of a rigorous peer evaluation.

– ensure, when not foreseen in other applicable Community legislation, that national authorities are given equivalent means of intervention and the necessary authority to intervene in the market to be able to restrict or withdraw non compliant or unsafe products. It ensures cooperation as between the internal authorities and the customs authorities controlling products entering the market from third countries and sets the framework for

the exchange of information between national authorities and cooperation between them in the case of products on the markets of more than one Member State.

The decision should:

– set the general framework for future sectoral legislation and give guidance on how to use the common elements to ensure as much coherence in future sectoral legislation as can be politically and technically possible.

– set out harmonised definitions, common obligations for the economic operators, criteria for the selection of the conformity assessment bodies, criteria for the national notifying authorities and rules for the notification process. These elements are supported by the provisions on accreditation. It also sets out the rules for the selection of conformity assessment procedures as well as the harmonised range of procedures.

– provide a single definition for the CE marking and rules of responsibility for those who affix it and provide for its protection as a Community collective mark, for those directives which already provide for it.

– put into place a proper information and market surveillance procedure as a prolongation of the GPSD system, for the effective enforcement of Community harmonisation legislation and to make the link with the safeguard clauses of such legislation.

– provide harmonised provisions for the future safeguard mechanisms as a complement to those for market surveillance.

- Legal basis

The proposals are based on Article 95 of the Treaty. The Regulation is also based on Article 133 for the control of products from 3rd countries.

- Subsidiarity principle

For over 20 years, in spite of Community policy initiatives for cooperation and development of common tools, the national instruments continue to vary and create problems for an equivalent level of protection throughout the Community. Experience in the implementation of Community legislation has shown that national non harmonised initiatives have the effect of creating discrepancies which counteract the advantages of harmonisation and the internal market.

Most of the contents of the proposal are geared to completing and bringing coherence to the legislative instruments used by the Community institutions to harmonise the national legislations which have created barriers to trade in the past or could create them in the future. They are not designed to create a new European superstructure but to set a framework for better coordination and operation of infrastructures at the national level.

The objective of Community legislation is to create a sufficient level of trust as between national authorities and as between operators throughout the Union. This can only be done if the criteria for the operation of legislative requirements are fixed in common and that the national systems put in place for their implementation can show that that they follow similar rules, processes and give equivalent results.

If these activities are not harmonised the legislation misses its major objective which is to contribute to the protection of the citizen and to the operation of the Internal Market.

- Proportionality principle

The present proposals are in most cases built on existing practices, procedures and infrastructures and constitute more their consolidation and extension than the creation of new measures and infrastructures. In the field of accreditation the proposals confirm the existing system giving it a Community legal basis and framework. In the field of market surveillance, the objective of the proposals is to coordinate the effective functioning of subsidiarity activities and responsibilities by the national authorities. The information tools will be geared to extending existing tools (such as RAPEX) as opposed to creating new ones. The contents of the sui generis decision, by definition, do not create in themselves any measures which impound on national powers and responsibilities. The implementation of these measures in future sectoral EU legislation will also be based on the techniques used today in the field of the elimination of technical barriers to trade, i.e. based very much on national implementation and intervention as opposed to Commission action. Community intervention is reduced to coordination, cooperation and information in most cases. Where the Community intervenes is in cases of safeguard clauses where only the Community can take decisions. The objective of these proposals is to reinforce the operation of Community legislation in the field and to avoid as much as possible the need for further Community intervention.

- Choice of instruments

The Commission has taken the option of splitting its proposal into two separate legal texts in order to take on board the consequences in legal terms of the contents of the proposals: the regulation sets the overall framework that completes all the existing legislation in relation to accreditation and market surveillance. This Regulation does not modify existing EU legislation but complements it and helps make the notification of conformity assessment bodies and the operation of safeguard clauses more operational The Decision sets guidelines for the future legislator. For this purpose a sui generis decision is proposed, as was done in 1993 in this same area, in order to set out the common elements for the future, accompanied by guidelines for their implementation. Future sectoral legislation, new or revisions of existing legislation, should use these elements wherever possible to ensure coherence, simplification and to follow rules of better regulation.

4. BUDGETARY IMPLICATION

The Community financial contribution is extremely reduced in overall terms. In the field of accreditation a financial contribution of some 15% of the operational costs of EA which correspond to 75.000 €, is foreseen for the purpose of ensuring the proper operation of the European peer evaluation system and therefore remains very modest. Moreover, it is foreseen to provide a budget intervention of one million € for inter comparison testing which represents 10% of possible costs if all safeguard clause cases were to lead to inter comparison testing. In the field of market surveillance a 1.2 million € contribution for the cooperation of all national market surveillance as well as the exchange of information procedures between them covering the full range of industrial products and covering controls of products manufactured in the Community and imported from third countries is minute compared to the present non coordinated costs of national market surveillance

5. ADDITIONAL INFORMATION

- Simplification

The proposal provides for simplification of legislation, simplification of administrative procedures for public authorities (EU or national), simplification of administrative procedures for private parties.

The simplification will concern the contents of legislation and the manner in which it is drawn up with consolidated ranges of solutions which have already been tested and have proven their effectiveness, meaning that the legislator will be faced with a catalogue of best practices.

The proposals set standard rules and processes to operate across all sectors, in the form of best practices. By consolidating the rules and procedures into a set range, life should be simpler for the national public authorities, for economic operators and the consequence should be a clearer legislative and administrative image of the Community and greater legal stability.

Standardised rules across all legislative sectors which apply to the same economic operators will lead to greater clarity, greater legal stability more coherence in the measures applicable to them and eventually a reduction of some of the burdens in conformity assessment when a harmonised market surveillance policy can take some of the weight off the pre marketing requirements.

The proposal is included in the Commission's Work and Legislative Programme under the reference CWLP 2006/ENTR 001.

- Repeal of existing legislation

The adoption of the proposal will lead to the repeal of Council regulation 93/339 EEC.

- European Economic Area

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

2007/0029 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 95 and 133 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Having regard to the opinion of the Committee of the Regions[3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[4],

Whereas:

(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.

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

(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[5] 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

---

1 OJ C […], […], p. […].
2 OJ C […], […], p. […].
3 OJ C […], […], p. […].
4 OJ C […], […], p. […].
5 OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

rules[6] 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[7], Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs[8] and [Council Regulation (EC) No […/…] of … on organic production and labelling of organic products[9]], it is appropriate that the provisions of this Regulation should apply for the purposes of those accreditation obligations.

(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[10] should be excluded from this Regulation.

(5) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC[11], 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[12], lay down a common regime for the products covered therein, which should not therefore be subject to this Regulation.

(6) Accreditation is part of an overall system including conformity assessment and market surveillance to assess and ensure the conformity of products with the applicable requirements.

(7) The particular value of accreditation lies in the fact that it provides an authoritative statement of the technical competence of bodies whose task is ensuring that products are in conformity with the requirements applicable to them.

(8) Accreditation, though so far not regulated at the Community level, is operated in all Member States. The lack of common rules for that activity has resulted in different approaches and differing systems throughout the Community, with the result that the degree of rigour applied in the performance of accreditation has varied between Member States. It is therefore necessary to develop a comprehensive framework for accreditation and to lay down at Community level the principles for its operation and organisation.

---

6 OJ L 165, 30.4.2004; corrected version in OJ L 191, 28.5.2004, p. 1.
7 OJ L 93, 31.3.2006, p. 1
8 OJ L 93, 31.3.2006, p. 12. Regulation as amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).
9 Proposal COM (2005) 671 final.
10 OJ L 194, 18.7.2001, p. 26.
11 OJ L 033, 8.2.2003, p. 30..
12 OJ L 102, 7.4.2004, p. 48.

(9) A system of accreditation which functions by reference to binding rules contributes to strengthening mutual confidence between Member States in the competence of conformity assessment bodies and consequently in the certificates and test reports issued by them. It thereby enhances the principle of mutual recognition and therefore the provisions on accreditation in this Regulation should apply in relation to bodies carrying out conformity assessments in both the regulated and non-regulated areas. The issue at stake is the quality of certificates and test reports irrespective of whether they fall under the regulated or non-regulated area and no distinction should therefore be made between those areas.

(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)[13] 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.

(11) Since the purpose of accreditation is to provide an authoritative statement of the competence of a body to perform conformity assessment activities, it is necessary to provide that Member States should not maintain more than one national accreditation body and should ensure that it is organised in such a way as to safeguard the objectivity and impartiality of its activities. Such national accreditation bodies should operate independently of commercial conformity assessment activities. It is therefore appropriate to provide that Member States ensure that in the performance of their tasks, national accreditation bodies are deemed to exercise public authority, irrespective of their legal status.

(12) For the assessment and continued monitoring of the competence of a conformity assessment body, it is essential to determine its technological knowledge and experience and its capability to carry out assessment. It is therefore necessary that the national accreditation body possesses the pertinent knowledge, competence and means for the proper performance of its tasks.

(13) Accreditation should in principle be operated as a self-supporting activity. Member States should ensure that financial support exists for the fulfilment of special tasks.

(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.

(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

---

[13] OJ L 114, 24.2.2001, p. 1). Regulation as last amended by Commission Regulation (EC) No 196/2006 (OJ L 32, 4.2.2006, p. 4).

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.

(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.

(17) In order to ensure the equivalence of the level of competence of conformity assessment bodies and to facilitate mutual recognition and promote the overall acceptance of accreditation certificates and conformity assessment results issued by accredited bodies, it is necessary that national accreditation bodies operate a rigorous and transparent peer evaluation system and regularly undergo such evaluation.

(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.

(19) Effective co-operation among national accreditation bodies is essential for the proper implementation of peer evaluation and with regard to cross-frontier accreditation. In the interests of transparency, it is, therefore, necessary to provide for an obligation for national accreditation bodies to exchange information among themselves as well as to provide the relevant information to the national authorities and the Commission. Updated and accurate information about the availability of accreditation activities operated by national accreditation bodies should also be made public and, therefore, accessible in particular to conformity assessment bodies.

(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.

(21) For the purposes of ensuring an equivalent and consistent enforcement of Community harmonisation legislation, this Regulation introduces a Community market surveillance framework, defining both minimum requirements against the background of the objectives to be achieved by Member States, and a framework for administrative cooperation including the exchange of information among Member States.

(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[14], Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products[15], Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[16], Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[17], 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 polluants from the internal combustion engines to be installed in non-road mobile machinery[18], Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices[19], 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[20], 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[21], 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[22], 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[23], 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[24], 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[25], 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[26], Regulation (EC) No 273/2004 of the European Parliament and of

14 OJ L 42, 23.2.1970, p. 1.

15 OJ L 262, 27.9.1976, p. 169.

16 OJ L 189, 20.7.1990, p. 17.

17 OJ L 169, 12.7.1993, p. 1.

18 OJ L 59, 27.2.1998, p. 1. Directive as last amended by Council Directive 2006/105/EC (OJ L 363, 20.12.2006, p. 368).

19 OJ L 331, 7.12.1998, p. 1.

20 OJ L 311, 28.11.2001, p. 1.

21 OJ L 311, 28.11.2001, p. 67.

22 OJ L 35, 11.2.2003, p. 28.

23 OJ L 124, 9.5.2002, p. 1.

24 OJ L 240, 7.9.2002, p. 1.

25 OJ L 171, 9.7.2003, p. 1.

26 OJ L 146, 30.4.2004, p. 1.

the Council of 11 February 2004 on drug precursors[27], 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[28].

(23) Directive 2001/95/EC of the European Parliament and of the Council on general product safety[29] 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.

(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.

(25) Situations of serious risk posed by a product require rapid intervention, which may entail the product being withdrawn from the market or recalled or prohibited being made available on the market. In those situations it is necessary to have access to a system of rapid exchange of information between Member States and the Commission. The system provided by Article 12 of Directive 2001/95/EC has proved its effectiveness and efficiency in the area of consumer products. To avoid unnecessary duplication, that system should be used for the purpose of this Regulation. Moreover, ensuring coherent market surveillance throughout the Community requires a comprehensive exchange of information on national activities in this context, going beyond this system.

(26) Information exchanged between competent authorities should be subject to the strictest guarantees of confidentiality and professional secrecy in order to ensure that investigations are not compromised and the reputation of economic operators is not unfairly harmed. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data[30] and Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data[31] apply in the context of this Regulation.

(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 OJ L 47, 18.2.2004, p. 1.

28 OJ L 136, 30.4.2004, p. 1.

29 OJ L 11, 15.1.2002, p. 4.

30 OJ L 281, 23.11.1995, p. 31. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

31 OJ L 8, 12.1.2001, p. 1.

(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[32] 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.

(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.

(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.

(31) The Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. Those penalties must be effective, proportionate and dissuasive.

(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[33], hereinafter "the Financial Regulation".

(33) For some specialised tasks, such as the production and revision of sectoral accreditation schemes, and for other tasks related to verification of the technical competence and facilities of laboratories and certification or inspection bodies the EA should be eligible for Community financing, since it is well adapted to provide the necessary technical expertise in this respect.

(34) Given the function of the EA in the peer evaluation of accreditation bodies and its ability to assist the Member States with the management of such peer evaluation, the Commission should be in a position to provide grants for the functioning of the EA secretariat which should provide ongoing support for accreditation activities at Community level.

(35) A partnership agreement should be signed, in accordance with the provisions of the Financial Regulation, between the Commission and the EA in order to fix the administrative and financial rules on financing accreditation activities.

---

[32] OJ L 40, 17.2.1993, p. 1. Regulation as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

[33] OJ L 248, 16.9.2002, p. 1. Regulation as last amended by Council Regulation (EC, Euratom) No 1995/2006 (OJ L 390, 30.12.2006, p. 1).

(36) In addition, financing should also be available to other bodies besides the EA as regards other activities in the field of conformity assessment, metrology, accreditation and market surveillance, such as drawing up and updating of guidelines, inter-comparison activities linked to the operation of safeguard clauses, preliminary or ancillary activities in connection with the implementation of Community legislation in the said areas and programmes of technical assistance and co-operation with non-member countries as well as enhancement of the policies in the said areas at Community and international level.

(37) This Regulation respects the fundamental rights and observes the principles reflected in the Charter of Fundamental Rights of the European Union.

(38) Since the objective of the Regulation, namely to ensure that products on the market covered by Community legislation respect a high level of health and safety and other public interests, whilst guaranteeing the functioning of the internal market, by providing a framework for accreditation and market surveillance, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve this objective,

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PROVISIONS

Article 1

Subject matter and scope

1. This Regulation lays down rules on the organisation and operation of accreditation of conformity assessment bodies performing assessment of any substance, preparation or other product, whether or not such substance, preparation or product has undergone transformation, to be placed on the Community market.

   It also provides a framework for market surveillance and the control of products from third countries to ensure that substances, preparations and transformed products subject to Community legislation harmonising the conditions for the marketing of products, hereinafter "Community harmonisation legislation" respect a high level of protection of public interests such as health and safety in general, of health and safety at the workplace, protection of consumers, of the environment, and of security.

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

   (a) food law as defined in Article 3 of Regulation (EC) N° 178/2002 with the exception, as regards Chapter II, of Regulation (EC) N° 509/2006,

510/2006 and […/…] [on organic production and labelling of organic products];

(b) feed law as defined in Article 3 of Regulation (EC) N° 882/2004;

(c) Directive 2001/37/EC;

(d) Directive 2002/98/EC;

(e) Directive 2004/23/EC.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

(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;

(2) "placing on the market" means the first making available of a product on the Community market;

(3) "manufacturer" means a natural or legal person who designs or manufactures a product or who has such a product designed or manufactured, under his name or trademark;

(4) "authorised representative" means any natural or legal person established within the Community who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under the relevant Community legislation;

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

(6) "importer" means any natural or legal person established within the Community, who places a product from a third country on the Community market;

(7) "economic operators" means the manufacturer, the importer, distributor and the authorised representative;

(8) "technical specification" has the meaning assigned to it by point 3 of Article 1 of Directive 98/34/EC;

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

(10) "accreditation" means a third-party attestation, related to a conformity assessment body, conveying formal demonstration of its competence to carry out specific conformity assessment tasks;

(11) "national accreditation body" means the sole authoritative body in a Member State that performs accreditation with authority derived from government;

(12) "recall" means any measure aimed at achieving the return of a product that has already been made available to the end user.

(13) "withdrawal" shall mean any measure aimed at preventing the making available on the market of a product in the supply chain.

CHAPTER II
ACCREDITATION

Article 3

Scope

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.

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].

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

Article 4

General principles

1. Accreditation shall be operated in each Member State by a single national accreditation body.

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.

3. A Member State shall inform the Commission and the other Member States where a national accreditation body is established and for which conformity assessment activities it performs accreditation, including any changes thereto.

It shall inform the Commission and the other Member States where, in accordance with paragraph 2, recourse is had to a national accreditation body of another Member State.

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

5. The responsibilities and tasks of the national accreditation body shall be clearly distinguished from those of other national authorities.

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.

7. Member States shall ensure that their national accreditation body has the appropriate resources, both financial and personnel, for the proper performance of its tasks.

8. The national accreditation body shall seek membership of European co-operation for Accreditation (EA).

Article 5

Operation of accreditation

1. National accreditation bodies shall, when requested by a conformity assessment body, evaluate whether the conformity assessment body is competent to carry out a specific conformity assessment activity and, where that is the case, issue an accreditation certificate to that effect.

2. The national accreditation body shall monitor any conformity assessment body to which it has issued an 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 to restrict, suspend or withdraw its accreditation certificate.

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

Article 6

Cross-frontier accreditation

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).

However, a conformity assessment body may request accreditation by a national accreditation body other than those referred to in the first subparagraph in any one of the following situations:

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

(b) where the national accreditation bodies referred to in the first subparagraph do not perform accreditation in respect of the conformity assessment activities for which accreditation is sought;

(c) where the national accreditation bodies referred to in the first subparagraph have not yet, or have not successfully, undergone the peer evaluation under Article 9 in respect of the conformity assessment activities for which accreditation is sought.

2. Where a national accreditation body receives a request under paragraph 1 (b) or (c), it shall inform the national accreditation body of the Member State in which the requesting conformity assessment body is established. In such cases, the national accreditation body of the Member State in which the requesting conformity assessment body is established may require to participate as an observer.

3. A national accreditation body may request another national accreditation body to carry out a part of the assessment activity. In such a case, the accreditation certificate shall be issued by the requesting body.

Article 7

Requirements for national accreditation bodies

A national accreditation body shall fulfil the following requirements:

(1) it shall be organised in such a manner as to make it independent from the conformity assessment bodies which it assesses and from commercial pressures and to ensure that no conflicts of interest occur with conformity assessment bodies;

(2) it shall document the duties, responsibilities and authorities of personnel who could affect the quality of the assessment and attestation of competence;

(3) it shall be organised and operated so as to safeguard the objectivity and impartiality of its activities;

(4) it shall ensure that each decision relating to the attestation of competence is taken by competent persons different from those who carried out the assessment;

(5) it shall have adequate arrangements to safeguard the confidentiality of the information obtained;

(6) it shall identify the conformity assessment activities for which it is competent to perform accreditation, referring, where appropriate, to relevant Community or national legislation and standards;

(7) it shall set up the necessary procedures to ensure efficient management and appropriate internal controls;

(8) it shall have a sufficient number of competent personnel for the proper performance of its tasks;

(9) it shall establish, implement and maintain procedures for monitoring the performance and competence of the personnel involved.

Article 8

Compliance with requirements

1. Member States shall monitor their national accreditation bodies at regular intervals in order to ensure that they fulfil the requirements laid down in Article 7.

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

2. Where a national accreditation body does not meet the requirements, or fails to fulfil the obligations, under this Regulation, the Member State concerned shall take the appropriate corrective action or shall ensure that such corrective action is taken, and shall inform the Commission thereof.

Article 9

Peer evaluation

1. National accreditation bodies shall operate a peer evaluation system and participate in it.

2. Member States shall ensure that their national accreditation bodies regularly undergo peer evaluation.

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.

4. The peer evaluation shall ascertain whether the national accreditation bodies meet the requirements laid down in Article 7.

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

6. The Commission shall oversee the rules and the proper functioning of the peer evaluation system.

Article 10

Presumption of conformity

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

Article 11

Information obligation

1. A national accreditation body shall inform the other national accreditation bodies of the conformity assessment activities in respect of which it operates accreditation and of any changes and extensions thereto.

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.

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.

Article 12

Requests to EA

The Commission, following consultation of the Committee set up by Article 5 of Directive 98/34/EC, may request the EA to contribute to the development, maintenance and implementation of accreditation in the Community.

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

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.

CHAPTER III
COMMUNITY MARKET SURVEILLANCE FRAMEWORK AND CONTROLS OF PRODUCTS ENTERING THE COMMUNITY MARKET

SECTION 1

GENERAL PROVISIONS

Article 13

Scope

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

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.

3. Articles 14 to 23 shall not apply in cases governed by the following Community harmonisation legislation:

   (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;

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.

Article 14

General requirements

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

SECTION 2

COMMUNITY MARKET SURVEILLANCE FRAMEWORK

Article 15

Information obligations

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".

Article 16

Obligations of the Member States as regards organisation

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

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.

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

4. Member States shall establish, implement and periodically update market surveillance programmes.

5. Member States shall periodically review and assess the functioning of their surveillance activities.

Article 17

Market surveillance measures

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.

   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.

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.

3. The market surveillance authorities shall carry out their duties with due independence and observe confidentiality and professional secrecy.

Article 18

Products presenting a serious risk

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.

Article 19

Restrictive measures

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.

2. Such measures shall be communicated without delay to the economic operator concerned, who shall at the same time be informed of the remedies available under the national law in force in the Member State concerned and of the time limits to which such remedies are subject.

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.

Article 20

Exchange of information – Community Rapid Information System

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 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.

2. Member States shall also notify to the Commission any voluntary measures taken by an economic operator in the case of a serious risk presented by a product which he has made available on the market.

3. The notification under paragraphs 1 and 2 shall provide all available details, in particular as regards the necessary data for the identification of the product, the origin and the supply chain of the product, the related risk, the nature and the duration of the national measure taken and any voluntary measures taken by economic operators.

4. For the purposes of paragraphs 1, 2 and 3 of this Article the market surveillance and information exchange system provided for in Article 12 of Directive 2001/95/EC shall be used. Paragraphs 2, 3 and 4 of Article 12 of Directive 2001/95/EC shall apply mutatis mutandis.

Article 21

Information support system

1. The Commission shall develop and maintain a general archiving and exchange of information system on issues relating to market surveillance activities.

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.

   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.

Article 22

Principles of cooperation between the Member States and the Commission

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.

2. For the purposes of paragraph 1, the market surveillance authorities of one Member State shall provide, on request, assistance to market surveillance authorities of other Member States by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measure or by participating in investigations initiated in other Member States.

Article 23

Sharing resources

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.

2. For the purposes of paragraph 1, the Commission, in cooperation with Member States shall:

   (a) develop and organise training programmes and exchange of national officials;

   (b) set up appropriate programmes for the exchange of experience, information and best practice, programmes and actions for common projects, information campaigns, joint visit programmes and the sharing of resources.

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

SECTION 3

CONTROLS OF PRODUCTS ENTERING THE COMMUNITY MARKET

Article 24

Controls of products entering the Community market

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.

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:

(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;

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

The customs authorities shall immediately notify the market surveillance authorities of any such suspension.

3. In the case of perishable products, the market surveillance authorities and the customs authorities shall, as far as possible, seek to ensure that any requirements they may impose with regard to the storage of the products or the parking of the vehicles used for transport are not incompatible with the preservation of those products.

4. For the purposes of this section, Article 22 shall apply in respect of customs authorities, without prejudice to the application of Community law providing for more specific systems of cooperation between those authorities.

Article 25

Release of products

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.

2. Where the market surveillance authorities find that the product in question does not present a serious risk to health and safety or cannot be regarded as being in breach of Community harmonisation legislation, the product in question shall be released provided that all the other requirements and formalities pertaining to such release have been met.

Article 26

National measures

1. Where the market surveillance authorities responsible find that the product concerned presents a serious risk, they shall take measures to prohibit the product from being placed on the market and ask the customs authorities to include the

following endorsement on the commercial invoice accompanying the product and on any other relevant accompanying document:

'Dangerous product - 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, 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 …/..',

3. Where the product concerned is subsequently declared for a customs procedure other than release and provided the market surveillance authorities do not object, the endorsements listed in paragraphs 1 and 2 shall also be included, under the same conditions, on the documents used in connection with that procedure.

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

CHAPTER IV
COMMUNITY FINANCING

Article 27

Body pursuing an aim of general European interest

European co-operation for Accreditation (EA) shall be considered to be a body pursuing an aim of general European interest according to Article 162 of Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Regulation (EC, Euratom) N° 1605/2002[34].

Article 28

Activities eligible for Community financing

1. The Community may finance the following activities in connection with the application of this Regulation:

[34] OJ L 357, 31.12.2002, p. 1.

(a) the production and revision of sectoral accreditation schemes referred to in the third paragraph of Article 12;

(b) the activities of the central secretariat of EA, such as the coordination of accreditation activities, the processing of technical work linked to the operation of the peer evaluation system, the provision of information to interested parties and EA's participation in the activities of international organisations in the field of accreditation;

(c) the drawing up and updating of contributions for guidelines in the fields of accreditation, notification to the Commission of conformity assessment bodies, conformity assessment and market surveillance;

(d) intercomparison activities linked to the operation of safeguard clauses;

(e) the putting at the disposal of the Commission technical expertise for the purposes of assisting it in its implementation of market surveillance administrative cooperation, market surveillance decisions and safeguard clause cases;

(f) the performance of preliminary or ancillary work in connection with the implementation of the conformity assessment, metrology, accreditation and market surveillance activities linked to the implementation of Community legislation, such as studies, programmes, evaluations, guidelines, comparative analyses, mutual joint visits, research work, databases (development and maintenance), training activities, laboratory work, proficiency testing, inter-laboratory tests and conformity assessment work;

(g) activities seeking to carry out programmes of technical assistance, cooperation with non-member countries and the promotion and enhancement of the European conformity assessment, market surveillance and accreditation policies and systems among interested parties in the Community and at international level.

2. The activities referred to in paragraph 1(a) shall be eligible for Community financing only if the Committee set up by Article 5 of Directive 98/34/EC has been consulted on the requests to be submitted to EA.

Article 29

Bodies eligible for Community financing

Community financing may be granted to EA for the implementation of the activities listed in Article 28.

However, Community financing may also be granted to other bodies for the carrying out of the activities set out in Article 28 except those set out in paragraph 1 (a) and (b).

Article 30

Financing

The appropriations allocated to the activities referred to in this Regulation shall be determined each year by the budgetary authority within the limits of the current financial framework.

Article 31

Financing arrangements

1. Community financing shall be provided:

   (a) without a call for proposals, to EA to carry out those activities referred to in Article 28(1) (a) to (g) for which grants can be awarded in accordance with the Financial Regulation;

   (b) in the form of grants after a call for proposals, or by public procurement procedures, to other bodies to carry out the work referred to in Article 28(1) (c) to (g).

2. The activities of the central secretariat of EA, referred to in Article 28(1)(b), may be financed on the basis of operating grants. In the event of renewal, the operating grants shall not be decreased automatically.

3. Grant agreements may authorize flat-rate cover of the beneficiary's overheads up to a maximum of 10% of total eligible direct costs for actions, except where indirect costs of the beneficiary are covered through an operating grant financed from the Community budget.

4. The common cooperation objectives and the administrative and financial conditions relating to the grants awarded to EA may be defined in a framework partnership agreement signed by the Commission and EA, in accordance with the Financial Regulation and Regulation (EC, Euratom) No 2342/2002. The European Parliament and the Council shall be informed of the conclusion of such agreement.

Article 32

Management and monitoring

1. The appropriations determined by the budgetary authority for the financing of conformity assessment, accreditation and market surveillance activities may also cover the administrative expenses relating to actions involving preparation, monitoring, inspection, auditing and evaluation which are directly necessary for achieving the objectives of this Regulation, and particularly studies, meetings, information and publication activities, expenses relating to informatics networks for the exchange of information and any other expenditure on administrative and technical assistance which the Commission may use for conformity assessment and accreditation activities.

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

Article 33

Protection of the Community's financial interests

1. The Commission shall ensure that, when the activities financed under this Regulation are implemented, the Community's financial interests are protected by the application of preventive measures against fraud, corruption and other illegal activities, by effective checks and by the recovery of amounts unduly paid and, if irregularities are detected, by effective, proportionate and dissuasive penalties, in accordance with Council Regulation (EC, Euratom) N° 2988/95 of 18 December 1995 on the protection of the European Communities financial interests[35], Council Regulation (Euratom, EC) N° 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interest against fraud and other irregularities[36] and Regulation (EC) N° 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF)[37].

2. For the Community activities financed under this Regulation, the notion of irregularity referred to in Article 1(2) of Regulation (EC, Euratom) No 2988/95 shall mean any infringement of a provision of Community law or any breach of a contractual obligation resulting from an act or omission by an economic operator which has, or would have, the effect of prejudicing the general budget of the European Communities or budgets managed by them by an unjustified item of expenditure.

3. Any agreements and contracts resulting from this Regulation shall provide for monitoring and financial control by the Commission or any representative which it authorizes and for audits by the Court of Auditors, which if necessary may be conducted on the spot.

---

35 OJ L 312, 23.12.1995, p. 1.
36 OJ L 292, 15.11.1996, p. 2.
37 OJ L 136, 31.5.1999, p. 1.

FINAL PROVISIONS

Article 34

Technical Guidelines

In order to facilitate the implementation of this Regulation, the Commission shall draw up guidelines.

Article 35

Transitional provisions

1. Accreditation certificates issued before the entry into force of this Regulation shall remain valid until the date of their expiry. This Regulation shall, however, apply in the case of their extension or renewal.

2. Where in a Member State accreditation is not operated by a single national accreditation body and that Member State intends to continue to operate accreditation, it shall make the necessary structural adaptations in order to establish a single national accreditation body by 1 January 2010 at the latest.

Article 36

Penalties

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

Article 37

Repeal

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

Any references to the repealed Regulation shall be construed as references to this Regulation.

Article 38

This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union.

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

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, […]

For the European Parliament	*For the Council*
The President	*The President*
[...]	*[...]*

LEGISLATIVE FINANCIAL STATEMENT

1. NAME OF THE PROPOSAL:

Proposal for a Regulation of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the conditions for the marketing of products.

2. ABM / ABB FRAMEWORK

Policy Area(s) concerned and associated Activity/Activities: ABB2 – Internal Market for Goods and Sectoral Policies.

3. BUDGET LINES

3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B..A lines)) including headings:

02.03.01

3.2. Duration of the action and of the financial impact:

Continuous

3.3. Budgetary characteristics:

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
02.03.01	Non-comp	Diff	NO	YES	NO	1a

4. SUMMARY OF RESOURCES

4.1. Financial Resources

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Section no.		2009	2010	2011	2012	2013	2014 and later	Total
Operational expenditure[38]									
Commitment Appropriations (CA)	8.1.	a	1,175	1,175	1,175	1,175	1,175	1,175	
Payment Appropriations (PA)		b	0,352	1,175	1,175	1,175	1,175	1,175	
Administrative expenditure within reference amount[39]									
Technical & administrative assistance (NDA)	8.2.4.	c	1,1	1,1	1,1	1,1	1,1	1,1	
TOTAL REFERENCE AMOUNT									
Commitment Appropriations		a+c	**2,275**	**2,275**	**2,275**	**2,275**	**2,275**	**2,275**	
Payment Appropriations		b+c	**1,452**	**2,275**	**2,275**	**2,275**	**2,275**	**2,275**	
Administrative expenditure <u>not</u> included in reference amount[40]									
Human resources and associated expenditure (NDA)	8.2.5.	d	0	0	0	0	0	0	0
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6.	e							
Total indicative financial cost of intervention									
TOTAL CA including cost of Human Resources		a+c +d+ e	2,275	2,275	2,275	2,275	2,275	2,275	
TOTAL PA including cost of Human Resources		b+c +d+ e	**1,452**	**2,275**	**2,275**	**2,275**	**2,275**	**2,275**	

38 Expenditure that does not fall under Chapter xx 01 of the Title xx concerned.

39 Expenditure within article xx 01 04 of Title xx.

40 Expenditure within chapter xx 01 other than articles xx 01 04 or xx 01 05.

Co-financing details:

No co-financing

4.1.2. Compatibility with Financial Programming

The proposal is compatible with existing financial programming.

4.1.3. Financial impact on Revenue

The proposal has no financial implications on revenue

4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

Annual requirements	2009	2010	2011	2012	2013	2014 and later
Total number of new human resources	4*					

* supplementary staff should be foreseen over the entire period

5. CHARACTERISTICS AND OBJECTIVES

5.1. Need to be met in the short or long term

The proposal provides for the reinforcement of European cooperation for Accreditation as the means of ensuring that accreditation can play the role of the final level of control in the proper functioning of EU legislation which has recourse to professional conformity assessment bodies. This in turn requires that certain activities be carried out for the purpose of Community legislation and in particular the proper and rigorous operation of a peer evaluation system of control of the national accreditation bodies at the European level answering the needs of public authorities.

Effective European participation and input to international activities at the international level are indispensable in order to promote and defend European interests in this area of activity.

In order to be able to manage complaints and disputes as well as safeguard clause cases under EU legislation, the Commission needs to be able to dispose of the technical means and resources. The provision of a Community budgetary programme would enable the Commission to meet these needs which it does not dispose of naturally within its services.

More generally in the field of market surveillance, it is necessary to provide for a number of coordinating activities at the European level in particular for: the establishment and coordination of ad hoc market surveillance projects in order to share resources and expertise: develop and organise training programmes and exchange of national officials including customs authorities; promote the exchange

of experience and share resources on risk analysis activities; set up appropriate programmes for the exchange of information and best practices, through programmes for common projects, information campaigns, joint visit programmes, etc

The general objectives of the proposal are set out in the explanatory memorandum.

5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy

The creation of the internal market for goods is one of the objectives of the European Community. Pursuant to Article 14(2) of the EC Treaty, the internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaty. The Community harmonisation of legislative requirements for the safety of products has contributed considerably to the achievement of the Treaty's objectives.

The objective of this proposal is to put into place the means to ensure the proper level of credibility of EU legislation and trust that public authorities can place in its implementation and in particular in the CE marking regime.

Ensuring the proper coherence and coordination of the technical tools to implement the political levels of protection set out in the legislation is a sine qua non for success.

The capacity of the Commission to intervene quickly and on the basis of sound technical infrastructures and decisions can also contribute considerably to the overall objective of creating trust in the EU system.

A comparison of the options set out in the impact assessment points clearly to a regulatory approach on the basis of Article 95(1) EC Treaty to give a legal basis to these activities and to reinforce their Community nature. Moreover in the face of differing national legislation, Community legislation is the only feasible option.

5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework

In the context of the enlarged single market, action at EU level carries an evident added value, providing European businesses with a large, single market and allowing economies of scale. At the same time, the smooth functioning of this market requires for its very supra-national nature an EU-level intervention, while limiting the EC intervention to what is strictly necessary.

The main objective of the proposal is to ensure the free movement of goods in the harmonised area. It should impose the minimum economic burden consistent with achieving this objective, and it should be applied effectively and easily. The impact assessment comprises a more detailed and technical description of the objectives and the expected results.

A proper functioning of EU legislation through the implementation of this proposal should lead to reduction in diverging national measures in relation to products on the market and to a greater acceptance of and trust in test reports and certification/inspection certificates.

This should in turn lead economic operators to have less need of recourse to unnecessary multiple certification and marking and to fewer interventions of the Commission under the safeguard clauses.

5.4. Method of Implementation (indicative)

Direct centralised management by the Commission

6. MONITORING AND EVALUATION

6.1. Monitoring system

The monitoring shall be carried out by the Commission itself, assisted both by the Committee set up under Directive 98/34 laying down a procedure for the provision of information in the field of technical standards and regulations, as well as by the Group of Experts called the Group of Government Officials in the field of standards and conformity assessment.

6.2. Evaluation

6.2.1. Ex-ante evaluation

A real ex ante evaluation is not a simple affair when introducing a new Community policy, however past experience in the operation of harmonisation legislation (mutual joint visit programme), experience of the operation of the present infrastructures in the field of accreditation and an extrapolation of the experiences of the European standardisation programme show that a small Community budgetary contribution can be effective and ensure proper and effective public authority protection f public interests. (See ex ante evaluation in annex).

6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

Not applicable.

6.2.3. Terms and frequency of future evaluation

The terms and the frequency of future evaluation activities will be determined in accordance with the applicable rules.

7. ANTI-FRAUD MEASURES

Full application of internal control standards No 14, 15, 16, 17, 18, 19, 20, 21.

The Commission shall ensure that, when actions financed under the present programme are implemented, the financial interests of the Community are protected by the application of preventive measures against fraud, corruption and any other illegal activities, by effective checks and by the recovery of the amounts unduly paid and, if irregularities are detected, by effective, proportional and dissuasive penalties, in accordance with Council Regulation (EC, Euratom) No 2988/95 of 18 December

1995 on the protection of the European Communities financial interests, and with Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-Fraud Office (OLAF).

8. DETAILS OF RESOURCES

8.1. Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	2009		2010		2011		2012		2013		2014 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
Contribution to the operation of the peer evaluation system, Contribution to the participation in international work and general secretariat support	Service contract		1 report	0,075	1 report	0,075	1 report	0,075	1 report	0,075	1 report	0,070	1 report	0,075		
Inter-comparisons programmes	Service contract		50 prelim reports	1,000	50 reports	1,000	50 reports	1,000	50 reports	1,000		1,000		1,000		
Market surveillance and accreditation guidelines	Service contract		3-4 guidelines	0,100	3-4 guidelines	0,100	3-4 guidelines	0,100	3-4 guidelines	0,100	3-4 guidelines	0,100	3-4 guidelines	0,100		
TOTAL COST				1,175		1,175	0	1,175		1,175	0	1,175	0	1,175	0	

8.2. Administrative Expenditure

8.2.1. Number and type of human resources

Types of post		Staff to be assigned to management of the actions using supplementary resources (**number of posts/FTEs**)					
		2009	2010	2011	2012	2013	2014
Officials or temporary staff[41] (XX 01 01)	A*/AD	2AD*					
	B*, C*/AST	2AST*					
Staff financed[42] by art. XX 01 02		0	0	0	0	0	0
Other staff[43] financed by art. XX 01 04/05		0	0	0	0	0	0
TOTAL		4*					

* supplementary staff should be foreseen over the entire period

8.2.2. Description of tasks deriving from the action

Besides the follow-up of the proposal and the assessment of the implementation of the legislative texts at the national level, the task will consist of managing:

- the political and contractual relations with European co-operation for Accreditation

- the financial relations with EA

- the cooperation of the national market surveillance authorities in general and more particularly under the safeguard cases

- management of the inter comparisons programmes both from the technical and the financial points of view

- management of the mutual joint visits programme, co-operation and training programmes and information tools.

8.2.3. Sources of human resources (statutory)

Posts to be redeployed using existing resources within the managing service (internal redeployment)

---

41 Cost of which is NOT covered by the reference amount

42 Cost of which is NOT covered by the reference amount

43 Cost of which is included within the reference amount

8.2.4. Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)

EUR million (to 3 decimal places)

Budget line (number and heading)	2009	2010	2011	2012	2013	2014 and later	TOTAL
1 Technical and administrative assistance (including related staff costs)							
Executive agencies	0	0	0	0	0	0	0
Other technical and administrative assistance: Administrative cooperation, studies, training programmes, exchange of national experts, mutual joint visits etc	0,500	0,500	0,500	0,500	0,500	0,500	
- *intra muros* ***Extension of Rapex web tool***	0,200	0,200	0,200	0,200	0,200	0,200	
- *extra muros* ***Development of ICSMS information tool***	0,400	0,400	0,400	0,400	0,400	0,400	
Total Technical and administrative assistance	1.1	1.1	1.1	1.1	1.1	1.1	

8.2.5. Financial cost of human resources and associated costs <u>not</u> included in the reference amount

EUR million (to 3 decimal places)

Type of human resources	2009	2010	2011	2012	2013	2
Officials and temporary staff (XX 01 01)	0	0	0	0	0	0
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.) (specify budget line)	0	0	0	0	0	0
Total cost of Human Resources and associated costs (NOT in reference amount)	0	0	0	0	0	0

8.2.6. Other administrative expenditure not included in reference amount

EUR million (to 3 decimal places)

	2009	2010	2011	2012	2013	2014 and later	TOTAL
XX 01 02 11 01 – Missions							
XX 01 02 11 02 – Meetings & Conferences							
XX 01 02 11 03 – Committees[44]							
XX 01 02 11 04 – Studies & consultations							
XX 01 02 11 05 - Information systems							
2 Total Other Management Expenditure (XX 01 02 11)							
3 Other expenditure of an administrative nature (specify including reference to budget line)							
Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)							

[44] Specify the type of committee and the group to which it belongs.