



NOTE TO THE SENIOR OFFICIALS GROUP ON
STANDARDISATION AND CONFORMITY ASSESSMENT POLICY

Title:	CERTIF 2005–16 Rev. 2: Elements for a horizontal legislative approach to technical harmonisation		
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Abstract:			
This paper attempts to bring together the results of the discussions and consultations on all the preparatory documents (Certif docs) drawn up for the revision of the New Approach, and to present them in a form that could lead to the elaboration of a formal Commission proposal in the course of 2006. It builds on the texts of the Council Resolutions of 7 May 1985 and 21 December 1989, as well as on Council Decision 93/465/EC.			
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References:	Council Resolutions of 7 May 1985 and 21 December 1989, Council Decision 93/465/EC, draft CERTIF docs 2004-1 and 2005-1 to 15		



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ELEMENTS FOR A HORIZONTAL LEGISLATIVE APPROACH TO TECHNICAL HARMONISATION

This is NOT a Commission proposal. It is a working document which attempts to set out the results and present state of consultations. A number of issues, both of a technical and legal nature, remain to be settled including in particular the legal format and content of the future Commission proposal.

A. THE LEGISLATIVE STRATEGY

The content of the common horizontal Act will attempt to:

- 1) set the overall framework for safety (and other issues of public interest protection) legislation for products made available on the European Union market (industrial and non industrial?) in order to reassert the conditions for the free marketing of products as a consequence of their level of safety or the degree to which they respond to required levels of protection (environment etc)
- 2) provide the legal base for a number of activities which do not yet have a Union legal base, such as accreditation and market surveillance
- 3) contain all the essential requirements relating to the common elements to be found in sectoral legislation on the basis of the overall framework, i.e.:
 - common definitions and basic notions (including determining the processes for the development and recognition of guideline documents)
 - requirements for the development of European standards or recognition of other technical specifications
 - commonly recognised referential conformity assessment procedures, including a common approach to quality management requirements (i.e. rules relating to the recognition of ISO 9001: 2000)
 - essential requirements for the competence of conformity assessment bodies as well as for the designating and notifying authorities
 - requirements for the operation and organisation of accreditation at the national level and the role of public authorities
 - requirements and rules of operation of accreditation at the European level and the role of public authorities

- set the common requirements for marking of conformity
- common essential elements for market surveillance systems at the national level (including control of products from third countries)
- common requirements in terms of needs and resources for the market surveillance at the national level
- the legal base and the rules of operation for the information and consultative system for market surveillance inspired by the present RAPEX system
- requirements for the administrative cooperation as between conformity assessment bodies and for cooperation as between national market surveillance authorities
- the rules and procedures for a common “safeguard” mechanism
- possibly the legal base and budgetary support for a Union programme for metrology and inter-comparisons

The content of the sectoral legislative texts could then restrict themselves to setting

- 1) the essential requirements for all the relevant aspects of protection which concern the product sector in question (safety, but also health, safety at the place of work, protection of the environment etc)
- 2) the relevant mechanism for the determination of product or conformity assessment technical specifications (European standards or other technical specifications)
- 3) the choices of conformity assessment procedures appropriate for the given sector of activity
- 4) (by derogation, and therefore by exception) the specific sectoral requirements on the common elements when the latter do not answer the specific sectoral needs.

The proposal texts should then refer to the horizontal common text for all common requirements. Should the objective of putting all the requirements which necessitate national implementing measures into the horizontal legislative text be reached this could then vouch for the recourse to regulations as opposed to directives, thus eliminating the need for national transposition (which would have intervened at the stage of implementation of the common horizontal legislative Act).

The timing sequence

The common horizontal proposal is intended to leave the Commission towards the middle of 2006, and will then go through the co-decision process in the Council and EP. It is only once this document finds political stability that an examination of the existing sectoral texts should be envisaged in order to bring them into coherence to the extent necessary to simplify implementation for economic operators and national authorities. In other words the proposal to modify existing legislation, either with a horizontal framework directive including modifications to a number of directives, or as separate individual proposals would only be envisaged as from 2007-8. New sectoral legislative initiatives could be launched on the basis of the new horizontal text in 2007 depending on the level of stability of the contents of the text in the co-decision process.

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B. MOTIVATIONS

1. INTRODUCTION

- a) Member States have the responsibility of ensuring safety on their territory (in the home, at the workplace etc) of persons, domestic animals and goods, or the respect of other essential collective protection requirements for public interest issues, such as health, consumer or environmental protection etc with regard to risks or potential risks which products could present.

But the national provisions ensuring such protection must be harmonised in order to ensure a similar level of protection throughout the entire European Union, and to ensure the free making available of goods, without lowering existing and justified levels of protection in the Member States.

- b) The proposal shall refer back to existing Resolutions, communications, decisions and directives on standardisation policy, information and notification, new approach, global approach and CE marking, which have led to an overall safety legislation policy for industrial products.
- c) The new approach has been a success story for the free circulation of products and development of a safety/risk approach as opposed to a simple free circulation approach based on the application of Article 28 of the Treaty. However, incompleteness and incoherence of implementation and controls still lead to the approach being perceived as a free circulation one rather than safety and protection.
- Unnecessary incoherent application of the different horizontal instruments in the various sectoral legislations has led to confusion for economic operators, public authorities and consumers.
 - The Lisbon agenda has set some priorities for reinforcing the competitiveness of European industry which concern amongst others, better regulation, simplification and market surveillance. These priorities are also intrinsically those of the completion of the internal market, inscribed in the Treaties themselves. Incompleteness of the horizontal instruments to date has led to complicated and divergent legislative and burdensome administrative technical solutions for economic operators and national authorities, as well as to an imbalance in their respective responsibilities. The tendency of EU free circulation legislation has been to place most of the burden of safety and protection on the economic operators in the absence or weakness of the public authorities' intervention.

There is therefore a necessity to create an appropriate Community legislative framework for accreditation (both at national and European levels), for market surveillance, for a revised approach to Community safeguard mechanisms to balance out the responsibilities of the economic operators and public authorities (at national and Community levels), as well as to balance out pre and post marketing controls. The extension of the recourse to European standardisation and the new approach techniques to wider fields of activity than in the past, is dependant on this completion and readjustment.

2 LEGAL PROTECTION REQUIREMENTS AND TECHNICAL SPECIFICATIONS

- a) The scopes of EU legislation should concentrate on all requirements relevant to risks and hazards for as large, but as coherent, sectors and categories of activity as possible, covering safety, health, consumer and environment protection, as well as different types of risks and hazards such as chemical, mechanical, electrical, for example, but also of environmental pollution, for example.

Essential requirements shall, wherever technically possible, be expressed in terms of performance rather than of design, and shall be worded precisely enough to create legally binding obligations which can be enforced and to which direct conformity can be demonstrated, even in the absence of harmonised European standards. However, they should avoid being so precise as to be technology related.

- b) The task of drawing up the technical specifications needed for the production and making available on the market of products conforming to the essential requirements established by the EU legislation, while taking into account the current state of technology, is entrusted to organisations competent in the field of standardisation, preferably at the European level.

These technical specifications are not mandatory and maintain their status of voluntary standards. Conformity to these standards demonstrated through the implementation of the relevant conformity assessment procedures will constitute a presumption of conformity to the essential requirements they relate to. These technical specifications can relate to products but also to services, including conformity assessment activities.

The texts relating to the EU policy on European standardisation remain applicable in their present state.

Where technical specifications are drawn up by organisations other than the European Standardisation Organisations (CEN/Cenelec/ETSI), EU legislation should nevertheless provide for a similar system based on the setting of EU essential requirements against which these technical specifications can be gauged. The organisations involved should ensure an appropriately balanced representation of all the relevant stakeholders and conform to the standardisation principles.

- c) The intensification of EU legislation in the area of safety of products in both old and new approach sectors without the application of an overarching coherent oversight has led to different uses of definitions and expressions which, in fine, can no longer be justified in the face of the legislative and administrative confusion which has been created. The present initiative is the ideal opportunity to bring coherence and transparency into this area and therefore favour simplification and reduction of burdens. Such transparency will also lead to clearer lines of responsibility as between public authorities and economic operators.

3 CONFORMITY ASSESSMENT

The experience of the implementation of the new and global approaches has clearly demonstrated that a common and transparent approach to conformity assessment at the Union level is a necessary element to ensure confidence as between national authorities throughout the Union. The existing policy and procedures have proved their effectiveness in this respect but have also shown weaknesses and incoherencies which necessitate legislative intervention to put these right.

Council Decision of December 1989 set out the reference conformity assessment procedures and the basic rules for their use in new approach directives. Over 20 directives have thus had recourse to these procedures with success, and experience has shown that a) they require some fine tuning but no fundamental revision, b) apart from some cases, they cover all the procedures

required for legislative purposes and are used, in one shape or form, in non new approach sectors thus proving their relative universality and c) they have contributed to the simplification and overall coherence of EU legislation.

- a) The Council decision opened the option of the recognition of quality management certificates as a complement, and in some cases as an alternative route, to classical product certification. The international market place has modified and modernised, through the international standardisation bodies ISO/IEC, the international series of ISO 9000 of standards. In order for past and future EU legislation to adapt to this evolution, the conformity assessment procedures adopted in the 1989 Council decision also require to be updated, but not necessarily fundamentally questioned.
- b) Experience of the implementation of the existing directives has brought to light an important weakness in the provisions of many of the directives. National legislators and market surveillance authorities have the responsibility ensuring that only safe products are on their markets and to penalise those economic operators who contravene the law. However, the national authority stops at national boundaries and makes these obligations complicated to implement. This in turn has led the EU legislator in many cases to overburden the conformity assessment requirements. Appropriate systematic traceability requirements on operators and products coupled with appropriate coordination, consultation and information mechanisms between national market surveillance authorities should contribute to answering this preoccupation.
- c) The Council Resolution of 7 May 1985 and more importantly the Decision of December 1989 provided for conformity assessment bodies in the market place to carry out the procedures set out in the EU legislation, on designation and notification by national authorities to the Commission and other Member States, and set the general conditions for their intervention and operation.

The rules and procedures put in place since 1985 have operated well but have shown their limits in creating complete confidence in the conformity assessment mechanisms under the existing directives and have led in many instances to reinforcement of burdensome control systems and market surveillance interventions. Weaknesses identified centre on four major issues: the disparity of the notifying processes in the Member States, incomplete criteria for assessing the technical competence of the notified bodies, weakness of the accreditation infrastructures the national and European levels and the uneven coordination put into place as between the notified bodies to ensure coherent implementation of the directives

- d) National authorities have had regular recourse to their national accreditation infrastructures, but without the presence of a Community legal base, or common rules relating to their status and Community role. Accreditation can play an important role as the last layer of control in the conformity assessment system instigated in the framework of the new approach, but only under conditions. The major condition is that all public authorities recognise accreditation as being a public authority activity and that, on that basis, commercial competition be forbidden between the accreditors.

The national accreditation bodies have set up a private association at the European level (European co-operation for Accreditation - EA), in order to coordinate their activities and to operate a peer evaluation system so as to maintain a degree of recognition of the value of their activities. However, this system has not been officially recognised in the context of the implementation of EU legislation, nor systematically at the national level. It is now opportune to give this organisation an official recognition and to set rules for its role as between national authorities and the Commission. It is in particular important to have common rules on the relationship between national authorities and their national

accreditation infrastructures and more importantly between national authorities, the Commission and the peer evaluation system of EA to reinforce confidence in the notified body system in particular. Public authorities must be committed to taking action in the presence of a negative peer evaluation result.

- e) The CE marking of conformity to the essential requirements was developed with the adoption the first new approach directives and was coordinated through a horizontal directive in 1993. This marking system is now applied by some 25 directives and is to be found on a very large number of products (both consumer and industrial products) not only in the Union but in the whole world. Its meaning has become confused over the years and the fact that it is not properly protected in law has not helped. Moreover, national market surveillance authorities do not always react in the same manner in its presence or its absence. It is therefore necessary to revisit its provisions and to clarify them.

4 MARKET SURVEILLANCE AND COMMUNITY SAFEGUARDS

Traditionally market surveillance is the responsibility of national authorities and rightly so. They are the only authorities close enough to the market to have the means to intervene on unsafe or illegal products. All EU product safety legislation (old and new approach) recognises this role and leaves it to the national authorities to put into place the necessary measures, without specifying what is appropriate. Implementation experience has demonstrated that national authorities implement different rules and interpretations and have very different means of intervention. Lack of clear common rules has led to new level of barriers to trade, to an uneven level of protection in the EU and to a certain degree of distortion of competition as between the national markets.

Within the Lisbon agenda, the Commission has recognised the importance of market surveillance for the development of the European economy, for the quality of protection accorded to citizens and for the very competitiveness of European enterprises. This is therefore an opportune moment to put into place a Community policy in this area, which respects the national prerogatives and responsibilities, but which ensures a common approach and better coordination mechanisms, both for products manufactured in the EU and for those imported from third countries:

- a) This entails setting common essential elements and rules for the operation of market surveillance in the Member States, some minimal common requirements as to infrastructures and the development of EU cooperation, consultation and information mechanisms as between the authorities in the field.

Market surveillance measures taken by national authorities within the framework of EU legislation (market restrictions, requests for corrective actions or withdrawal of products) should be seen as being taken in implementation of the EU legislation.

- b) The consultation, information and cooperation measures set up at EU level should ensure as much as possible that problems are solved at the national level. It is only when there is difference of opinion between Member States or when the Commission disagrees with a national measure that an issue should be brought up to the EU level for settlement. This should lead to simplification of the safeguard mechanism and reduce the need for burdensome EU decision making procedures.
- c) In order to reinforce common understanding, to reduce conflicts and differences of interpretation on the technical issues, the Commission should be empowered to set up a programme for carrying out testing intercomparisons and for having at its disposal a pool of external expertise. This mechanism could also prove useful in the context of the cooperation groups of notified bodies.

In line with its policy in favour of e governance, the Commission shall have published, and continuously updated, on its public internet web site the lists of notified bodies, the consensus developed explanatory guidelines and the references of the harmonised European standards. The Commission should examine whether the provisions of this legislative initiative and its implementation would allow for further EU product legislation which would refer to this text for much of their content, could take the form of regulations rather than directives, in order to contribute to legal and administrative simplification.

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C. CONTENTS OF THE POSSIBLE HORIZONTAL LEGISLATIVE ACT

1 SCOPE AND ESSENTIAL REQUIREMENTS

The scopes of EU legislation should concentrate on all essential requirements relevant to risks and hazards for as large, but as coherent, sectors and categories of activity as possible, be expressed in terms of performance rather than of design, and should avoid being so precise as to be technology related. These will be backed up preferably by harmonised European standards, which remain voluntary, and conformity to which grants presumption of conformity to the essential requirements.

The texts relating to the EU policy on European standardisation remain applicable in their present state. Where technical specifications are drawn up by organisations other than the European Standardisation Organisations (CEN/Cenelec/ETSI), EU legislation should nevertheless provide for a similar system based on the setting of EU essential requirements against which these technical specifications can be gauged.

Products covered by EU legislation may be made available only if they do not endanger the health, safety and other issues of public interest protection, when properly installed and maintained and used for the purposes for which they are intended. Member States shall consider that those products satisfy the required high level of health, safety or other issues of public interest protection, which have demonstrated their compliance with the EU legislation under the conditions set out therein and have undergone the appropriate conformity assessment procedures.

2 OBLIGATIONS FOR ECONOMIC OPERATORS

The obligations for economic operators shall correspond to their respective roles in the supply chain and be determined in accordance with the proportionality principle.

The manufacturer shall:

- design and manufacture the product (or have the product designed and manufactured) in accordance with the essential requirements
- carry out or have carried out conformity assessment, including drawing up the technical documentation, the EC declaration of conformity and affixing the CE marking
- provide all supplementary information and documentation required by the directive (instruction manuals, warnings,..)
- affix his name and address to the product or to the accompanying documents
- identify each individual product by type, batch or serial number
- keep a record of the importer/distributor(s) to whom he supplies the product
- bring non-compliant products into conformity
- co-operate with market surveillance authorities (provide information and documentation, ensure withdrawal of products)

The authorised representative shall:

in all cases:

- keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities
- co-operate with market surveillance authorities (provide information and documentation, ensure withdrawal)

depending on the extent of his mandate, carry out the following tasks on behalf of the manufacturer:

- declare that the product complies with the requirements, i.e. draw up the EC declaration of conformity
- in certain cases: affix the CE marking
- carry out other tasks relating to the performance of the conformity assessment procedures

The importer shall:

- act with due diligence
- assure himself by means of documentation that the appropriate conformity assessment procedure has been carried out by the manufacturer
- assure himself that the manufacturer has drawn up the EC declaration of conformity, to keep a copy of it
- assure himself that the manufacturer has duly affixed the CE marking to the product
- assure himself that the manufacturer has drawn up the technical documentation and to ensure a way of making it available to the surveillance authorities, upon request
- assure himself that the manufacturer has affixed his name and the address to the product or the accompanying documentation
- assure himself that the product has been identified by the manufacturer by type, batch or serial number
- ensure that his name and address are affixed to the product or the accompanying documentation
- keep a record of the supplier and the distributors to whom he supplies the product
- ensure that storage or transport conditions do not negatively affect the compliance of the product with the essential requirements
- co-operate with market surveillance authorities (provide information and documentation, ensure withdrawal)

Where the importer, after having carried out the abovementioned obligations with due diligence, discovers that the manufacturer has not fulfilled his obligations, he may supply the product only by carrying out these obligations himself (i.e. he becomes the manufacturer)

- where the product is in conformity but the conformity assessment procedure has not been carried out or not been duly carried out by the manufacturer: carry out the applicable conformity assessment procedure, establish the technical documentation (or

get it from the original manufacturer), draw up and sign the EC declaration of conformity and affix the CE marking;

- where the product is not in conformity: bring the product in conformity, carry out the conformity assessment procedure, establish the technical documentation (or get it from the original manufacturer), draw up and sign the EC declaration of conformity, affix the CE marking.

The distributor shall:

- act with due diligence
- assure himself that the product bears the CE marking, is accompanied by the EC declaration of conformity (if required) and other required documents
- assure himself that the manufacturer's and, if applicable, the importer's name and address are affixed to the product or to the accompanying documentation
- assure himself that the products are identified by type, batch or serial number
- keep a record of the supplier of the product
- ensure that storage or transport conditions do not negatively affect the compliance of the product with the essential requirements
- cooperate with market surveillance authorities (provide information and documentation, ensure withdrawal)

Where the distributor, after having carried out the abovementioned obligations with due diligence, discovers that the manufacturer has not fulfilled his obligations, he may supply the product only by carrying out these obligations himself (i.e. he becomes the manufacturer)

- where the product is in conformity but the conformity assessment procedure has not been carried out or not been duly carried out by the manufacturer: carry out the applicable conformity assessment procedure, establish the technical documentation (or obtain it from the original manufacturer), draw up and sign the EC declaration of conformity and affix the CE marking;
- where the product is not in conformity: bring the product in conformity, carry out the conformity assessment procedure, establish the technical documentation (or obtain it from the original manufacturer), draw up and sign the EC declaration of conformity, affix the CE marking.

3 TRACEABILITY REQUIREMENTS

Ensuring traceability of a product throughout the whole supply chain will make an important contribution to rendering market surveillance simpler and more efficient. Traceability should allow identifying the manufacturer or the importer of the product in order to get access to the declaration of conformity and the technical documentation. The following elements constitute the minimum requirements which should figure in every legislative instrument:

- ***Obligation to identify the manufacturer and the importer*** on the product, the packaging or in the documentation accompanying the product: This requirement already exists for manufacturers in almost all directives and should be extended to the importer of the product. The minimum information should contain the name and the address of the company.

- ***Obligation to identify every individual product*** by type, batch or serial number.
- ***Obligation for all economic operators to keep a record of the supplier of the product:*** An obligation to keep relevant documentation already exists for taxation purposes and could be used for the purpose of traceability. Thus, no additional burden on enterprises would be created. This obligation does not apply to consumers or end-users.
- ***Obligation for the manufacturer and the importer to keep a record of the distributors to whom they supply their products***
In view of avoiding administrative burdens, the requirement to keep also the records of the purchasers of a product should only apply to the manufacturer or the importer respectively. This obligation does not cover sales to end-users/consumers.

The following options should be used only where duly justified:

- ***Obligation to have an authorised representative in the EU:*** An obligation to appoint an authorised representative already exists in the medical devices directives. This requirement constitutes a considerable burden for enterprises. Recourse to this measure should therefore be restricted to duly justified cases.
- ***Registration system:*** The Directives could provide for an obligation for manufacturers established in the EU as well as for importers to enter certain information (e.g. name and address, product identification, electronic copy of declaration of conformity) into a database operating at EU level. The management of such a system would however create a certain amount of administrative workload.

4 CONFORMITY ASSESSMENT PROCEDURES

4.1 The principal guidelines for the use of conformity assessment procedures in technical harmonization directives are the following:
(*Modules decision text*):

- a) the essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers;
- b) conformity assessment can be subdivided into modules which relate to the design phase of products and to their production phase;
- c) as a general rule a product should be subject to both phases before being able to be placed on the market if the results are positive ;
- d) there are a variety of modules which cover the two phases in a variety of ways. The directives must set the range of possible choices which can be considered by the Council to give the public authorities the high level of safety they seek, for a given product or product sector;
- e) in setting the range of possible choices open to the manufacturer, the directives, will take into consideration, in particular, such issues as the appropriateness of the modules to the type of products, the nature of the risks involved, the economic infrastructures of the given sector (e.g. existence or non-existence of third parties), the types and

importance of production, etc. The factors that have been taken into account must be explicitly spelled out by the Commission in these directives;

- f) the directives will, in setting the range of possible modules for a given product or product sector, attempt to leave as wide a choice to the manufacturer as is consistent with ensuring compliance with the requirements.

The directives will set out the criteria governing the conditions in which the manufacturer chooses the most appropriate modules for his production from the modules laid down by the directives;

- g) the directives should avoid imposing unnecessarily modules which would be too onerous relative to the objectives of the directive concerned;
- h) notified bodies should apply the modules without unnecessary burden for the economic operators. Consistency in the technical application of the modules shall be ensured through appropriate coordination and co-operation between notified bodies;
- i) in order to protect the manufacturers, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessment of conformity. Legal protection of confidential information is required;
- j) whenever directives provide the manufacturer with the possibility of using modules based on quality assurance techniques, the manufacturer must also be able to have recourse to a combination of modules not using quality assurance, and vice versa, except where compliance with the requirements laid down by the directives requires the exclusive application of a certain procedure;

(Texts on CE marking and the explanatory notes on the modules themselves are not included here. They will be adapted and integrated when the proposal on marking and the modules are stabilised)

4.2 Conformity assessment modules and procedures

(Modules decision text largely unchanged, except:

- *Modules D, E, H would be modified to reflect the options presented in draft Certif 2005-1 rev.1, i.e. either replaced by Module Q containing guidelines for directives on determining the requirements of the quality system (ISO 9001:2000 equivalent) that apply in each product sector, or modified to reflect the requirements of ISO 9001:2000.*
- *A module on design examination would be introduced, by copying the relevant requirement of the existing module H (as suggested in draft Certif 2005-14);*
- *A module on technical documentation would be introduced, by copying points 2 and 3 of Module A, and deleting the corresponding footnotes in modules D,E and F (as suggested in draft Certif 2005-14);*
- *A module on inspection would be introduced, as suggested in draft Certif 2005-14.)*

5 CONFORMITY ASSESSMENT BODIES/ NOTIFIED BODIES

5.1 Notification

Member States shall notify the Commission and the other Member States of the bodies under their jurisdiction, which they have chosen from the bodies designated to carry out the conformity assessment procedures referred to in the applicable Community legislative

instrument, together with the tasks, including the specific scope of designation and the conformity assessment module(s) for which each body has been designated, and the identification numbers assigned to them beforehand by the Commission. Member States shall notify the Commission and the other Member States of any subsequent amendment to the notification. Member States shall take the overall responsibility for the proper operation of the bodies notified by them. Notification is at the discretion of the Member States. Member States are not obliged to notify bodies, nor are they obliged to notify all the designated bodies complying with the applicable essential requirements.

5.2 Designation

Wherever possible, designation of conformity assessment bodies shall be supported by formal accreditation conveying demonstration of their competence to fulfil conformity assessment tasks specified in the applicable Community legislation and policies. In duly justified cases, the Commission, together with the Member States, may accept the notification of a conformity assessment body designated on the basis of competence assessment not using formal accreditation, provided that such notifications are verified, recognised and regularly monitored to ensure an equivalent level of mutual confidence.

Demonstration of competence of a conformity assessment body entails the obligation for Member States to define and implement procedures to assess and determine whether applicant conformity assessment bodies fully comply with all the essential requirements and other applicable requirements resulting from the specific conformity assessment procedures in combination with the product category/categories applied for (“scope of conformity assessment”). Member States shall ensure that the conformity assessment bodies notified by them continually meet these requirements, which implies the establishment and implementation of procedures that guarantee regular and efficient monitoring, including in particular of subcontracting and cross-border activities of notified bodies, including activities subcontracted to a foreign body. The requirement for notified bodies to come under the jurisdiction of the notifying Member State implies the need for bodies to be established on the territory of that Member State. Foreign subsidiaries of the notified body or other related legal entities established outside the Member State on the territory of which the notified body is established, may not issue statements of conformity on behalf or in the name of the (parent) notified body.

- For the purposes of transparency and mutual confidence, Member States shall be obliged to inform the Commission and the other Member States of their relevant national procedures and documents used for the assessment, designation and regular monitoring of notified bodies under the various scopes of the Community legislative instruments, using a standard format, and to ensure that the information is kept up to date. The Commission shall make the information publicly available.
- The Member State responsible for the designation and notification of the body shall take all appropriate measures with respect to the validity of the notification when the notified body no longer meets the essential requirements or when it seriously fails to fulfil its responsibilities. The measures to be taken shall be proportionate to the non-compliances or non-conformities identified and include the conditioning, restriction, suspension and withdrawal of notification. The Member State concerned shall immediately inform the Commission and the other Member States accordingly.
- In the case of withdrawal of notification or where the notification has been restricted, conditioned or suspended or the notified body has otherwise ceased its activities, the Member State concerned shall take the appropriate steps to ensure that the files of its

clients are either processed by another notified body or are kept available to the competent designating authorities in order to ensure continuity.

- Member States shall ensure that the notified bodies keep their designating authorities informed of the performance of their tasks and inform them as soon as possible of any cases of suspension or withdrawal of certificates or other relevant conformity assessment results and, on request, of certificates or other relevant conformity assessment results issued or denied. Member States shall establish a procedure through which the notified body can fulfil this obligation.
- Moreover, Member States shall ensure:
 - a. Exchange of information between:
 - designating authorities and market surveillance authorities in the case of information from notified bodies on certificates suspended or withdrawn and, on request, on certificates issued or denied;
 - designating authorities and the Commission services responsible for administering safeguard clauses, upon request by the Commission services.
 - b. Participation in exchange of experience, to be established by the Commission, between the Member States' national authorities responsible for policy on designation and between the designating authorities and accreditation bodies.

5.3 Essential requirements for national authorities responsible for the assessment, designation and monitoring of conformity assessment bodies (designating authorities)

Where, by way of exception, Member States do not make use of formal accreditation performed by their nationally recognised accreditation body, they shall ensure that their designating authorities comply with the essential requirements referred to in [Annex 3](#).

5.4 Conformity assessment bodies / notified bodies

Essential requirements for conformity assessment bodies

Member States shall apply the essential requirements referred to in [Annex 4](#) for the assessment, designation and monitoring of conformity assessment bodies. This set of essential requirements shall be deemed to be exhaustive. Insofar as the technical competence requirement is concerned, further specification shall be provided by the specific Community legislative instrument, where necessary.

The conformity assessment body shall be independent to the extent that is required with regard to the conditions under which it performs its services under the applicable Community legislative instrument. Depending on these conditions, the body shall meet the independence requirement for either a fully independent third party body or an in-house inspection body supplying conformity assessment services exclusively to its parent organisation. Notified bodies shall be fully independent third-party bodies. For certain specific conformity assessment tasks, Community legislation may have recourse to the specific expertise of in-house inspection bodies, where duly justified. These bodies shall not be referred to as notified bodies and the regime under which these bodies carry out their tasks shall be clearly separated in order to avoid confusion. They shall not be formally notified to the Member States and the Commission and shall not be given an identification number. In principle, notified bodies shall be used where products are intended to be marketed freely and mutual confidence between Member States requires third party conformity assessment with regard to the specific risk potential involved.

Presumption of conformity for notified bodies

- a) Notified bodies shall be able to demonstrate their compliance with the essential competence requirements through reliance on technical criteria contained in the relevant consensus standards for accreditation (EN 45000/17000 series of standards). Bodies which can demonstrate their conformity with the criteria laid down in the relevant national standards adopted pursuant to the harmonised standards, the references of which have been published in the OJEU, by submitting an accreditation certificate, shall be presumed to fulfil the corresponding essential requirements.
- b) Where Member States use formal accreditation in support of designation, the accreditation certificate shall be issued by a nationally recognised accreditation body signatory to the relevant part(s) of the multilateral agreement (MLA) operated by the European accreditation infrastructure. Presumption of conformity shall be limited to the specific conformity assessment activities for which such accreditation has been granted.

Where formal accreditation has not been used in support of designation or where the accreditation certificate has not been issued by a signatory to the relevant part(s) of the MLA operated by the European accreditation infrastructure, the Member State concerned shall provide the Commission with all documentary evidence necessary for the verification, recognition and regular monitoring of the notification in order to ensure an equivalent level of mutual confidence.

Moreover, notified bodies shall:

- restrict, suspend or withdraw certificates, approvals or other relevant conformity assessment results, taking into account the principle of proportionality, where the body finds that pertinent requirements of the relevant Community legislation have not been met or are no longer met by the manufacturer, unless compliance is ensured through the implementation of appropriate corrective measures.
- provide information
 - to the designating authorities on: suspension and withdrawal of certificates as well as of their issue or refusal, upon request; conformity assessment activities performed within the scope of designation and, on request, on any other activity performed such as, in particular, cross-border activities; changes concerning the scope of and conditions for designation; subcontracting etc.;
 - to the bodies carrying out similar conformity assessment activities (e.g. type examination or approval, quality assurance) and covering the same scope of products under the relevant Community legislation, about the certificates, approvals or other conformity assessment results and any additions thereto issued, restricted, suspended or withdrawn.
- take into account, and may accept, conformity assessment results issued by an accredited manufacturer's laboratory or inspection body or by any other accredited third party conformity assessment body for a subset of the overall assessments and examinations required for a given scope of conformity assessment, provided that the scope of accreditation covers the scope of conformity assessment concerned and the accreditation certificate has been issued by a signatory to the MLA operated by the European accreditation infrastructure.

5.5 The Commission

The Commission shall make publicly available, for information, the list of the bodies notified under the relevant Community legislation, including the identification numbers

that have been allocated to them and the tasks and scopes for which they have been notified. The Commission shall ensure that this list is kept up to date.

The Commission, in co-operation with the Member States, shall ensure that appropriate coordination and cooperation between notified bodies is put into place and properly operated in the form of sectoral and cross sectoral groups of bodies notified under specific legislation or under groups of pieces of legislation. These groups shall be answerable to the Commission and to the groups of national experts set up under the various legislative instruments to assist the Commission in their implementation.

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for policy on designation.

The Commission shall, together with the other Member States, determine the procedure to be applied for the verification and monitoring of equivalence in the case of notification of bodies on the basis of designation not using formal accreditation or where accreditation has not been issued by a signatory to the relevant part(s) of the MLA operated by the European accreditation infrastructure.

The Commission shall investigate all cases brought to its attention where doubt arises as to the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities placed on it. The notifying Member States shall provide the Commission with all information related to the basis for designation or the maintenance of the competence of the body concerned. The Commission may call upon the expertise available in the relevant recognised professional organisations, such as the European accreditation infrastructure, to assist it in such investigations, including the performance of assessments, verifications, proficiency testing or other comparisons as deemed appropriate. The Commission shall ensure that all information obtained in the course of its investigations is treated confidentially. The Member State concerned shall act upon the conclusions of the investigations, as appropriate, and inform the Commission of the action taken. Where a notifying Member State fails to provide the relevant information or to take appropriate action following the conclusions of the investigations, the Commission shall bring this to the attention of the other Member States for discussion and/or initiate the procedure foreseen in Article 226 of the EC Treaty.

6 ACCREDITATION

6.1 Responsibilities at national level

Member States shall organise and operate accreditation as a public authority activity in accordance with the general principles and operational obligations set down below.

a) General principles

- Where Member States decide to operate accreditation under their jurisdiction, they shall establish and maintain a national accreditation body or system of accreditation bodies on the basis of a specific public authority act or decision.
- Where accreditation is not operated by the public authorities themselves (e.g. as part of a ministry or as a public agency), Member States shall ensure that there is a strong link between the national accreditation body and the public authorities, as defined in the specific act or decision, whereby the national accreditation body:

- is entrusted with the operation of accreditation as a service of general interest and
 - is granted formal recognition on behalf of government, authorising it to operate accreditation under the authority and responsibility of the public authorities.
- In view of the recognition of accreditation as a public authority activity, and considering the added value of accreditation to serve as the last and authoritative level of control of conformity assessment activities with regard to technical competence in order to create mutual confidence, Member States shall organise accreditation free from commercial competition and entrust its operation to a single national accreditation body or to a system of single accreditation bodies.

These principles shall apply irrespective of whether accreditation services are provided to support conformity assessment in the regulatory and/or non-regulatory spheres, and irrespective of the legal status of the accreditation body.

b) Operational obligations

Member States shall support accreditation and take responsibility for, and exercise efficient political control over, the functioning and proper operation of their nationally recognised accreditation bodies. More specifically, in order to fulfil this obligation, Member States shall:

- support the nationally recognised accreditation body in the achievement of its objectives, in particular, by encouraging businesses and public authorities requiring third-party conformity assessment services to source such services, where they exist, from conformity assessment bodies accredited either by their nationally recognised accreditation body or by an equivalent accreditation body that is signatory to the European or international multilateral agreements;
- ensure that financial support exists for the fulfilment of special tasks, although accreditation should in principle be operated as a self-supporting activity. Such tasks include in particular the nationally recognised accreditation body's activities in European and international accreditation organisations and activities that are required to support government policy and are not self-financing;
- work with the nationally recognised accreditation body, and establish an efficient control mechanism, to ensure that it operates in the general interest and meets the essential requirements placed on it as well as the obligations set out in the act or decision giving formal recognition. In particular, where the nationally recognised accreditation body operates accreditation in support of the implementation of Community legislation, Member States shall ensure that the accreditation body has the necessary technical expertise and capabilities to assess, attest and regularly monitor the technical competence of conformity assessment bodies as required by the specific scope of conformity assessment foreseen in the relevant legislative instrument, including its product-/technology-related knowledge and its competence to assess products directly for compliance with the applicable essential requirements. As for the framework conditions for impartiality, it shall be ensured that there is a clear separation between the technical and the political decision-making;
- determine or approve the accreditation rules or criteria against which assessment of competence is performed by the nationally recognised accreditation body, on the basis of the relevant European and international standards and application documents for accreditation;

- ensure that their nationally recognised accreditation body submits regular accounts of its financial situation and resources (including fees charged) and undergoes periodic audit;
- ensure that appropriate procedures are established within the nationally recognised accreditation body for the resolution of appeals and complaints made against its accreditation decisions;
- ensure the safeguard of the specific public interest aspects of accreditation and the maintenance of the required high level of technical competence;
- ensure that the nationally recognised accreditation body has the appropriate resources, both financial and personnel, for the proper performance of its tasks at national level and within the European accreditation infrastructure.

6.2 Responsibilities towards the European accreditation system

Member States shall take all appropriate steps and measures for the furtherance of a coherent European accreditation system that operates in compliance with, and in support of the implementation of, Community legislation and policies. To this end,

- Member States, together with the EFTA Member States and the Commission, shall acknowledge their shared responsibility for guaranteeing the safeguard of the public interest mission of the European accreditation system and for providing the authority under which the European accreditation infrastructure performs its activities;
- Member States shall ensure that their nationally recognised accreditation bodies participate in adequate co-operation and co-ordination of their policies at European level within the European accreditation infrastructure, commensurate with the size of the body and the volume of its operations. This does not preclude the possibility for accreditation bodies to collaborate with, or be represented by, another nationally recognised accreditation body in view of the fulfilment of this obligation;
- Member States shall ensure that their national public authorities themselves are adequately represented within the European accreditation infrastructure in order to guarantee the proper safeguard of the public interest aspects of accreditation and underpin the objective of promoting further the recourse made to accreditation for the implementation of legislation;
- Member States shall support the proper functioning of the European accreditation system, and ensure that their nationally recognised accreditation body fully respects the agreed rules and procedures governing the functioning of the European accreditation infrastructure and properly implements the decisions taken;
- In view of their shared political responsibility for the proper functioning of a coherent notified body system ensuring mutual confidence, the national authorities shall commit themselves to respect the rules and procedures adopted at European level and to support the decisions taken by the European accreditation infrastructure, in particular those in respect of the peer evaluation process, as a basis for their designation and notification decisions, subject to an appeals procedure;
- Member States shall ensure that their nationally recognised accreditation body participates in regular peer evaluation at European level as a signatory to the relevant part(s) of the multilateral agreement (MLA) operated by the European accreditation infrastructure. Appropriate arrangements, such as joint accreditation together with another MLA signatory to be foreseen by the relevant national legislation, should be sought in those cases where signing the MLA is not considered to be economically meaningful or sustainable;

- Member States shall ensure that their nationally recognised accreditation body properly implements the decisions taken by the European accreditation infrastructure in respect of the peer evaluation process, subject to an appeals procedure, and follows up findings of the evaluation by corrective or other action, as required;
- Member States shall recognise the equivalence of other MLA signatories' accreditation systems and therefore accept, for a specified scope of accreditation, both the accreditation certificates issued by other signatories to the relevant part(s) of the MLA and the conformity assessment results issued by conformity assessment bodies accredited by them.

6.3 Nationally recognised accreditation bodies

In order for accreditation to be performed in the general interest, the national accreditation body shall operate either as a public authority body or with authority derived from, and under the responsibility of, the public authorities and in accordance with the essential requirements and further operational obligations set out below.

a) Essential requirements

The essential requirements shall be those laid down for the authorities responsible for the assessment, designation and monitoring of CABs (designating authorities). Nationally recognised accreditation bodies that comply with the criteria laid down in the relevant national standard adopted pursuant to the harmonised standard, the reference of which has been published in the OJEU¹, are presumed to fulfil the essential requirements.

b) Operational obligations

Moreover, nationally recognised accreditation bodies shall

- operate accreditation as a non-profit distributing activity, i.e. the accreditation body may not deliver surplus to its owners, whether public or private;
- consult and co-operate with all interested parties and be accountable to, and take into account the interests of, all stakeholders and parties concerned;
- not compete with the bodies they accredit. Nor shall they proactively compete with other nationally recognised accreditation bodies, whether within the national territory or across national boundaries. However, nationally recognised accreditation bodies may operate across national boundaries if they are asked to do so, in co-operation with the local accreditation body, where applicable;
- operate accreditation without unnecessary burden for the economic operators;
- work together and co-operate, within the European accreditation infrastructure and the relevant international bodies and fora, to promote the international acceptance of accredited conformity assessment;
- where applicable, make publicly available information about international arrangements in relation to accreditation, in which they are involved;
- make publicly available information about the accreditation schemes they operate and about any changes to those schemes. They shall inform the European accreditation infrastructure of the sectoral schemes they operate and of new schemes they intend to operate sufficiently well in advance in order to allow the

¹ i.e. EN 17011

members of the European accreditation infrastructure to react appropriately. They shall also inform the Commission of the accreditation schemes operated in support of the implementation of Community harmonisation legislation and shall update such information as necessary;

- actively contribute to the relevant activities at European and international levels, so as to enable the European accreditation infrastructure to fulfil its missions set out in its founding documents. The contributions shall be proportionate to the size and scope of the accreditation body's activities and competences.

6.4 The European accreditation infrastructure

The European accreditation infrastructure shall

- bring together and serve as a co-operative network of all European nationally recognised accreditation bodies for the furtherance of equivalence, transparency, consistency and efficiency of accreditation operated throughout the EU, EFTA and beyond;
- serve the public interest mission of generating and maintaining confidence in the bodies performing calibration as well as testing, certification, inspection and other conformity assessment activities, in particular for the proper functioning of the single market, the common commercial and external trade policy of the EU and the Community's policy on technical assistance to third countries;
- operate a rigorous and transparent peer evaluation system, consistent with relevant international practice, to ensure the equivalence of the level of competence of its members and to facilitate mutual recognition and promote the overall acceptance of accreditation certificates and accredited conformity assessment results in both the regulatory and non-regulatory spheres, whether issued in the EU/EFTA or in third countries;
- contribute to the consistent and coherent interpretation and application of the standards for accreditation and draw up supplementary guidance, where necessary;
- ensure appropriate representation by all stakeholders in European accreditation.

The European accreditation infrastructure shall be the *European co-operation for Accreditation, EA*.

7 CE MARKING OF CONFORMITY

The principal requirements for the affixing and use of the CE marking are the following:

Text to be established following the outcome of the consultation on draft Certif 2005-11, mainly on the meaning of the CE marking and the Member States' actions for protecting it.

8. MARKET SURVEILLANCE

8.1 Essential requirements for a Community market surveillance system

Member States shall organise and operate market surveillance as a public authority activity in accordance with the following essential requirements.

Member States shall:

- a) Adopt national measures to organise and perform efficient and effective surveillance in order to ensure that products may be made available on the market only if they satisfy the relevant provisions of the Directives.
- b) Designate authorities competent to monitor the conformity of products with the applicable provisions of the Directives and arrange for such authorities to have the necessary powers to take the measures incumbent upon them i.e. to carry out their duties with the speed required, in cases where the non-conformity of a product poses a risk to users.
- c) Define the organisation of the national market surveillance system and the tasks of the competent authorities.
- d) Organise an effective overall communication and co-ordination at national level between the market surveillance authorities (sectoral and local) and the other organisations which intervene in the field of safety of products, e.g. health and safety at work authorities or customs authorities, by defining the objectives, organisation and co-operation methods of their market surveillance authorities.
- e) Empower the customs authorities to perform, at least, documentary and physical checks on products covered by Community legislation.
- f) Have recourse to best practices and sound management of resources. They must, in particular, be able to detect serious cases of non-conformity. Priority shall be given to the fields in which the probability of risk is the highest or to cases which are of individual interest (complaints, accidents, etc).
- g) Adopt rules concerning sanctions applicable to infringements of the national legislation (as adopted in line with Community law) and to outline an appropriate appeals procedure. The penalties provided for shall be effective, proportionate and dissuasive. Sanctions shall be used only where all other deterrent means (e.g. correctives measures, withdrawals, bans) have not succeeded in restoring safety conformity.
- h) Organise market surveillance activities up to the final stage of use or consumption of a product through documentary, physical and, where appropriate, laboratory checks, from its placing on the market to its use and possible final withdrawal. The objective is to ensure that the market surveillance activities implemented reach a level such that manufacturers, importers and distributors, as well as users, know that products made available on the market are likely to be effectively controlled.
- i) Ensure that market surveillance activities cover the full range of products subject to the Directives concerned, including, where appropriate, products for consumer and professional use.
- j) Organise the market surveillance system in order to include the procedures necessary to:
 - record and ensure the follow-up of complaints or reports concerning non-compliant products;
 - monitor accidents and damage to health involving the products concerned;
 - implement market surveillance programmes for categories of product or of risk.

- k) Empower their market surveillance authorities to take the following actions, where necessary:
- carry out checks on the conformity of products after they have been placed on the market or, in some cases, after they have been put into service (e.g. unit manufactured products, etc);
 - require that the necessary documents and information from the parties concerned are provided;
 - take samples of product and submit them to the necessary inspections and/or tests;
 - instigate the relevant enforcement procedures and, in case of serious and immediate risk, inform, without delay through RAPEX, of the restrictive measures taken.
- l) Take appropriate provisional measures, on the basis of a risk analysis carried out in accordance with the precautionary principle.
- m) Ensure that market surveillance authorities observe confidentiality.
- n) Allow competent national authorities to take part in the overall Community cooperation activities and ensure that all requests for mutual assistance contain sufficient information to enable the requested authority to fulfil the request.
- o) Appoint for each sector the national sectoral contact point in charge of notifications for the RAPEX system.

8.2 Community control

The Commission shall ensure, within its role as guardian of the Treaty, the overall compliance with the above “essential elements”. Consequently, the Member States shall inform the Commission and the other Member States of their market surveillance implementing measures and of any subsequent changes to them.

The Commission shall facilitate the transmission of data on the implementation of the national provisions adopted by the Member States by the provision of a standard file including a standard notification form. This should also make it possible to have homogeneous data concerning the national systems.

8.3 Community cooperation

Community co-operation aims to guarantee the homogeneous and effective application of Community legislation and to establish mutual confidence and transparency between national authorities. Co-operation at the Community level between the Member States shall be organised as follows:

8.3.1 Administrative cooperation

a) General activities

The system for administrative cooperation shall provide for:

- i. The adoption of appropriate national measures in order to ensure that the national authorities responsible for implementing the concerned Directives cooperate with

each other and provide each other and the Commission with information and to assist each other in cases of non compliance.

ii. The administrative cooperation and exchange of information shall take utmost advantage of electronic means of communication.

iii. The definition of common principles of management which shall:

- specify the nature and structure of the exchange of information between the Commission and Member States and set up the determination of the types of cases for which the information communication is useful, the means of information transmission, etc.
- organise meetings at sectoral level such as the AdCo groups. The general objectives and the tasks of these groups are referred to in Annex 7. These groups play a fundamental role as a co-operative network (e.g. to share views in particular on problems with implementation, follow-up measures in respect of formal non-compliances, risk analysis, etc.);
- ensure coordination of the activities of the above-mentioned groups by setting up administrative cooperation at inter sectoral level where the questions of general coordination will be treated requiring the participation and the technical support of national experts from various sectors (e.g. application of the sectoral directives, Regulation 339/93, GPSD, Customs Code, etc). The general objectives and the tasks of this group are referred to in Annex 7;
- empower the Commission to ensure that administrative cooperation is effective and includes all the Member States;
- all rules concerning the effectiveness and the proper functioning of the sectoral and inter sectoral groups should be detailed in a guidance document.

b) Exchange of information and communication between national authorities:

i. Exchange of information shall be ensured for notifications of serious non compliances requiring a rapid intervention by the use of the existing **RAPEX**² system which is essentially aimed at rapid exchange of information in the event of a serious risk posed by industrial products intended for consumers or likely to be used by consumers. It is envisaged to extend the use of this system also to products intended for professional use only.

The general requirements for RAPEX implementation and notifications in line with Annex II of Directive 2001/95/EC on General Product Safety are set out in Annex 6. The content and standard form of the non compliances notifications should also be harmonised and, in particular, shall provide precise information on the conditions for which the notification is relevant (e.g. if the effects can go beyond the national territory, information on the safety of the product, etc.).

All rules concerning the effectiveness and the proper functioning of the RAPEX system should be detailed in a guidance document (see Annex 6 § 8).

ii. Wider information concerning the overall cooperation activities will be stored in a single database. It is suggested to use the existing **ICSMS**³ database. This

² The **RAPEX** system uses an Internet-based software application as a communication tool between the contact points linked to a database containing all the information from the notifications and reactions. Currently, RAPEX works in eleven languages.

³ The **ICSMS** database (an Internet-based Information and Communication System for Market Surveillance) laid the foundations for effective and efficient co-operation in the fields of notification and distribution of information on the safety of products. This involves a reasonably rapid cross-border exchange of information.

database will be made available, at different levels, to all stakeholders (national authorities, private organisations, industries, consumers, etc.).

This database shall serve the following purposes:

- The exchange of general information on market surveillance activities, including on detected non conformities;
- The development of certain particular aspects (statistics, information by sector, by product, etc.);
- The making available of information on risk analysis methodologies and results;
- The notification of the non conformities not covered by the RAPEX system (Community safeguard procedures and positions taken: withdrawals, prohibitions or marketing limitations for the products covered by directives and which present a potential danger or any other serious risk; voluntary corrective measures);
- The analyses of accidents giving the possibility, by the publication of comparative data (benchmarking), to enable Member States to exchange and adopt best practices;
- Possibly, the information on counterfeits that could have an impact on health, safety or other issues of public interest protection covered;
- an Early Warning System (EWS) for other aspects than those covered by RAPEX.

The sectoral directives may, where appropriate, lay down individual specific means (see e.g. the vigilance system provided for by the directives on medical devices) in order to take account of their specific characteristics.

- iii. The existing **CIRCA**⁴ system will continue to be used for general communication between national authorities, including the customs authorities (e.g. for the relevant committees, working groups, AdCo groups, the inter sectoral AdCo group). All rules concerning the proper functioning of the CIRCA system should be specified in a guidance document.
- c) Sharing of resources (testing and inspection infrastructures, etc.); the possibility for specific collaboration on site in order to avoid duplication of efforts.

Member States should request assistance from other Member States concerned.

The Commission, in cooperation with the national authorities, shall:

- develop and organise training programmes and exchange of national officials, in particular, for customs authorities;
- promote and share resources on risk analysis activities;
- set up appropriate programmes for exchange of information and best practices, through multi annual programmes for common projects, information campaigns, joint visit programmes, for example.

⁴ **CIRCA** (Communication and Information Resource Centre Administrator) is a tool for information exchange in the framework of the exchange of data between administration programmes (IDA). It is used in multiple fields such as employment, health, agriculture, fishing, statistics and competition. It is also used by co-ordination groups under several New Approach Directives.

8.3.2 External border controls

Within the context of Council Regulation 339/93 shall be examined the means of empowering customs authorities to perform, at least, documentary and physical checks on products covered by Community legislation. Moreover, confusion should be avoided and it should be specified that the list of products in Decision n° 93/583/EEC is not exhaustive and that it is given only as example.

The Commission shall develop the initiative aiming to work out a practical guide (or several sectoral guides), in particular, to help the customs authorities to examine the aspects concerning the safety of an imported product. This guide should in particular specify the procedures to be followed when a potential non conformity is detected, give indications on how to avoid that a product refused in a Member State is marketed in another, etc and to comprise an inventory of controls to be carried out.

8.4 Safeguard Procedures

The Community Safeguard Procedures (CSP) operate on the basis of the results of the proper functioning of the national market surveillance systems and only when there is a dimension to the problem which extends beyond the territory of a single Member State.

The CSP cover:

a) Measures for products believed to be non-compliant with EU legislation

The CSP for products believed to be non-compliant with EU legislation is constituted of two main elements:

- **A national procedure (information procedure)**

Firstly, the national surveillance authority shall evaluate the situation in relation to the given product and shall:

- i) where the product presents a risk: contact the manufacturer or his authorised representative or, where these contacts cannot be established, any other person having made the product available on the EU market. This may entail communicating via market surveillance colleagues in another Member State.

The evaluation of a non compliance shall, whenever possible, be carried out with the participation of the manufacturer (or importer, distributor as above; and together with other parties concerned, e.g. the notified body) and shall cover all the requirements concerned.

The surveillance authority then requires the manufacturer (importer, distributor) to take corrective action to bring the product into compliance with the requirements of the legislation, in due time, or to withdraw it from the EU market. The corrective actions imply that the manufacturer (importer, distributor) takes them throughout the Union. If adequate measures are agreed by the manufacturer (importer, distributor), the surveillance authority **informs** the Commission and the other Member States in order to enable them to ensure that the corrective measures are effectively implemented throughout the EU.

Where the manufacturer (importer, distributor) does not agree to take adequate corrective measures within the imparted delay, or object to withdraw it, or where non conformance continues, the surveillance authority shall take the

appropriate measures to ensure that the non-compliant and unsafe product is withdrawn from its national market. The national authority shall **trigger** the Community procedure and notify the Commission and inform the other Member States of the measures taken, with the underlying reasons.

It is considered that the national decision to question the conformity of products is an act of implementation of European legislation, and is therefore considered to be a priori appropriate. The Member State shall inform the Commission and the other Member States of its decision. In case no other Member State disagrees, the national decision stands. Also, if the manufacturer (importer, distributor) does not disagree with the non-conformity, de facto, the measure taken will be presumed justified. Should the Commission consider that the decision is contrary to the EU legislation it could discuss with the Member State and if there is no agreement have recourse to the infringement procedure (Article 226 of the Treaty).

At this stage, if the manufacturer (importer, distributor) does not agree with the above situation (acceptance of the national measure) he should, in the first place, have recourse to the nationally available remedial procedures, including the national courts. Should he consider it necessary and appropriate, he may present a complaint to the Commission and plead for an infringement procedure to be opened.

ii) where the product presents a severe risk requiring rapid intervention:

The Member State shall **immediately notify** it through the RAPEX system, enabling the Commission and the other Member States to be alerted rapidly, without waiting for corrective measures to be agreed.

If the non-compliance is confirmed and/or continues, the non compliant product will be submitted to the Community safeguard procedures. In this case, the Member State who has initiated the information procedure must continue the procedure as above.

- **The Community safeguard procedure**

This should remain an exceptional procedure.

Where a Member State disagrees with the national measures taken in another Member State or where the Commission considers that the national decision is contrary to the EU legislation, the Commission shall consult, without delay, all the parties concerned, evaluate the measure and take a position as to whether or not the measure is considered justified. The Commission notifies its position to the Member States and informs the interested parties. If the national measure is considered justified, the Member States shall take the necessary measures to ensure that the unsafe product is withdrawn from their national market and inform the Commission. If the national measure is considered unjustified, the Member State concerned shall withdraw it.

Measures in respect of formal non-compliances

Formal non-compliances shall not reach the Community phase. Member States shall inform the Commission and the other Member States of the measures taken.

Measures entailing restriction of free circulation

Member States shall provide for an appeals procedure against national measures restricting the free circulation of products.

b) Measures in respect of products in conformity with the relevant EU legislation and which nevertheless present a risk to health or safety

The Commission shall examine what appropriate actions can be taken and what modifications should be proposed to the initial EU legislation when the notified non compliance related to a product which complies with the EU legislation, but nevertheless present a risk to health and safety.

8.5 Enforcement measures

The Commission shall:

- Organise and take part in the management of the “Administrative Co-operation - AdCo” sectoral groups which shall develop and facilitate:
 - the exchange of information on market surveillance national activities, risk assessment, dangerous products, tests methods and results, scientific developments, control activities, etc.;
 - the establishment and execution of market surveillance common programmes (e.g. information campaigns, joint mutual visit programmes, joint actions programmes),
 - the exchange of information of expertise and best practices;
 - the cooperation in training activities;
 - the cooperation in the detection of non compliant products and in the community safeguard procedures.
- Organise and take part in the management of the inter sectoral AdCo market surveillance working group.
- Have develop all necessary guidance documents (Community safeguard procedures, RAPEX notification system, CIRCA, sectoral and inter sectoral groups, customs and Community safeguard procedures) and regularly update them.
- Create and manage the database.
- Adapt and extend the existing RAPEX notification system to all the EU product legislation and harmonise the content and standard form of the non compliances notifications.
- Develop with Member States multi annual programmes of joint market surveillance actions.
- Support and develop, if appropriate, training activities.
- Examine the necessity of amending Regulation 339/93 accordingly.
- Develop the provision of a standard file including a standard notification form for the implementation of the EU requirements.

8.6 Technical assistance

Member States shall nominate experts to a pool at the Commission level in order to assist the Commission in:

- the evaluation of national measures notified impeding the free circulation of products.
- any matter concerning the enforcement of the requirements, in particular evaluation of the national market surveillance systems, market surveillance and monitoring activities.
- the development and update of guidelines detailing the RAPEX notification system (see Annex 6 § 8).
- the development of all other guidance documents.
- the development and enforcement of the multi annual joint market surveillance programmes.

9 PUBLICATIONS

The Commission shall have published, and continuously updated, on its public internet web site the lists of notified bodies, the consensus developed, explanatory guidelines and the references of the harmonised European standards.

10 FUTURE EU PRODUCT SAFETY LEGISLATION

The Commission is examining whether the provisions of this legislative initiative and its implementation would allow for further EU product legislation which would refer to this text for much of their content, could take the form of regulations rather than directives, in order to contribute to legal and administrative simplification.

D. ANNEXES

Annex 1: Definitions.

Annex 2: Conformity assessment procedures.

Annex 3: Essential requirements for designating authorities.

Annex 4: Essential requirements for conformity assessment bodies.

Annex 5: Relationships between European co-operation for Accreditation (EA) and the European Commission and the EFTA.

Annex 6: General requirements for RAPEX implementation and notifications.

Annex 7: General objectives and tasks of the administrative cooperation groups (AdCo) and the inter sectoral AdCo group.

ANNEX 1

DEFINITIONS

Essential requirements

An essential requirement is the statement by the EU legislator of the level of protection that society can expect for the protection of the health and safety of the European citizen, in his private or professional capacity, for the protection of the environment and all other areas of protection for the development of the European social model.

Harmonised standard

A European standard adopted by one of the European Standardisation Bodies recognised in Annex 1 to Directive 98/34/EC and in accordance with a request from the European Commission following the procedure laid down in Article 6 paragraph 3 of that Directive and which, alone or in conjunction with other standards, provides solutions for compliance with a legal provision.

Guideline documents

The Commission shall have drawn up explanatory guideline documents in order to establish common understanding of the EU legislative requirements and to ensure their common implementation. They may be of a sectoral or general nature and concern in particular the implementation of the technical specifications, conformity assessment or market surveillance requirements. These guidelines can be initiated in the notified bodies coordination groups, market surveillance administrative coordination groups or in the groups of national experts set up to assist the Commission in the implementation of the EU legislation. They shall be developed on the basis of a public consensus procedure, which involves the different stakeholders. The guidelines shall be published by the Commission on its public internet web site.

Making available on the market

This term will replace “placing on the market” in those provisions where the reference to the first making available on the EU market is too restrictive.

Example 1: Member States must ensure that products are made available on the market only if they comply with the requirements of the directive.

Example 2: Member states may not restrict the making available of a product which complies with the requirements of the directive.)

Making available covers the whole period during which the product is circulating on the EU market, starting from the moment it is first made available (i.e. “placing on the market”) and ending with the final transfer to the end user. For certain products (assembled and/or installed directly at the place of the end user), this is the moment when the product is “put into service”.

The term “making available” does not need a definition in the horizontal instrument. A guidance document might clarify which situations are covered by this concept.

Placing on the market

The first making available of a product on the Community market (for distribution, consumption or use).

Putting into service

The first use of a product in the Community by the end user.

This notion is reserved to the provisions relating to the control of the product at the moment it is first used by the end user.

Presumption of conformity

Presumption of conformity to a legal provision, conferred by compliance with a harmonised standard, implies the obligation for a public authority to consider that a solution that complies with the specifications of a harmonised standard, the references of which have been published in the OJEU, complies with the legal provisions covered by those specifications.

Manufacturer

Any natural or legal person who designs and/or manufactures a product or who has such a product designed and/or manufactured, under his own name or trademark.

An importer or a distributor who transforms or modifies a product in a way that compliance with the essential requirements may be affected shall be considered to be the manufacturer.

Authorised representative

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 responsibilities under the relevant Community legislation.

Distributor

Any natural or legal person in the supply chain, who makes a product available in the course of his business.

Importer

Any natural or legal person established in the Community, who makes a product from a third country available on the Community market for the first time in the course of his business.

Conformity assessment

Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled.

Conformity assessment can be performed as a first-party, second-party or third-party activity and covers, but not exclusively, activities such as testing, inspection and certification.

Conformity assessment body (CAB)

Body that performs conformity assessment services in support of the implementation of Community legislation.

Designation

Governmental authorisation of a conformity assessment body to perform specified conformity assessment activities.

Notification

Formal administrative procedure whereby a Member State informs the Commission and the other Member States of the designation of a conformity assessment body to carry out certain specified conformity assessment tasks under Community legislation.

Notified body

Conformity assessment body that has been designated and notified by a Member State to carry out third-party conformity assessment tasks under Community legislation.

Not all conformity assessment bodies carrying out conformity assessment under Community legislation and policies are formally notified to the Member States and the Commission.

Accreditation

Third-party attestation, related to a conformity assessment body, conveying formal demonstration of its competence to carry out specific conformity assessment tasks.

Accreditation is a public authority activity performed in the general interest. For the purpose of supporting the implementation of Community harmonisation legislation and policies, accreditation shall be issued on the basis of compliance with all requirements contained in the relevant harmonised standards for accreditation⁵ and implies the requirement for accreditation bodies to comply themselves with the relevant harmonised standard⁶ (formal accreditation).

Accreditation body

Authoritative body that performs accreditation and that is either part of government or operates under the responsibility of, and with authority derived from, government.

⁵ i.e. EN 45000 / 17000 series and, where applicable, further sector-specific competence standards (e.g. EN 15189)

⁶ i.e. EN 17011

ANNEX 2

CONFORMITY ASSESSMENT PROCEDURES

Table 1: Modules Decision of 1989 unchanged

Table 2: Proposal to modify module B and present option 1 for ISO 9001-2000 (single flexible quality assurance procedure)

Table 3: Proposal to modify module B and present option 2 for ISO 9001-2000 (maintain 3 modules for quality assurance)

TABLE 1: CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION - COUNCIL DECISION 93/465/EEC

D E S I G N	<p>A. (Internal control of production)</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Keeps technical documentation at the disposal of national authorities <p>Aa.</p> <ul style="list-style-type: none"> > Intervention of notified body 	<p>B. (type examination)</p> <p>Manufacturer submits to notified body</p> <ul style="list-style-type: none"> > technical documentation > type <p>Notified Body</p> <ul style="list-style-type: none"> > Ascertains conformity with essential requirements > Carries out tests, if necessary > Issues EC type-examination certificate 				<p>G. (unit verification)</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > submits technical documentation 	<p>H. (full quality assurance)</p> <p style="text-align: center;">EN 29001</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > operates an approved quality system for design > submits technical documentation and type to NB (1) <p>Notified Body</p> <ul style="list-style-type: none"> > carries out surveillance of the QS > verifies conformity of design and issues EC design examination certificate (1)
	P R O D U C T I O N	<p>A.</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Declares conformity with essential requirements > Affixes the CE marking <p>Aa.</p> <p>Notified body:</p> <ul style="list-style-type: none"> > Tests on specific aspects of the product (1) > Products checks at random intervals (1) 	<p>C. (conformity to type)</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Declares conformity with approved type > Affixes the CE marking <p>Notified Body</p> <ul style="list-style-type: none"> > Tests on specific aspects of the product (1) > Product checks at random intervals (1) 	<p>D. (production quality assurance)</p> <p style="text-align: center;">EN 29002</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Operates an approved quality system for production and testing > Declares conformity with approved type > Affixes the CE marking <p>Notified Body</p> <ul style="list-style-type: none"> > Approves the QS > Carries out surveillance of the QS 	<p>E. (product quality assurance)</p> <p style="text-align: center;">EN 29003</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Operates an approved quality system for inspection and testing > Declares conformity with approved type, or with essential requirements > Affixes the CE marking <p>Notified Body</p> <ul style="list-style-type: none"> > Approves the QS > Carries out surveillance of the QS 	<p>F. (product verification)</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Declares conformity with approved type, or with essential requirements > Affixes the CE marking <p>Notified Body</p> <ul style="list-style-type: none"> > Verifies conformity with essential requirements > Issues certificate of conformity 	<p>Manufacturer</p> <ul style="list-style-type: none"> > Submits product > Declares conformity > Affixes the CE marking <p>Notified body</p> <ul style="list-style-type: none"> > Verifies conformity with essential requirements > Issues certificate of conformity

(1) Supplementary requirements which may be used in specific Directives

TABLE 2: CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION - (option 1)

D E S I G N	A. (Internal control of production) Manufacturer > Keeps technical documentation at the disposal of national authorities Aa. > Intervention of notified body	DESIGN MODULES		Q. (quality system) EN ISO 9001:2000 Manufacturer > operates an approved quality system > Declares conformity > Affixes the CE marking	G. (unit verification) Manufacturer > submits technical documentation
	B. (type examination) Manufacturer submits to notified body > technical documentation > type Notified Body > Ascertains conformity with essential requirements > Carries out tests, if necessary > Issues EC type-examination certificate	B1. (technical documentation) Manufacturer > Keeps technical documentation at the disposal of national authorities	B2. (design examination) Manufacturer submits to notified body > technical documentation Notified Body > Verifies conformity of design and issues EC design examination certificate	(see note 2)	Notified body > Carries out surveillance of the QS
A. Manufacturer > Declares conformity with essential requirements > Affixes the CE marking Aa. Notified body: > Tests on specific aspects of the product (1) > Products checks at random intervals (1)	C. (conformity to type)	F. (product verification)	I. INSPECTION (4)		
P R O D U C T I O N	A. Manufacturer > Declares conformity with essential requirements > Affixes the CE marking Aa. Notified body: > Tests on specific aspects of the product (1) > Products checks at random intervals (1)	C. (conformity to type) Manufacturer (3) > Declares conformity with approved type > Affixes the CE marking Notified body > Tests on specific aspects of the product (1) > Product checks at random intervals (1)	F. (product verification) Manufacturer > Declares conformity with approved type, or with essential requirements > Affixes the CE marking Notified Body > Verifies conformity > Issues certificate of conformity	Notified body > Carries out surveillance of the QS	Manufacturer > Submits product > Declares conformity > Affixes the CE marking Notified body > Verifies conformity with essential requirements > Issues certificate of conformity

(1) Supplementary requirements which may be used in specific Directives
 (2) The link is optional for the directives using the combination of a design module with Q
 (3) Module C is only to be used in combination with Module B
 (4) To be used only in combination with a design and production module

TABLE 3: CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION - (option 2)

D E S I G N	A. (Internal control of production)	DESIGN MODULES				H. (full quality)	G. (unit verification)
	<p>Manufacturer</p> <ul style="list-style-type: none"> > Keeps technical documentation at the disposal of national authorities <p>Aa.</p> <ul style="list-style-type: none"> > Intervention of notified body 	<p style="text-align: center;"><u>B. (type examination)</u></p> <p>Manufacturer submits to notified body</p> <ul style="list-style-type: none"> > technical documentation > type <p>Notified Body</p> <p>Ascertains conformity with essential requirements - carries out tests, if necessary - issues EC type examination cert.</p> <hr/> <p style="text-align: center;"><u>B1. (technical documentation)</u></p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Keeps technical documentation at the disposal of national authorities <hr/> <p style="text-align: center;"><u>B2. (design examination)</u></p> <p>Manufacturer submits to notified body</p> <ul style="list-style-type: none"> > technical documentation <p>Notified Body</p> <ul style="list-style-type: none"> > Verifies conformity of design and issues EC design examination certificate 				<p style="text-align: center;">EN ISO 9001:2000</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > operates an approved quality system for design <p>Notified Body</p> <ul style="list-style-type: none"> > carries out surveillance of the QS 	<p>Manufacturer</p> <ul style="list-style-type: none"> > submits technical documentation
P R O D U C T I O N	<p>A.</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Declares conformity with essential requirements > Affixes the CE marking <p>Aa.</p> <p>Notified body:</p> <ul style="list-style-type: none"> > Tests on specific aspects of the product (1) > Products checks at random intervals (1) 	<p>C. (conformity to type)</p> <hr/> <p style="text-align: center;">EN ISO 9001:2000</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Declares conformity with approved type > Affixes the CE marking <p>Notified Body</p> <ul style="list-style-type: none"> > Tests on specific aspects of the product (1) > Product checks at random intervals (1) 	<p>D. (production quality)</p> <hr/> <p style="text-align: center;">EN ISO 9001:2000</p> <p style="text-align: center;">excl. Clause 7.3</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Operates an approved quality system for production and testing > Declares conformity with approved type, or with essential requirements > Affixes the CE marking <p>Notified Body</p> <ul style="list-style-type: none"> > Approves the QS > Carries out surveillance of the QS 	<p>E. (product quality)</p> <hr/> <p style="text-align: center;">EN ISO 9001:2000 excl.</p> <p style="text-align: center;">Cl.7.1, 7.2.3,7.3 7.4,7.5.1/3</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Operates an approved quality system for inspection and testing > Declares conformity with approved type, or with essential requirements > Affixes the CE marking <p>Notified Body</p> <ul style="list-style-type: none"> > Approves the QS > Carries out surveillance of the QS 	<p>F. (product verification)</p> <p>Manufacturer</p> <ul style="list-style-type: none"> > Declares conformity with approved type, or with essential requirements > Affixes the CE marking <p>Notified Body</p> <ul style="list-style-type: none"> > Verifies conformity with essential requirements > Issues certificate of conformity 	<p>Manufacturer</p> <ul style="list-style-type: none"> > Operates an approved QS for production and testing > Declares conformity > Affixes the CE marking <p>Notified body</p> <ul style="list-style-type: none"> > Carries out surveillance of the QS 	<p>Manufacturer</p> <ul style="list-style-type: none"> > Submits product > Declares conformity > Affixes the CE marking <p>Notified body</p> <ul style="list-style-type: none"> > Verifies conformity with essential requirements > Issues certificate of conformity
	I. INSPECTION (3)						

(1) Supplementary requirements which may be used in specific Directives
(2) The link is optional for the directives using the combination of H with a design module
(3) To be used only in combination with a design and production module

ANNEX 3

ESSENTIAL REQUIREMENTS FOR DESIGNATING AUTHORITIES

1. *[Legal responsibility]* Where the designating authority is part of a larger governmental entity, the designating authority shall be identified in a way that no conflicts of interest with governmental conformity assessment bodies (CABs) occur. Where the designating authority delegates, subcontracts or otherwise entrusts the assessment, designation or monitoring of CABs, the delegated, subcontracted or otherwise entrusted body shall be a registered legal entity and shall have arrangements to cover liabilities arising from its activities.

2. *[Structure]* The designating authority shall be responsible for its decisions relating to the assessment and attestation of competence. The designating authority shall document the duties, responsibilities and authorities of personnel who could affect the quality of the assessment and attestation of competence. The designating authority shall identify the top management having overall authority and responsibility in particular for:

- a) the development of policies relating to the operation of the accreditation body;
- b) the supervision of the implementation of the policies and procedures;
- c) the decisions relating to the assessment and attestation of competence.

3. *[Impartiality]* The designating authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities. All designating authority personnel and committees, which could influence the assessment and attestation process, shall act objectively and be free from any undue pressures which could compromise impartiality. The designating authority shall ensure that each decision relating to the attestation of competence is taken by competent person(s) different from those who carried out the assessment. The designating authority shall not offer or provide any service that affects its impartiality.

4. *[Confidentiality]* The designating authority shall have adequate arrangements to safeguard the confidentiality of the information obtained. It shall not disclose confidential information about a particular CAB outside the designating authority without written consent of the CAB, except where the law requires such information to be disclosed without such consent.

5. *[Competence assessment activities]* The designating authority shall clearly describe its activities relating to competence assessment, referring to the relevant standards or other normative documents.

6. *[Management]* The designating authority shall establish, implement and maintain a management system. The management shall ensure effective communication of the needs of interested parties. The management shall also ensure that the policies are understood, implemented and maintained at all levels of the designating authority. The designating authority shall establish procedures to control all documents (internal and external) that relate to its competence assessment activities. The procedures shall define the controls needed.

7. *[Technical competence]* The designating authority shall have a sufficient number of competent personnel (internal or external) at its disposal that possess the education, training, technical knowledge, skills and experience necessary for handling the type, range and volume of work performed. The designating authority shall ensure that assessors and experts are familiar with the procedures, criteria and other relevant requirements for the assessment and attestation of competence and that they have undergone appropriate training and have thorough knowledge of the relevant assessment methods.

8. *[Monitoring]* The designating authority shall ensure the satisfactory performance of the assessment and the attestation decision-making process by establishing, implementing and maintaining procedures for monitoring the performance and competence of the personnel involved.

ANNEX 4

ESSENTIAL REQUIREMENTS FOR CONFORMITY ASSESSMENT BODIES

1. *[Independence]*

- a) The body providing third party conformity assessment services shall meet the following criterion:

The body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of these parties. They shall not become directly involved in the design, manufacture/construction, marketing, installation, use or maintenance of these products, nor represent the parties engaged in these activities. They shall not provide consultancy related to the conformity assessment activities for which they are notified and relating to products intended to be placed on the market and/or put into service in the EU. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body and the use of assessed products that are necessary for the operations of the body. The body shall ensure that activities of related bodies do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.

- b) The in-house inspection body which forms a separate and identifiable part of an organisation involved in the design, manufacture, supply, installation, use or maintenance of the products it assesses and has been established to supply conformity assessment services to its parent organisation shall meet the following criterion:

The body and its personnel must be organisationally identifiable and have reporting methods within the parent organisation which ensure and demonstrate its impartiality. They must not be responsible for the design, manufacture, supply, installation, operation or maintenance of the products which they assess, and must not engage in any activities that might conflict with their independence of judgment and integrity in relation to their assessment activities. The body shall supply its services exclusively to the organisation of which it forms a part.

2. *[Impartiality, integrity]* The conformity assessment body and its personnel must carry out the conformity assessment activities with the highest degree of professional integrity and requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially from persons or groups of persons with an interest in the results of these activities. The procedures under which the body operates shall be administered in a non-discriminatory manner.

3. *[Technical competence]* The conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to such a body by the respective provisions of the Directive and for which it has been designated, whether those tasks are

carried out by the body itself or on its behalf and under its responsibility. At all times and for each conformity assessment procedure and kind(s)/category of products for which it is designated, the body shall have at its disposal the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks. It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

The personnel responsible for carrying out the conformity assessment activities shall have:

- a) sound technical and vocational training covering all the conformity assessment activities of the relevant scope for which the body has been designated;
- b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out such operations;
- c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of the Directive and relevant implementing regulations;
- d) the ability required to draw up the certificates, records and reports to demonstrate that the assessments have been carried out.

The impartiality of the conformity assessment body, its top level management and assessment personnel shall be guaranteed. The remuneration of the body's top level management and assessment personnel shall not depend on the number of the assessments carried out or on the results of such assessments.

4. *[Subcontracting]* Where the conformity assessment body subcontracts specific tasks connected with the assessment of conformity, it shall first ensure and be able to demonstrate that the subcontractor meets the requirements of the Directive and, in particular, the essential requirements for its competence. This does not release the body from the responsibility for the proper performance of the subcontracted tasks. In particular, the body shall maintain its responsibility for the determination of conformity and shall have the necessary competence, or have access to a qualified and experienced person in cases involving specialised activities, to form an independent assessment of the results of these subcontracted tasks. Activities may be subcontracted only where agreed by the client. The body shall keep at the disposal of the national authorities the relevant documents concerning the assessment of the subcontractor's qualifications and the work carried out by the subcontractor under the Directive.

5. *[Liability insurance]* The conformity assessment body shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

6. *[Confidentiality]* The personnel of the conformity assessment body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks under the Directive or any provision of national law giving effect to it (except vis-à-vis the competent administrative authorities of the Member State in which its activities are carried out). Proprietary rights shall be protected.

7. *[Participation in co-ordination and standardisation activities]* The conformity assessment body shall participate in, or ensure that its assessment personnel is informed

of, the relevant standardisation activities and the activities of the notified body coordination group established under the Directive and apply as general guidance the administrative decisions and documents produced as a work result of that group.

ANNEX 5

RELATIONSHIPS BETWEEN EUROPEAN CO-OPERATION FOR ACCREDITATION AND THE EUROPEAN COMMISSION AND THE EFTA

1. General guidelines for the co-operation between European co-operation for Accreditation (EA) and the European Commission and the EFTA

With the aim of maintaining and promoting overall confidence in the European accreditation system, and in order to ensure that co-operation and activities within EA can operate in compliance with, and in support of, Community policies and legislation, in particular with regard to the single market, EA and its member bodies shall apply the following principles for co-operation.

EA and its member bodies shall:

- ensure that they maintain and continue to develop the MLA and its various parts in order to ensure a common accreditation practice and a consistent and credible application of the EN 45000/17000 series of standards throughout Europe. In particular, where member bodies operate accreditation in support of the implementation of Community legislation, it shall be ensured that the peer evaluation system conveys assurance that the MLA signatory accreditation body has the necessary technical expertise and capabilities to assess, attest and regularly monitor the technical competence of conformity assessment bodies as required by the specific scope of conformity assessment foreseen in the relevant Community legislative instrument. The operation of an accreditation scope in the harmonised regulatory sphere shall be properly reflected in the scope of the MLA signatory status. Peer evaluation between the members of EA shall be operated in such a way that the results may be made public and can be justified 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 foreseen;
- be responsive towards the Commission and the Member States' national authorities with regard to activities related to Community competencies;
- ensure proper monitoring of their accredited bodies. Where this is related to bodies operating in support of the implementation of Community legislation, necessary co-ordination with the public authorities shall be ensured;
- take due account of advice and guidance offered by the Commission, after consultation with the Member States, on policy matters related to accreditation;
- ensure openness, transparency and competence in the operation of their procedures. In particular, the elaboration of guidance documents shall be open to all interested parties in order to ensure acceptance and adherence. This also involves ensuring regular information of the public authorities and CABs. Coherence with the international level (ILAC, IAF) shall be ensured, wherever appropriate;
- acknowledge their responsibility towards a broad range of interests involved, including industry, labour, consumers, environmental interests and public authorities,

and establish and maintain an appropriate mechanism for them to make their views known, so as to ensure that they do not act on the basis of vested interests;

- ensure that they continue to have the confidence of the conformity assessment market and that the co-operation between EA and the EU/EFTA maintains the capacity of EA to satisfy the requirements of both the free market and legislation;
- aim at ensuring overall coherence of the European accreditation system through harmonisation, peer evaluation, support to candidates and other suitable activities;
- ensure that they respond readily and appropriately to differing market needs in different sectors, with due respect of the fundamental principles of European accreditation in support of Community legislation and policies;
- be committed to the delivery of efficient and high quality accreditation that brings added value to the entire conformity assessment market. In particular, EA and its member bodies shall develop and implement appropriate strategies and procedures designed to allow for continuous improvement in terms of both efficiency and competence. Peer evaluation shall also serve as a benchmarking tool in order to identify potential for, and stimulate, further improvement;
- endeavour to support the development of the quality infrastructures of candidate countries for EU membership;
- inform the Commission about policies and activities under development that are of mutual interest.

2. Framework partnership agreements between European co-operation for Accreditation (EA) and the European Commission and the EFTA

The Commission

- shall consult and cooperate with EA and involve EA on technical matters related
 - to the implementation and operation of Community legislation and policy in the field of conformity assessment, including with regard to third countries;
 - to accreditation, in particular in view of promoting a harmonised, consistent and credible application of the EN 45000/17000 series of standards in relation to Community policy and legislation (e.g. in relation to the notified bodies system under the New Approach Directives), and in view of international work on accreditation, whether in international fora such as ILAC and IAF or in ISO and IEC;
- may call upon EA and its expertise in developing specific arrangements to support Community initiatives;
- shall, where appropriate and after consultation of the national authorities, draw up mandates for EA to contribute to the accreditation aspects of EU policy instruments;
- shall ensure the possibility of effective contribution of EA to different sectoral working groups responsible for the development and implementation of directives on issues relating to accreditation as well as in the meetings of the various notified bodies' co-operation groups under sectoral Directives when issues relating to the transparency and the performance of conformity assessment are in question.

- may ask EA to answer technical requests from the Commission or provide necessary expertise on an ad hoc basis, on issues relating to disputes on accreditation and notification decisions, including in the case of such issues being raised in the context of safeguard clause cases.

The Commission will also examine to what extent it can have recourse to EA services in its international discussions with third countries or international organisations as well as in the implementation of third country trade agreements, when issues relating to the quality and competence of CABs are in question.

ANNEX 6

GENERAL REQUIREMENTS FOR RAPEX IMPLEMENTATION AND NOTIFICATIONS

1. RAPEX covers products that pose a serious risk to the health and safety either to consumers or to users when they are intended for professional use only.
2. RAPEX is essentially aimed at a rapid exchange of information in the event of a serious risk. The guidelines referred to in point 8 hereafter define specific criteria for identifying serious risks.
3. Member States notifying a non-compliance of a product that poses a serious risk shall provide all available details. In particular, the notification shall contain the information stipulated in the guidelines referred to in point 8 and at least:
 - (a) information enabling the product to be identified;
 - (b) a description of the risk involved, including a summary of the results of any tests/analysis and of their conclusions which are relevant to assessing the level of risk;
 - (c) the nature and the duration of the measures or action taken or decided on, if applicable;
 - (d) information on supply chains and distribution of the product, in particular on destination countries.

Such information must be transmitted using the special standard notification form and by the means stipulated in the guidelines referred to in point 8.

When the measure notified seeks to limit the free circulation or use of a dangerous or chemical substance or preparation, the Member States shall provide the relevant data relating to these substances or preparations considered and the anticipated effects of the measure on consumer/user health and safety together with the assessment of the risk in conformity with the EU legislation. The guidelines referred to in point 8 shall define the details and procedures for the information requested in that respect.

4. When a Member State has informed the Commission of a serious risk before deciding to adopt measures, it must inform the Commission within 45 days whether it confirms or modifies this information.
5. The Commission shall, in the shortest time possible, verify the conformity with the provisions of the related Directives of the information received and, *in case no other Member State disagrees, the national decision stands. Also if the manufacturer does not disagree with the non-conformity, de facto, the measure taken will be presumed justified. Should the Commission consider that the decision is contrary to the EU legislation it could discuss with the Member State and if there is no agreement have recourse to the infringement procedure (Article 226 of the Treaty).*

In the case of such an investigation, Member States shall supply the Commission with the requested information to the best of their ability.

6. Upon receipt of a notification the Member States are requested to inform the Commission, at the latest within the set period of time stipulated in the guidelines

referred to in point 8, of any appropriate information in order to evaluate the non conformity.

7. Member States shall immediately inform the Commission of any modification or lifting of the measure(s) or action(s) in question.

8. The Commission shall prepare and regularly update guidelines concerning the management of RAPEX by the Commission and the Member States.

9. The Commission may inform the national contact points concerned about products posing serious risks, imported into or exported from the Community and the European Economic Area.

10. Responsibility for the information provided lies with the notifying Member State.

11. The Commission shall ensure the proper functioning of the system, in particular classifying and indexing notifications according to the degree of urgency. Detailed procedures shall be laid down by the guidelines referred to in point 8.

ANNEX 7 (draft)

**GENERAL OBJECTIVES AND TASKS OF THE ADMINISTRATIVE
COOPERATION GROUPS (AdCo) AND THE INTER SECTORAL AdCo GROUP**

To be completed