COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a common framework for the marketing of products

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- Grounds for and objectives of the proposal

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

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

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

– a certain lack of trust in conformity marking.

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

The proposals, following the Council's Resolution of 10 November 2003, have the objective to provide a common framework for the existing infrastructures for accreditation for the control of conformity assessment bodies, and market surveillance for the control of products and economic operators, by reinforcing and extending what exists and not weakening existing instruments such as the General Product Safety Directive which is very successful and effective. Secondly they set out agreed references for the organisation of the revision of existing product related Community harmonisation legislation, where necessary and for the development of future product related legislation.

- General context

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

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

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

- Existing provisions in the area of the proposal

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

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

- Consistency with the other policies and objectives of the Union

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

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- Consultation of interested parties

Consultation methods, main sectors targeted and general profile of respondents

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

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

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

Summary of responses and how they have been taken into account

The contributions received confirm that the proposals should build on what exists as opposed to creating a new system. Thus the existing accreditation system requires a legal base as opposed to being replaced by another system. They reaffirm it as a public authority activity and that, as such, should be free of commercial competition. The conformity assessment body system requires stricter selection criteria and harmonised national selection processes. Support was given to the harmonised definitions and the obligations set out for the economic operators. It was confirmed that a systematic requirement for authorised representatives did not solve the problem of traceability. Practically all contributions supported a Community market surveillance system with information and cooperation system between national authorities in

extension to the mechanisms of the GPSD and without creating new tools. The option of abandoning the CE marking was contested and clarifying its meaning and protecting it legally were supported.

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

- Collection and use of expertise

Scientific/expertise domains concerned

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

Methodology used

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

Main organisations/experts consulted

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

Summary of advice received and used

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

Means used to make the expert advice publicly available

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

- Impact assessment

Basically there are three general options:

(1) The first option consists in keeping the current situation unchanged. Products covered by Community harmonisation legislation would be marketed under the conditions created by the existing legal framework and the non-legislative measures currently in place.

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

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

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

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

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

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

3. LEGAL ELEMENTS OF THE PROPOSAL

- Summary of the proposed action

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

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

The regulation:

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

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

The decision:

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

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

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

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

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

- Legal basis

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

- Subsidiarity principle

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

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

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

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

- Proportionality principle

The present proposals are in most cases built on existing practices, procedures and infrastructures and constitute more their consolidation and extension than the creation of new measures and infrastructures. In the field of accreditation the proposals confirm the existing system giving it a Community legal basis and framework. In the field of market surveillance,

the objective of the proposals is to coordinate the effective functioning of subsidiarity activities and responsibilities by the national authorities. The information tools will be geared to extending existing tools (such as RAPEX) as opposed to creating new ones. The contents of the sui generis decision, by definition, do not create in themselves any measures which impound on national powers and responsibilities. The implementation of these measures in future sectoral EU legislation will also be based on the techniques used today in the field of the elimination of technical barriers to trade, i.e. based very much on national implementation and intervention as opposed to Commission action. Community intervention is reduced to coordination, cooperation and information in most cases. Where the Community intervenes is in cases of safeguard clauses where only the Community can take decisions. The objective of these proposals is to reinforce the operation of Community legislation in the field and to avoid as much as possible the need for further Community intervention.

- Choice of instruments

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

4. BUDGETARY IMPLICATION

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

5. ADDITIONAL INFORMATION

- Simplification

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

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

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

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

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

- Repeal of existing legislation

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

- European Economic Area

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

2007/0030 (COD)

Proposal for a

DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a common framework for the marketing of products

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

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

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

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

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

Whereas:

(1) On 7 May 2003 the Commission issued a Communication to the Council and the European Parliament on "Enhancing the Implementation of the New Approach Directives". The Council acknowledged in its Resolution of 10 November 2003 the importance of the New Approach as an appropriate and efficient regulatory model, allowing technological innovation and enhancing competitiveness of European industry and confirmed the necessity to extend the application of its principles to new areas, at the same time recognising the need for a clearer framework for conformity assessment, accreditation and market surveillance.

(2) This Decision provides common principles and reference provisions intended to apply across sectoral legislation in order to provide a coherent basis for revision or recasts of that legislation. This Decision therefore constitutes a general framework of a horizontal nature for future legislation harmonising the conditions for the marketing of products and a reference text for existing such legislation. However, the specificities of sectoral needs may provide grounds for having recourse to other regulatory solutions.

(3) This Decision provides, in the form of reference provisions, definitions and general obligations for economic operators and a range of conformity assessment procedures

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1 OJ C , , p. .
2 OJ C , , p. .
3 OJ C , , p. .
4 OJ C , , p. .

from which the legislator can select as appropriate. It also lays down rules for the CE marking. Furthermore, reference provisions are provided as regards the requirements for conformity assessment bodies to be notified to the Commission as being competent to carry out the relevant conformity assessment procedures and the notification procedures. In addition, this Decision includes reference provisions concerning procedures dealing with products presenting a risk in order to ensure the safety of the market place.

(4) Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[5] and Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules[6], Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products[7], Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[8], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[9], Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC[10], and Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[11], Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[12] already lay down a common and uniform regime on matters covered by this Decision and should therefore not be subject to this Decision.

(5) Specific product legislation should, wherever possible, avoid going into technical detail but should limit itself to the expression of the essential requirements. Such legislation should, where appropriate, have recourse to harmonised standards adopted pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations[13] for the purpose of expressing detailed technical

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

6 OJ L 165, 30.4.2004; corrected version in OJ L 191, 28.5.2004, p. 1.

7 OJ L 194, 18:07:2001; p. 26.

8 OJ L 311, 28.11.2001, p. 1.

9 OJ L 311, 28.11.2001, p. 67.

10 OJ L 033, 8.2.2003, p. 30.

11 OJ.L.102, 7.4.2004, p.48.

12 OJ L 136, 30.4.2004, p. 1.

13 OJ L 204, 21.7.1998, p. 37. Directive as last amended by the 2003 Act of Accession.

specifications. In that way, this Decision builds on and complements the standardisation system provided for by that Directive. However, where safety, clarity and practicability so require, detailed technical specifications may be set out in the legislation concerned.

(6) The presumption of conformity to a legal provision, conferred by the conformity to a harmonised standard, should enhance recourse to compliance with those harmonised standards.

(7) It should be possible for Member States or the Commission to object in cases in which a harmonised standard does not entirely satisfy the requirements in Community harmonisation legislation. The Commission should have the possibility of deciding not to publish such a standard.

(8) Essential requirements should be worded precisely enough in order to create legally binding obligations. They should be formulated so as to enable the assessment of conformity with those requirements even in the absence of harmonised standards or in a case in which the manufacturer chooses not to apply the latter. The degree of detail of the wording will depend on the characteristics of each sector.

(9) The successful accomplishment of the required conformity assessment procedure enables economic operators to demonstrate and the competent authorities to ensure that products made available on the market conform to the applicable requirements.

(10) The modules for the conformity assessment procedures to be used in the technical harmonisation legislation were initially set out in Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives[14]. This Decision replaces that Decision.

(11) It is necessary to offer a choice of clear, transparent and coherent conformity assessment procedures, restricting the possible variants. This Decision provides for a menu of modules, enabling the legislator to choose from the least to the most stringent procedure, proportionate to the level of risk involved and the level of safety required.

(12) For the purposes of ensuring inter-sectoral coherence and to avoid ad-hoc variants, it is desirable that the procedures which are to be used in sectoral legislation are chosen from among the modules listed in accordance with the general criteria set out.

(13) In the past, legislation on the free movement of goods has used a set of terms, partly without defining them, therefore, necessitating guidelines for explanation and interpretation. Where legal definitions have been introduced they differ to some extent in their wording and sometimes in their meaning, which gives rise to difficulties in their interpretation and correct implementation. This Decision therefore introduces clear definitions of certain fundamental concepts.

(14) All economic operators intervening in the supply and distribution chain should take the appropriate measures to ensure that they make available on the market only

[14] OJ L 220, 30.8.1993, p. 23.

products which are in conformity with the applicable legislation. This Decision provides a clear and proportionate distribution of obligations which correspond to the respective role of each operator in the supply and distribution process.

(15) As certain tasks can only be executed by the manufacturer, it is necessary to clearly distinguish between the manufacturer and the operators further down the distribution chain. It is furthermore necessary to clearly distinguish the importer and the distributor, as the importer introduces products from third countries on the Community market. He has thus to ensure that these products comply with the applicable Community requirements.

(16) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure. Importers and distributors perform a trading function and do not have any influence on the production process. The conformity assessment should therefore remain the obligation of the manufacturer alone.

(17) Since importers and distributors are downstream operators they cannot in the normal course of events be obliged to ensure themselves that the design and production of the product is in compliance with the applicable requirements. Their obligations in relation to the compliance of the product should be limited to certain control measures to ascertain whether the manufacturer has fulfilled his obligations, such as verifying whether the product bears the required conformity marking and whether the required documents have been supplied. However, it can be expected of both importers and distributors to act with due care in relation to the applicable requirements when placing or making available products on the market.

(18) Where an importer or a distributor either places a product on the market under his own name or trademark or modifies a product in such a way that compliance with applicable requirements may be affected, he should be considered to be the manufacturer.

(19) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by national authorities, and should be prepared to participate actively, providing the competent authorities with all necessary information relating to the product concerned.

(20) Ensuring traceability of a product throughout the whole supply chain contributes to rendering market surveillance simpler and more efficient. An efficient traceability system facilitates the task of market surveillance authorities to trace the economic operator responsible for supplying non-compliant products.

(21) The CE marking, materialising conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the use of the CE marking, and rules as to its affixing, to be applied in Community harmonisation legislation providing for the use of that marking should therefore be set out in this Decision.

(22) It is crucial to make clear to both manufacturers and users that by affixing the CE marking to the product the manufacturer declares that the product is in conformity with all applicable requirements and that he takes full responsibility therefor.

(23) The legal protection of the CE marking which is granted by its registration as a Community collective mark allows public authorities to ensure proper enforcement and to legally pursue violations.

(24) In certain circumstances the conformity assessment procedures prescribed by the applicable legislation require the intervention of conformity assessment bodies, which are notified by the Member States to the Commission.

(25) Experience has shown that the criteria set out in sectoral Directives which conformity assessment bodies have to fulfil to be notified to the Commission are not sufficient to ensure a uniformly high level of performance of notified bodies throughout the Community. It is, however, essential that all notified bodies perform their functions to the same level and under conditions of fair competition. This requires the setting of obligatory requirements for the conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(26) In order to ensure a coherent level of quality in the performance of conformity assessment it is not only necessary to consolidate the requirements that conformity assessment bodies wishing to be notified have to fulfil, but also, in parallel, to set requirements that notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies have to fulfil.

(27) The system set out in this Decision is complemented by the accreditation system as foreseen in Regulation [….] of the European Parliament and the Council of … setting out the requirements for accreditation and market surveillance relating to the marketing of products. Since accreditation is an essential means of verifying the competence of conformity assessment bodies its use should also be encouraged for the purposes of notification.

(28) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the products to be placed on the Community market, it is essential that for the performance of the conformity assessment tasks subcontractors and subsidiaries meet the same requirements as notified bodies. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified and the monitoring of bodies already notified cover also the activities carried out by subcontractors and subsidiaries.

(29) It is necessary to increase the efficiency and transparency of the notification procedure and, in particular, to adapt it to new technologies so as to enable on-line notification.

(30) Since notified bodies may offer their services throughout the territory of the Community, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning the body notified. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(31) For the purposes of competitiveness it is crucial that notified bodies apply the modules without unnecessary burden for the economic operators. For the same reason and to ensure equal treatment of economic operators, consistency in the technical application

of the modules has to be ensured. This can best be achieved through appropriate coordination and co-operation between notified bodies.

(32) To ensure the proper functioning of the certification process, certain procedures, such as exchange of experience and exchange of information as between notified bodies and notifying authorities and as between notified bodies, should be consolidated.

(33) Community harmonisation legislation already provides for a safeguard procedure which intervenes only in a case of disagreement between the Member States as to measures taken by a Member State. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard clause procedure, with the aim of making it more efficient and of drawing on expertise available in Member States.

(34) The existing system should be complemented by a procedure allowing interested parties to be informed of measures intended with regard to products presenting a risk for the health and safety of persons or for other issues of public interest protection. It also allows market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such products.

(35) In a case in which Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required,

HAVE DECIDED AS FOLLOWS:

Title I

General principles for the drawing up of Community legislation laying down the conditions for the marketing of products

Article 1

Subject matter and scope

This Decision sets out the common principles determining the content of Community legislation harmonising the conditions for the marketing of products, hereinafter "Community legislation", with the exception of the following legislation:

(a) food law as defined in Article 2 of Regulation (EC) No 178/2002;

(b) feed law as defined in Article 2 of Regulation (EC) No 882/2004;

(c) Directive 2001/37/EC;

(d) Directive 2001/82/EC;

(e) Directive 2001/83/EC;

(f) Directive 2002/98/EC;

(g) Directive 2004/23/EC;

(h) Regulation (EC) No 726/2004.

For the purposes of this Decision "product" shall mean any substance, preparation or transformed product.

Community legislation shall have recourse to the general principles of Title I and to the relevant reference provisions of Title II and of Annexes I and II, while, where necessary, taking into account the specificities of the legislation concerned.

Article 2

Level of protection of public interests

1. As regards the protection of public interest, Community legislation shall restrict itself to setting out the essential requirements determining the level of such protection and shall express those requirements in terms of the results to be achieved.

   Where recourse to essential requirements is not possible or not appropriate, detailed specifications may be set out in the Community legislation concerned.

2. Where Community legislation sets out essential requirements, it shall provide for recourse to be had to harmonised standards, adopted in accordance with Directive 98/34/EC, which shall express such requirements in technical terms and which shall, alone or in conjunction with other harmonised standards, provide presumption of conformity with such requirements.

Article 3

Conformity assessment procedures

1. Where Community legislation requires conformity assessment to be performed in respect of a particular product, the procedures which are to be used shall be chosen from among the modules set out and specified in Annex I, in accordance with the following criteria:

   (a) whether the module concerned is appropriate to the type of product;

   (b) the nature of the risks entailed by the product and the extent to which such risks can be managed by conformity assessment;

   (c) the need for the manufacturer to have a choice between quality assurance and product certification modules as set out in the Annex;

   (d) the need to avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned.

2. Where a product is subject to several Community acts within the scope of this Decision, coherence in the conformity assessment procedures shall be ensured.

3. The modules referred to in paragraph 1 shall be applied as appropriate in respect of the product concerned and in accordance with the instructions set out in those modules.

Article 4

EC Declaration of conformity

Where Community legislation requires a statement by the manufacturer that fulfilment of requirements relating to a product has been demonstrated, hereinafter "EC declaration of conformity", the legislation shall provide that the declaration is to contain all relevant information to identify the Community legislation to which it relates, and where a product is subject to requirements set out in several Community acts, it shall provide that a declaration is drawn up in respect of all those acts, mentioning the publication references of the acts concerned.

Article 5

Conformity assessment

1. Where Community legislation requires there to be conformity assessment, it may provide for such assessment to be carried out by public authorities, by manufacturers or by conformity assessment bodies.

2. Where Community legislation provides for conformity assessment to be carried out by public authorities, the legislation shall provide that the conformity assessment bodies on which these authorities rely for technical assessments are to comply with the same criteria as those set out in this Decision for notified bodies.

Title II

Reference provisions for Community legislation laying down the conditions for the marketing of products

Chapter 1
Definitions

Article 6

Definitions

For the purposes of this … [type of instrument] the following definitions shall apply:

(1) "making available on the market" means any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

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

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

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

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

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

(7) "technical specification", "national standard", "international standard" and "European standard" shall have the meanings assigned to them by Directive 98/34/EC;

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

(9) "accreditation" has the meaning assigned to it by Regulation (EC) No […];

(10) "withdrawal" means any measure aimed at preventing the making available on the market of a product in the supply chain;

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

Chapter 2
Obligations of Economic Operators

Article 7

Obligations of manufacturers

1. Manufacturers shall ensure that their products are designed and manufactured in accordance with the requirements set out in … [reference to the relevant part of the legislation].

2. Manufacturers shall draw up the required technical documentation and carry out or have carried out the applicable conformity assessment procedure.

   Where the compliance of the product with the applicable requirements has been demonstrated by such procedure, manufacturers shall draw up an EC declaration of conformity and affix the conformity marking.

3. Manufacturers shall keep the technical documentation and the EC declaration of conformity for a period of ….[to be specified] after the product has been placed on the market.

4. Manufacturers shall ensure that procedures are in place to ensure the continued conformity of series production. Changes in the product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of a product is stated shall be adequately taken into account.

   Manufacturers shall, in all cases where appropriate, carry out sample testing of marketed products, investigating, and, if necessary, keeping a register of complaints, and keeping distributors informed of such monitoring.

5. Manufacturers shall ensure that their products bear a type, batch or serial number or any other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

6. Manufacturers shall indicate their name and the address at which they can be contacted on the product or, where the size or nature of the product does not allow it, on its packaging or in a document accompanying the product.

7. Manufacturers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the applicable Community legislation shall take the necessary corrective measures to bring that product into conformity or withdraw it from the market and recall it from end users, if appropriate. They shall immediately inform the national authorities of the Member States where they made the product available to this effect, giving details, in particular, of the non-compliance and of the corrective measures taken.

8. Manufacturers shall, on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the product. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by products which they have placed on the market.

Article 8

Authorised representatives

1. Manufacturers may appoint, by a written mandate, any natural or legal person established within the Community, ("the authorised representative"), to act on their behalf for specified tasks with regard to the obligations of manufacturers under this … [act].

   The obligations under Article [7(1)] and the drawing up of technical documentation may not form part of the authorised representative's mandate.

2. Where a manufacturer has appointed an authorised representative, the latter shall at least do the following:

(a) keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities for a period of … [to be specified];

(b) on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the product.

(c) cooperate with the competent authorities, at the request of the latter, on any action to avoid the risks posed by products covered by their mandate.

Article 9

Obligations of importers

1. When placing a product on the market importers shall act with due care in relation to the applicable requirements.

2. Before placing a product on the market importers shall verify that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall verify that the manufacturer has drawn up the technical documentation, that the product bears the required conformity marking(s), is accompanied by the required documents and that the manufacturer has respected the requirements set out in Article [7(5) and (6)].

   Where an importer discovers that the product is not in conformity with … [reference to the relevant part of the legislation], he may place the product on the market only after it has been brought into conformity with the applicable requirements set out in ... [reference to the relevant part of the legislation]

3. Importers shall indicate their name and the address at which they can be contacted on the product or, where the size or nature of the product does not allow it, on its packaging or in a document accompanying the product.

4. Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in … [reference to the relevant part of the legislation].

5. Importers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the applicable Community legislation shall take the necessary corrective measures to bring that product into conformity or withdraw it from the market and recall it from end users, if appropriate. They shall immediately inform the national authorities of the Member States where they made the product available to this effect, giving details, in particular, of the non-compliance and of the corrective measures taken.

6. Importers shall, for a period of … [to be specified], keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

7. Importers shall, on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the product. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by products which they have placed on the market.

Article 10

Obligations of distributors

1. When making a product available on the market distributors shall act with due care in relation to the applicable requirements.

2. Before making a product available on the market distributors shall verify that the product bears the required conformity marking(s) and is accompanied by the required documents and that the manufacturer and the importer have respected the requirements set out in Article [7 (5) and (6)] and [Article 9 (3)].

   Where a distributor discovers that a product is not in conformity with …[reference to the relevant part of the legislation], he may make the product available on the market only after it has been brought into conformity with the applicable requirements set out in …[reference to the relevant part of the legislation]. The distributor shall inform the manufacturer or the importer to this effect.

3. A distributor shall ensure that, while a product is under his responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in ... [reference to the relevant part of the legislation].

4. Distributors who consider or have reason to believe that a product which they have made available on the market is not in conformity with the applicable Community legislation shall take the necessary corrective measures to bring that product in conformity or withdraw it from the market and recall it from end users, if appropriate. They shall immediately inform the national authorities of the Member States where they made the product available to this effect, giving details, in particular, of the non-compliance and of the corrective measures taken.

5. Distributors shall, on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the product. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by products which they have made available on the market.

Article 11

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor who places a product on the market under his name or trademark shall be subject to the obligations of the manufacturer under Article [7].

An importer or a distributor, who modifies a product in such a way that compliance with the applicable requirements may be affected, shall be subject to the obligations of the manufacturer under Article [7] in respect of these modifications.

Article 12

Identification of economic operators

Economic operators shall be able to identify the following:

(a) any economic operator who has supplied them with a product;

(b) any economic operator to whom they have supplied a product.

To this end they shall have in place appropriate systems and procedures which allow for this information to be made available to the market surveillance authorities on request, for a period of … [to be specified].

Chapter 3
Conformity of the product

Article 13

Presumption of conformity

Products which are in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in … [reference to the relevant part of the legislation].

Article 14

Formal objection against harmonised standards

1. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in … [reference to the relevant part of the legislation], the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, hereinafter the "Committee", giving its arguments. The Committee shall deliver its opinion without delay.

2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union.

3. The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

Article 15

EC declaration of conformity

1. The EC declaration of conformity shall state that the fulfilment of requirements specified in … [reference to relevant part of the legislation] has been demonstrated.

2. The EC declaration of conformity shall as a minimum contain the elements specified in [the relevant modules set out in Annex I] and in this … [reference to the relevant part of the legislation] and shall continuously be updated. The EC declaration of conformity shall have the model structure set out in [Annex II].

3. By drawing up the EC declaration of conformity, the manufacturer shall assume the responsibility for the compliance of the product.

Article 16

General principles of the CE marking

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

   By affixing or having affixed the CE marking the manufacturer shall assume the responsibility for the conformity of the product with the requirements laid down in this … [act].

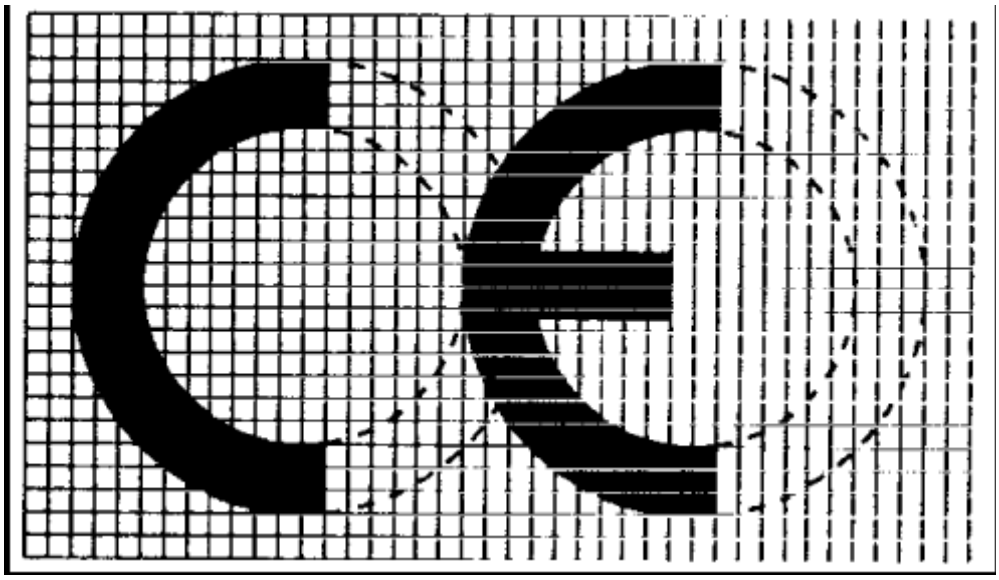
2. The CE marking shall be the only marking which attests conformity of the product with the applicable requirements. Member States shall refrain from introducing into their national regulations or shall withdraw any reference to a conformity marking other than the CE marking in connection with conformity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

3. The affixing on a product of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both, is prohibited. Any other marking may be affixed to the product provided that the visibility, legibility and meaning of the CE marking are not thereby impaired.

Article 17

Rules and conditions for the affixing of the CE marking

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



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

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

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

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

6. The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control phase.

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

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

Chapter 4
Notification of conformity assessment bodies

Article 18

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this … [act].

Article 19

Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article [24].

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by their national accreditation bodies within the meaning of and in accordance with Regulation (EC) No […].

3. Where the notifying authority delegates, subcontracts or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, the delegated, subcontracted or otherwise entrusted body shall be a legal entity and shall have arrangements to cover liabilities arising from its activities.

Article 20

Requirements relating to notifying authorities

1. The notifying authority shall meet the requirements set out in paragraphs 2 to 7.

2. The notifying authority shall be established in such a way that no conflicts of interest with conformity assessment bodies occur.

3. The notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

4. The notifying authority shall be organised in such a way that each decision relating to notification of the conformity assessment body is taken by competent persons different from those who carried out the assessment.

5. The notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy.

6. The notifying authority shall have adequate arrangements to safeguard the confidentiality of the information obtained.

7. The notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 21

Information obligation for the notifying authorities

Member States shall inform the Commission and the other Member States of their national procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes to that information.

The Commission shall make that information publicly available.

Article 22

Requirements for notified bodies

1. For the purposes of notification, a conformity assessment body shall meet the requirements set out in paragraphs 2 to 11 of this Article.

2. The conformity assessment body shall be established under national law and have legal personality.

3. The conformity assessment body shall be a third-party body independent from the organisation or the product it assesses.

4. The conformity assessment 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 those parties.

   Nor shall they become directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, nor represent the parties engaged in those 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 Community market. This shall not preclude the possibility of exchanges of technical information between the manufacturer and the conformity assessment body and the use of assessed products that are necessary for the operations of the conformity assessment body.

   The conformity assessment body shall ensure that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.

5. The conformity assessment body and its personnel shall 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 those activities.

6. The conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to such a body by the provisions of … [reference to relevant part of the legislation] and for which it has been notified, whether those

tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and for each kind or category of products for which it is notified, the conformity assessment 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.

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

   (a) sound technical and vocational training covering all the conformity assessment activities of the relevant scope for which the conformity assessment body has been notified;

   (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 relevant Community legislation 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.

8. The impartiality of the conformity assessment body, its top level management and assessment personnel shall be guaranteed.

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

9. 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.

10. 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 … [reference to the relevant part of the legislation] or any provision of national law giving effect to it, except in relation to the competent administrative authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. 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 co-ordination group established under the relevant Community

legislation and apply as general guidance the administrative decisions and documents produced as a work result of that group.

Article 23

Presumption of conformity

Where a conformity assessment body can demonstrate its conformity with the criteria laid down in the harmonised standards, the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in Article [22].

Article 24

Subsidiaries and subcontracting of notified bodies

1. Where the conformity assessment body subcontracts specific tasks connected with the assessment of conformity or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article [22].

2. The conformity assessment body shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. The conformity assessment body shall keep at the disposal of the national authorities the relevant documents concerning the assessment of the subcontractor's or subsidiary's qualifications and the work carried out by the subcontractor or the subsidiary under … [reference to the relevant part of the legislation].

Article 25

Accredited in-house bodies

1. For the purpose of conformity assessment procedures set out in [Annex 1 – modules A1, A2, C1 or C2], an accredited in-house body, which forms a separate and identifiable part of an undertaking involved in the design, manufacture, supply, installation, use or maintenance of the products that it assesses and which has been established to supply conformity assessment services to the undertaking of which it forms a part, may be used.

2. The in-house body shall meet the following criteria:

   (a) it shall be accredited in accordance with Regulation (EC) No […].;

   (b) the body and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which it forms a

part, which ensure its impartiality and demonstrate it to the relevant national accreditation body;

(c) the body and its personnel 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;

(d) the body shall supply its services exclusively to the undertaking of which it forms a part.

3. Accredited in-house bodies shall not be notified to the Member States or the Commission, but information about their accreditation shall be provided to the notifying authority, on request.

Article 26

Application for notification

1. A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2. The application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which the body claims to be competent, as well as by an accreditation certificate, where it exists, delivered by a national accreditation body within the meaning of Regulation (EC) No […],attesting that the conformity assessment body meets the requirements laid down in Article ...[22].

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article ...[22].

Article 27

Notification procedure

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article ...[22].

2. They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and product or products concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate referred to in Article ...[26(2)], the notifying authority shall provide the Commission and the other Member States with all documentary evidence necessary for the verification of the conformity assessment body's competence.

5. The body concerned may perform the activities of a notified body only where no objections have been raised by the Commission and the other Member States within two months following that notification.

   Only such a body shall be considered as a notified body for the purpose of this … [act].

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 28

Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to a notified body.

   It shall assign a single such number even where the body is notified under several Community acts.

2. The Commission shall make publicly available the list of the bodies notified under this … [act] , including the identification numbers that have been allocated to them and the activities for which they have been notified.

   The Commission shall ensure that this list is kept up to date.

Article 29

Changes to the notification

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements referred to in Article ...[22], or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification as appropriate. It shall immediately inform the Commission and the other Member States thereof.

2. In the case of withdrawal, restriction or suspension of notification or where the notified body has ceased activity, the notifying Member State concerned shall take the appropriate steps to ensure that the files are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities on request.

Article 30

Challenge of the competence of notified bodies

1. The Commission shall investigate all cases where it doubts or doubt is brought to its attention as to the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities placed on it.

2. The notifying Member State shall provide the Commission, on request, with all information related to the basis for notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet, or no longer meets, the requirements for its notification, it shall inform the notifying Member State thereof and request it to take the necessary corrective measures, including de-notification, if necessary.

Article 31

Operational obligations for notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in …[the relevant part of the legislation].

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burden for economic operators, in particular taking into consideration the size of companies and the relative complexity of the technology used by the products.

3. Where a notified body finds that requirements laid down in … [the relevant part of the legislation] or corresponding harmonised standards or technical specifications have not been met by the manufacturer, it shall require the manufacturer to take appropriate corrective measures and it shall not deliver any conformity certificate.

4. Where, in the course of the monitoring of conformity following the delivery of certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw its certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article 32

Information obligation for notified bodies

1. Notified bodies shall inform the notifying authority of the following:

(a) any refusal, restriction, suspension or withdrawal of certificates;

(b) any circumstances affecting the scope of and conditions for notification;

(c) any request for information which they have received from market surveillance authorities;

(d) on request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this … [act] carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 33

Exchange of experience

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

Article 34

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under … [the relevant act or other Community legislation] is put into place and properly operated in the form of (a) … [sectoral or cross sectoral] group(s) of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that (those) group(s).

Chapter 5
Safeguard procedures

Article 35

Procedure to deal with products presenting a risk at national level

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 18 of Regulation (EC) No …[] or where they have sufficient reason to believe that a product covered by … this [act] presents a risk for the health or safety of persons or for other issues of public interest protection covered by … this [act], they shall, together with the relevant economic operators, perform an evaluation in relation to the product concerned covering all the requirements laid down by this ..[act].

Where, in the course of that evaluation, the market surveillance authorities find that the product does not comply with the requirements laid down by this … [act], they shall require the relevant economic operator to take all appropriate corrective actions to bring the product into compliance with those requirements or to withdraw the product from the market or recall it within such reasonable period, commensurate with the nature of the risk, as they may prescribe.

2. Where the market surveillance authorities consider that the non-compliance is not limited to the national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3. The economic operator shall ensure that any corrective actions are taken in respect of all the products concerned which he has made available on the market throughout the Community.

4. Where the relevant economic operator, within the period referred to in the second subparagraph of paragraph 1, does not take adequate corrective actions, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the making available of the product on the national market or to withdraw the product from that market or to recall it.

They shall inform the Commission and the other Member States, without delay, of such measures.

5. The information referred to in paragraph 4 shall provide all available details, in particular as regards the necessary data for the identification of the non-compliant product, the origin of the product , the nature of the risk involved, the nature and duration of national measures taken. In particular, the market surveillance authorities shall indicate whether the non compliance is due to either of the following:

(a) failure of the product to meet the requirements related to the health or safety of persons or to other issues of public interest protection laid down by this … [act];

(b) shortcomings in the harmonised standards referred to in … [reference to the relevant part of the legislation] as conferring presumption of conformity.

6. Member States other than the Member State which initiated the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information relating to the non-compliance of the product concerned at their disposal, and, in the event of disagreement with the notified national measure, of their objections.

7. Where within …. [period to be specified] of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State in relation to the product concerned, the measure shall be deemed justified.

Article 36

Community safeguard procedure

1. Where, on completion of the procedure set out in Article [35 (3) and (4)], objections are raised against a national measure of a Member State or where the Commission considers the national measure to be contrary to Community legislation the Commission shall without delay enter into consultation with the Member States and the relevant economic operator(s) and shall proceed to the evaluation of the national measure. On the basis of the results of that evaluation, the Commission shall take a decision, indicating whether the measure is justified or not.

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

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

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

Article 37

Complying products which nevertheless present a risk to health and safety

1. Where a Member State after having performed an evaluation under Article [35 (1)] finds that although a product is in compliance with this … [act]., it presents a risk for the health or safety of persons or for other issues of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk or to withdraw the product from the market or recall it within such reasonable period, commensurate with the nature of the risk, as it may prescribe.

2. The economic operator shall ensure that any corrective actions are taken in respect of all the products concerned which he has made available on the market throughout the Community.

3. The Member State shall immediately inform the Commission and the other Member States. The information shall provide all available details, in particular as regards the necessary data for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved, the nature and duration of national measures taken.

4. The Commission shall without delay enter into consultation with the Member States and the relevant economic operator(s) and shall proceed to the evaluation of the national measure. On the basis of the results of that evaluation, the Commission shall

take a decision, indicating whether the measure is justified or not, and where necessary, propose appropriate measures.

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator(s).

Article 38

Formal non-compliance

1. Without prejudice to Article 35, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

   (a) the conformity marking has been affixed in violation of Article [16] or Article [17];

   (b) the conformity marking has not been affixed;

   (c) the EC declaration of conformity has not been drawn up;

   (d) the EC declaration of conformity has not been drawn up correctly.

2. Where the non-compliance referred to in paragraph 1 continues, the Member State shall take all appropriate measures to restrict or prohibit the making available on the market of the product or ensure that it is recalled or withdrawn from the market.

Title III

FINAL PROVISIONS

Article 39

Repeal

Decision 93/465/EEC is repealed.

References to the repealed Decision shall be construed as references to this Decision.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I
CONFORMITY ASSESSMENT PROCEDURES

Module A
Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation as described in the legislative instrument. The documentation shall enable the assessment of the product for its conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product[15].

3. Manufacturing

The manufacturer shall take all measures necessary in order that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. CE marking and declaration of conformity

4.1. The manufacturer shall affix the CE marking according to the applicable requirements of the legislative instrument.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it with the technical documentation at the disposal of the national authorities for a period of 10 years[16] after the last product has been manufactured. The declaration of conformity shall identify the product for which it has been drawn up.

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15 The content of the technical documentation shall be laid down in the specific legislative instrument in accordance with the products concerned.
For example, the documentation must contain so far as relevant for assessment:
- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- a list of the harmonised standards the references of which have been published in the OJEU, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where these harmonised standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

16 The specific legislative instruments may alter this period.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

5. Authorised representative

The manufacturer's obligations contained in points 4 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module A1
Internal production control plus supervised product testing

1. Internal production control plus supervised product testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation as described in the legislative instrument. The documentation shall enable the assessment of the product for its conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product[17].

3. Manufacturing

The manufacturer shall take all measures necessary in order that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. Product checks

For each individual product manufactured, one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in

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[17] The content of the technical documentation shall be laid down in the specific legislative instrument in accordance with the products concerned.
For example, the documentation must contain so far as relevant for assessment:
- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- a list of the harmonised standards the references of which have been published in the OJEU, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where these harmonised standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

order to verify conformity with the corresponding requirements of the legislative instrument[18]. At the choice of the manufacturer[19], the tests are carried out either by an accredited in-house body or under the responsibility of a notified body, chosen by the manufacturer.

Where the tests are carried out by a notified body, the manufacturer shall, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

5. CE marking and declaration of conformity

5.1. The manufacturer shall affix the CE marking according to the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it with the technical documentation at the disposal of the national authorities for a period of 10 years[20] after the last product has been manufactured. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

6. Authorised representative

The manufacturer's obligations contained in point 5 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module A2
Internal production control plus supervised product checks at random intervals

1. Internal production control plus supervised product checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation as described in the legislative instrument. The documentation shall enable the assessment of the product for its conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the

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18 The legislative instrument must specify the products concerned and the tests to be carried out

19 The choice may be limited by the specific legislative instrument

20 The specific legislative instruments may alter this period.

applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product[21].

3. Manufacturing

The manufacturer shall take all measures necessary in order that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. Product checks

At the choice of the manufacturer[22], either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the product, taking into account inter alia the technological complexity of the products and the quantity of production. An adequate sample of the final products, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard and/or technical specifications, or equivalent tests, shall be carried out to check the conformity of the product with the appropriate requirements of the legislative instrument.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the product at hand performs within acceptable limits. The appropriate tests, the adequate sampling schemes and the corresponding action to be taken by the body and/or the manufacturer shall be defined by the specific legislative instrument.

Where the tests are carried out by a notified body, the manufacturer shall, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

5. CE marking and declaration of conformity

5.1. The manufacturer shall affix the CE marking according to the applicable requirements of the legislative instrument.

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21 The content of the technical documentation shall be laid down in the specific legislative instrument in accordance with the products concerned.
For example, the documentation must contain so far as relevant for assessment:
- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- a list of the harmonised standards the references of which have been published in the OJEU, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where these harmonised standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

22 The choice may be limited by the specific legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it with the technical documentation at the disposal of the national authorities for a period of 10 years23 after the last product has been manufactured. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

6. Authorised representative

The manufacturer's obligations contained in point 5 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module B
EC type examination

1. EC Type examination is that part of a conformity assessment procedure whereby a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the legislative instrument that apply to it.

2. EC Type examination may be carried out in either of the following manners. The specific legislative instrument shall determine the appropriate manner and the specimens required:

– examination of a specimen, representative of the production envisaged, of the complete product (production type);

– assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type);

– assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The application for EC type examination shall be lodged by the manufacturer with a single notified body of his choice.

The application shall include:

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;

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23 The specific legislative instruments may alter this period.

– a written declaration that the same application has not been lodged with any other notified body;

– the technical documentation, as described in the legislative instrument. The technical documentation shall enable the assessment of the product for its conformity with the applicable requirements of the legislative instrument and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product[24];

– the specimens, representative of the production envisaged, as required by the specific legislative instrument. The notified body may request further specimens if needed for carrying out the test programme;

– the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any relevant documents that have been applied, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The notified body shall:

For the product:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

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[24] The content of the technical documentation must be laid down in the specific legislative instrument in accordance with the products concerned.
For example, the documentation must contain as far as is relevant for assessment:
- a general type-description,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- a list of the harmonized standards the references of which have been published in the OJEU, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where these harmonized standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

4.3. carry out the appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;

4.4. carry out the appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;

4.5. agree with the applicant manufacturer the location where the examinations and tests shall be carried out.

5. The notified body shall draw up an evaluation report that records the activities as undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of this report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of the specific legislative instrument that apply to the product concerned, the notified body shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, conclusions of the examination, conditions (if any) for its validity and the necessary data for identification of the approved type[25]. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products to be evaluated with the examined type.

Where the type does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue an EC type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself appraised of any changes of the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigations. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential requirements of the legislative instrument or the conditions for validity of the certificate. Such modifications require additional approval in the form of an addition to the original EC-type examination certificate.

8. Each notified body shall inform its notifying authorities about the EC-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying

[25] The specific legislative instruments may provide for the certificate to have a period of validity.

authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted[26].

Each notified body shall inform the other notified bodies about the EC-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon reasoned request, about the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on reasoned request, obtain a copy of the EC-type examination certificates and/or their additions. On reasoned request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall hold a copy of the EC-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for a period up to the end of the validity of the certificate[27].

9. The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation for a period of 10 years[28] after the last product has been manufactured at the disposal of the national authorities.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and carry out the obligations mentioned in points 7 and 9.

Module C
Conformity to type based on internal production control

1. Conformity to type based on internal production control is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type as described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary in order that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type as described in the EC-type examination certificate and with the requirements of the legislative instrument that apply to them.

3. CE marking and declaration of conformity

3.1. The manufacturer shall affix the CE marking to each individual product that is in conformity with the type as described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

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26 The specific legislative instruments may provide for different arrangements.

27 The specific legislative instruments may alter this period.

28 The specific legislative instruments may alter this period.

3.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for a period of 10 years[29] after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

4. Authorised representative

The manufacturer's obligations contained in point 3 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module C1
Conformity to type based on internal production control plus supervised product testing

1. Conformity to type based on internal production control plus supervised product testing is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type as described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary in order that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type as described in the EC-type examination certificate and with the requirements of the specific legislative instrument that apply to them.

3. Product checks

For each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument[30]. At the choice of the manufacturer, the tests are carried out either by an accredited in-house body or on the responsibility of a notified body, chosen by the manufacturer.

Where the tests are carried out by a notified body, the manufacturer shall, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. CE marking and declaration of conformity

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29 The specific legislative instruments may alter this period.

30 The legislative instrument must specify the products concerned and the tests to be carried out.

4.1. The manufacturer shall affix the CE marking to each individual product that is in conformity with the type as described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for a period of 10 years[31] after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

5. Authorised representative

The manufacturer's obligations contained in point 4 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module C2
Conformity to type based on internal production control plus supervised product checks at random intervals

1. Conformity to type based on internal production control plus supervised product checks at random intervals is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type as described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary in order that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type as described in the EC-type examination certificate and with the requirements of the specific legislative instrument that apply to them.

3. Product checks

At the choice of the manufacturer[32], either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the product, taking into account inter alia the technological complexity of the products and the quantity of production. An adequate sample of the final products, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or technical specifications, or equivalent tests, shall be

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31 The specific legislative instruments may alter this period.

32 The choice may be milited by the specific legislative insturment.

carried out to check the conformity of the product with the appropriate requirements of the legislative instrument.

The acceptance sampling procedure to be applied is designed to determine whether the manufacturing process of the product at hand performs within acceptable limits. The appropriate tests, the adequate sampling schemes and the corresponding action to be taken by the manufacturer shall be defined by the specific legislative instrument.

Where the tests are carried out by notified body, the manufacturer shall, on the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. CE marking and declaration of conformity

4.1. The manufacturer shall affix the CE marking to each individual product that is in conformity with the type as described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for a period of 10 years[33] after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

5. Authorised representative

The manufacturer's obligations contained in point 4 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module D

Conformity to type based on quality assurance of the production process

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type as described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

[33] The specific legislative instruments may alter this period.

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 3 and is subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the products concerned.

The application shall include:

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;

– a written declaration that the same application has not been lodged with any other notified body;

– all relevant information for the product category envisaged;

– the documentation concerning the quality system;

– the technical documentation of the approved type and a copy of the EC-type examination certificate.

3.2. The quality system shall ensure compliance of the products with the type as described in the EC-type examination certificate and with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.

It shall contain, in particular, an adequate description of:

– the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

– the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

– the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

– the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

– the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with these requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1., fifth indent to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations in view of ensuring compliance of the product with these requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2, or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the locations of manufacture, inspection, testing and storage and shall provide it with all necessary information, in particular:

– the quality system documentation,

– the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall carry out periodic[34] audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

[34] In the specific legislative instruments, the frequency may be specified.

4.4. Moreover, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and declaration of conformity

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1., the latter's identification number to each individual product that is in conformity with the type as described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for a period of 10 years[35] after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

6. The manufacturer shall, for a period ending at least 10 years[36] after the last product has been manufactured, keep at the disposal of the national authorities:

– the documentation referred to in point 3.1.;

– the change referred to in point 3.5., as approved;

– the decisions and reports from the notified body referred to in points 3.5., 4.3. and 4.4.

7. Each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted[37].

Each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended or withdrawn, and, upon request, of the quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations contained in points 3.1., 3.5., 5 and 6 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

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35 The specific legislative instruments may alter this period.

36 The specific legislative instruments may alter this period.

37 The specific legislative instruments may provide for different arrangements.

Module D1
Quality assurance of the production process

1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation as described in the legislative instrument. The documentation shall enable the assessment of the product for its conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product[38].

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for a period of 10 years[39] after the last product has been manufactured.

4. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 5 and is subject to surveillance as specified in point 6.

5. Quality system

5.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the products concerned.

The application shall include:

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;

– a written declaration that the same application has not been lodged with any other notified body;

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38 The content of the technical documentation shall be laid down in the specific legislative instrument in accordance with the products concerned.
For example, the documentation must contain so far as relevant for assessment:
- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- a list of the harmonised standards the references of which have been published in the OJEU, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where these harmonised standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

39 The specific legislative instruments may alter this period.

– all relevant information for the product category envisaged,

– the documentation concerning the quality system,

– the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.

It must contain, in particular, an adequate description of:

– the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

– the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

– the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

– the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

– the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with these requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations in view of ensuring compliance of the product with these requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2, or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. Surveillance under the responsibility of the notified body

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the locations of manufacture, inspection, testing and storage and shall provide it with all necessary information, in particular:

– the quality system documentation,

– the technical documentation referred to in point 2,

– the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

6.3. The notified body shall carry out periodic[40] audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

6.4. Moreover, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. CE marking and declaration of conformity

7.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 5.1., the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

7.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for a period of 10 years[41]

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[40] In the specific legislative instruments, the frequency may be specified.

[41] The specific legislative instruments may alter this period.

after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

8. The manufacturer shall, for a period ending at least 10 years[42] after the last product has been manufactured, keep at the disposal of the national authorities:

– the documentation referred to in point 5.1.;

– the change referred to in point 5.5., as approved;

– the decisions and reports from the notified body referred to in points 5.5., 6.3. and 6.4.

9. Each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted[43].

Each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended or withdrawn, and, upon request, of the quality system approvals which it has issued.

10. Authorised representative

The manufacturer's obligations contained in points 3, 5.1., 5.5., 7 and 8 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module E
Conformity to type based on product quality assurance

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type as described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

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42 The specific legislative instruments may alter this period.

43 The specific legislative instruments may provide for different arrangements.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the products concerned.

The application shall include:

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;

– a written declaration that the same application has not been lodged with any other notified body;

– all relevant information for the product category envisaged;

– the documentation concerning the quality system;

– the technical documentation of the approved type and a copy of the EC-type examination certificate.

3.2. The quality system shall ensure compliance of the products with the type as described in the EC-type examination certificate and with the applicable requirements of the legislative instrument.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.

It shall contain, in particular, an adequate description of:

– the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

– the examinations and tests that will be carried out after manufacture;

– the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

– the means of monitoring the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with these requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of

the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1., fifth indent to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations in view of ensuring compliance of the product with these requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2, or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the locations of inspection, testing and storage and shall provide it with all necessary information, in particular:

– the quality system documentation,

– the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall carry out periodic[44] audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Moreover, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and declaration of conformity

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[44] In the specific legislative instruments, the frequency may be specified.

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1., the latter's identification number to each individual product that is in conformity with the type as described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for a period of 10 years[45] after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

6. The manufacturer shall, for a period ending at least 10 years[46] after the last product has been manufactured, keep at the disposal of the national authorities:

– the documentation referred to in point 3.1.;

– the change referred to in point 3.5., as approved;

– the decisions and reports from the notified body referred to in points 3.5. final subparagraph, point 4.3. and point 4.4.

7. Each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted[47].

Each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended or withdrawn, and, upon request, of the quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations contained in points 3.1., 3.5., 5 and 6 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module E1
Quality assurance of final product inspection and testing

1. Quality assurance of final product inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in

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45 The specific legislative instruments may alter this period.

46 The specific legislative instruments may alter this period.

47 The specific legislative instruments may provide for different arrangements.

points 2, 4 and 7, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation as described in the legislative instrument. The documentation shall enable the assessment of the product for its conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product[48].

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for a period of 10 years[49] after the last product has been manufactured.

4. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in point 5 and is subject to surveillance as specified in point 6.

5. Quality system

5.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the products concerned.

The application shall include:

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;

– a written declaration that the same application has not been lodged with any other notified body;

– all relevant information for the product category envisaged,

– the documentation concerning the quality system,

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48 The content of the technical documentation shall be laid down in the specific legislative instrument in accordance with the products concerned.
For example, the documentation must contain so far as relevant for assessment:
- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- a list of the harmonised standards the references of which have been published in the OJEU, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where these harmonised standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

49 The specific legislative instruments may alter this period.

– the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.

It must contain, in particular, an adequate description of:

– the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

– the examinations and tests that will be carried out after manufacture;

– the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

– the means of monitoring the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with these requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations in view of ensuring compliance of the product with these requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.

5.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2, or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

6. Surveillance under the responsibility of the notified body

6.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the locations of manufacture, inspection, testing and storage and shall provide it with all necessary information, in particular:

– the quality system documentation,

– the technical documentation referred to in point 2,

– the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

6.3. The notified body shall carry out periodic[50] audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

6.4. Moreover, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. CE marking and declaration of conformity

7.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

7.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for a period of 10 years[51] after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

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50 In the specific legislative instruments, the frequency may be specified.

51 The specific legislative instruments may alter this period.

8. The manufacturer shall, for a period ending at least 10 years[52] after the last product has been manufactured, keep at the disposal of the national authorities:

– the documentation referred to in point 5.1.;

– the change referred to in point 5.5., as approved;

– the decisions and reports from the notified body referred to in points 5.5., 6.3. and 6.4.

9. Each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted[53].

Each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended or withdrawn, and, upon request, of the quality system approvals which it has issued.

10. Authorised representative

The manufacturer's obligations contained in points 3, 5.1., 5.5., 7 and 8 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module F
Conformity to type based on product verification

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 6, and ensures and declares on his sole responsibility that the products that have been subjected to the provisions of point 3 are in conformity with the type as described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary in order that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type as described in the EC-type examination certificate and with the requirements of the legislative instrument that apply to them.

3. Verification

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests in order to check the conformity of the products with the approved type as described in the EC-type examination certificate and the appropriate requirements of the legislative instrument.

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52 The specific legislative instruments may alter this period.

53 The specific legislative instruments may provide for different arrangements.

The examinations and tests to check the conformity of the products with the appropriate requirements will be carried out, at the choice of the manufacturer[54], either by examination and testing of every product as specified in point 4, or by examination and testing of the products on a statistical basis as specified in point 5.

4. Verification of conformity by examination and testing of every product

4.1. All products shall be individually examined and appropriate tests as set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify their conformity with the approved type as described in the EC-type examination certificate and the appropriate requirements of the legislative instrument. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection purposes by the national authorities for a period of 10 years[55] after the certification of the product.

5. Statistical verification of conformity

5.1. The manufacturer shall take all measures necessary in order for the manufacturing process and its monitoring to ensure the homogeneity of each lot produced, and shall present his products for verification in the form of homogeneous lots.

5.2. A random sample shall be drawn from each lot according to the requirements of point 5.3. All products in a sample shall be individually examined and appropriate tests as set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to ensure their conformity with the applicable requirements of the legislative instrument and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

5.3. The statistical procedure shall use the following elements:

(Relevant elements must be specified here by the legislative instrument, such as the statistical method to be applied, the sampling plan with its operational characteristics, etc.)

5.4. If a lot is accepted, all products of the lot are approved, except for those products from the sample that were found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

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54 The manufacturer's discretion may be limited in the specific legislative instrument.

55 The specific legislative instruments may alter this period.

The manufacturer shall, on the responsibility of the notified body, affix the latter's identification symbol during the manufacturing process.

The manufacturer shall keep the certificates of conformity available for the national authorities for a period of 10 years[56] after the certification of the product.

5.5. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent the placing on the market of that lot. In the event of frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

6. CE marking and declaration of conformity

6.1. The manufacturer shall affix the CE marking to each individual product that is in conformity with the approved type as described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

6.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities, for a period of 10 years[57] after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

If agreed upon by the notified body referred to in point 3, the manufacturer shall also affix the notified body's identification number to the products, under the responsibility of the notified body.

7. The manufacturer may, if agreed upon by the notified body and under its responsibility, affix the notified body's identification number to the products during the manufacturing process.

8. Authorised representative

The manufacturer's obligations may be fulfilled, on his behalf and under his responsibility, by his authorised representative, except for the obligations contained in points 2 and 5.1.

Module F1
Conformity based on product verification

1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4, 5 and 8, and ensures and declares on his sole responsibility that the products that have been

[56] The specific legislative instruments may alter this period.

[57] The specific legislative instruments may alter this period.

subjected to the provisions of point 5 are in conformity with the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation as described in the legislative instrument. The documentation shall enable the assessment of the product for its conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product[58].

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for a period of 10 years[59] after the last product has been manufactured.

3. Manufacturing

The manufacturer shall take all measures necessary in order that the manufacturing process and its monitoring ensure conformity of the manufactured products with the applicable requirements of the legislative instrument.

4. Verification

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests, or have them carried out, to check the conformity of the products with the applicable requirements of the legislative instrument.

The examinations and tests to check the conformity with these requirements will be carried out, at the choice of the manufacturer, either by examination and testing of every product as specified in point 6, or by examination and testing of the products on a statistical basis as specified in point 7.

5. Verification of conformity by examination and testing of every product.

5.1. All products shall be individually examined and appropriate tests, as set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, shall be carried out to verify their conformity with the requirements that apply to

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58 The content of the technical documentation shall be laid down in the specific legislative instrument in accordance with the products concerned.
For example, the documentation must contain so far as relevant for assessment:
- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- a list of the harmonised standards the references of which have been published in the OJEU, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where these harmonised standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

59 The specific legislative instruments may alter this period.

them. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

5.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for the national authorities for a period of 10 years[60] after the certification of the product.

6. Statistical verification of conformity

6.1. The manufacturer shall take all measures necessary in order for the manufacturing process to ensure the homogeneity of each lot produced, and shall present his products for verification in the form of homogeneous lots.

6.2. A random sample shall be drawn from each lot according to the requirements of point 7.3. All products in the sample shall be individually examined and appropriate tests as set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, to establish their conformity with the requirements that apply to them, shall be carried out to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

6.3. The statistical procedure shall use the following elements:

(Relevant elements must be specified here by the legislative instrument, such as the statistical method to be applied, the sampling plan with its operational characteristics, etc.)

6.4. If a lot is accepted, all products of the lot are approved, except for those products from the sample that were found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for the national authorities for a period of10 years[61] after the certification of the product.

6.5. If a lot is rejected, the notified body shall take appropriate measures to prevent the placing on the market of that lot. In the event of frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

7. CE marking and declaration of conformity

7.1. The manufacturer shall affix the CE marking to each individual product that satisfies the applicable requirements of the legislative instrument.

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60 The specific legislative instruments may alter this period.

61 The specific legislative instrument may alter this period.

7.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for a period of 10 years[62] after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

If agreed upon by the notified body referred to in point 5, the manufacturer shall also affix the notified body's identification number to the products, under the responsibility of the notified body.

8. The manufacturer may, if agreed upon by the notified body and under its responsibility, affix the notified body's identification number to the products during the manufacturing process.

9. Authorised representative

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The manufacturer's obligations may be fulfilled, on his behalf and under his responsibility, by his authorised representative, except for the obligations contained in points 4 and 7.1.

Module G
Conformity based on unit verification

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the product concerned, which has been subjected to the provisions of point 4, is in conformity with the requirements of the legislative instrument that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation as described in the legislative instrument and make it available to the notified body referred to in point 4. The documentation shall enable the assessment of the product for its conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product[63].

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62 The specific legislative instruments may alter this period.

63 The content of the technical documentation shall be laid down in the specific legislative instrument in accordance with the products concerned.
For example, the documentation must contain so far as relevant for assessment:
- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits,

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for a period of 10 years[64] after the last product has been manufactured.

3. Manufacturing

The manufacturer shall take all measures necessary in order that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of the legislative instrument.

4. Verification

A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests as set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, to check the conformity of the product with the applicable requirements of the legislative instrument, or have them carried out. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and affix its identification number to the approved product, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for the national authorities for a period of 10 years[65] after the certification of the product.

5. CE marking and declaration of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each product that satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for a period of 10 years[66] after the last product has been manufactured. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration shall be supplied with the product.

6. Authorised representative

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etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,
- a list of the harmonised standards the references of which have been published in the OJEU, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where these harmonised standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

64 The specific legislative instruments may alter this period.

65 The specific legislative instruments may alter this period.

66 The specific legislative instruments may alter this period.

The manufacturer's obligations contained in points 2 and 5 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module H
Conformity based on full quality assurance

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the products concerned.

The application shall include:

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;

– the technical documentation as described in the legislative instrument, for one model of each category of products intended to be manufactured;

– the documentation concerning the quality system;

– a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of:

– the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

– the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not

be applied in full, the means that will be used to ensure that the essential requirements of the legislative instrument that apply to the products will be met;

– the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered;

– the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

– the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

– the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

– the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with these requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1., second indent, to verify the manufacturer's ability to identify the applicable requirements of the legislative instrument and to carry out the necessary examinations in view of ensuring compliance of the product with these requirements.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.

3.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2., or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the locations of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:

– the quality system documentation;

– the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.;

– the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body shall carry out periodic[67] audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Moreover, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. CE marking and declaration of conformity

5.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1., the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for a period of 10 years[68] after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

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67 In the specific legislative instruments, the frequency may be specified.

68 The specific legislative instruments may alter this period.

6. The manufacturer shall, for a period ending at least 10 years[69] after the last product has been manufactured, keep at the disposal of the national authorities:

– the technical documentation referred to in point 3.1.;

– the documentation concerning the quality system referred to in point 3.1.;

– the change referred to in point 3.5., as approved;

– the decisions and reports from the notified body referred to in points 3.5., 4.3. and 4.4.

7. Each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted[70].

Each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended or withdrawn, and, upon request, of the quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations contained in points 3.1., 3.5., 5 and 6 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

Module H1
Conformity based on full quality assurance plus design examination

1. Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 5. The adequacy of the technical design of the products shall have been examined according to the provisions of point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with a notified body of his choice, for the products concerned.

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69 The specific legislative instruments may alter this period.

70 The specific legislative instruments may provide for different arrangements.

The application shall include:

– the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition;

– all relevant information for the product category envisaged;

– the documentation concerning the quality system;

– a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of:

– the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

– the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements of the legislative instrument that apply to the products will be met;

– the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered;

– the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

– the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

– the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.;

– the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with these requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national

standard that implements the relevant harmonised standard and/or technical specifications.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision. An appeal procedure must be available.

3.4. The manufacturer shall undertake to fulfil the obligations arising from the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.

The notified body shall evaluate the proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2., or whether a re-assessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. Each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted[71].

Each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended or withdrawn, and, upon request, of the quality system approvals which it has issued.

4. Design examination

4.1. The manufacturer shall lodge an application for examination of the design with the notified body referred to in point 3.1.

4.2. The application shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of the legislative instrument that apply to it. It shall include:

– the name and address of the manufacturer;

– a written declaration that the same application has not been lodged with any other notified body;

[71] The specific legislative instruments may provide for different arrangements.

– the technical documentation as described in the legislative instrument. The documentation shall enable the assessment of the product for its conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design and operation of the product;

– the supporting evidence for the adequacy of the technical design. This evidence shall mention any documents that have been applied, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4.3. The notified body shall examine the application, and where the design meets the requirements of the legislative instrument that apply to the product it shall issue an EC design examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, conditions (if any) for its validity and the necessary data for identification of the approved design[72]. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products to be evaluated with the examined design, and to allow for in-service control, where applicable.

Where the design does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal. An appeal procedure must be available.

4.4. The notified body shall keep itself appraised of any changes of the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigations. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of the legislative instrument or the conditions for validity of the certificate.. Such modifications require additional approval - from the notified body that issued the EC design examination certificate - in the form of an addition to the original EC design examination certificate.

4.5. Each notified body shall inform its notifying authorities about the EC design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying

[72] The specific legislative instruments may provide for the certificate to have a period of validity.

authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted[73].

Each notified body shall inform the other notified bodies about the EC design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, about the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on reasoned request, obtain a copy of the EC design examination certificates and/or their additions. On reasoned request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

The notified body shall hold a copy of the EC design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer for a period up to the end of the validity of the certificate[74].

4.6. The manufacturer shall keep a copy of the EC design examination certificate, its annexes and additions with the technical documentation for a period of 10 years[75] after the last product has been manufactured at the disposal of the national authorities.

4.7. The manufacturer's authorised representative may lodge the application referred to in points 4.1 and 4.2 and carry out the obligations mentioned in points 4.4 and 4.6.

5. Surveillance under the responsibility of the notified body

5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

5.2. The manufacturer shall, for assessment purposes, allow the notified body access to the locations of design, manufacture, inspection, testing and storage, and shall provide it with all necessary information, in particular:

– the quality system documentation;

– the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.;

– the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

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73 The specific legislative instruments may provide for different arrangements.

74 The specific legislative instruments may alter this period.

75 The specific legislative instruments may alter this period.

5.3. The notified body shall carry out periodic[76] audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

5.4. Moreover, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

6. CE marking and declaration of conformity

6.1. The manufacturer shall affix the CE marking, and, under the responsibility of the notified body referred to in point 3.1., the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

6.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for a period of 10 years[77] after the last product has been manufactured. The declaration of conformity shall identify the product model for which it has been drawn up and shall mention the number of the design examination certificate.

A copy of the declaration of conformity shall be supplied with each product that is made available on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than to individual products in those cases where a large number of products is delivered to a single user.

7. The manufacturer shall, for a period ending at least 10 years[78] after the last product has been manufactured, keep at the disposal of the national authorities:

– the documentation concerning the quality system referred to in point 3.1.;

– the change referred to in point 3.5., as approved;

– the decisions and reports from the notified body referred to in points 3.5., 5.3. and 5.4.

8. Authorised representative

The manufacturer's obligations contained in points 3.1., 3.5., 6 and 7 may be fulfilled, on his behalf and under his responsibility, by his authorised representative.

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76 In the specific legislative instruments, the frequency may be specified.

77 The specific legislative instruments may alter this period.

78 The specific legislative instruments may alter this period.

TABLE: CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

	A. Internal production control	B. Type examination	G. Unit verification	H. Full quality assurance
				EN ISO 9001:2000 (3)
DESIGN	Manufacturer > Keeps technical documentation at the disposal of national authorities	Manufacturer submits to notified body > technical documentation > supporting evidence for the adequacy of the technical design solution > specimen(s), representative of the production envisaged, as required Notified Body > Ascertains conformity with essential requirements > Examines technical documentation and supporting evidence to assess adequacy of the technical design > For specimen(s): carries out tests, if necessary > Issues EC-type examination certificate	Manufacturer > submits technical documentation	Manufacturer >operates an approved quality system for design >submits technical documentation Notified Body >carries out surveillance of the QS H1 Notified body >verifies conformity of design >issues EC-design examination certificate

	C. Conformity to type	D. Production quality assurance	E. Product quality assurance	F. Product verification		
		EN ISO 9001:2000 (1)	EN ISO 9001:2000 (2)			
PRODUCTION	A. Manufacturer > Declares conformity with essential requirements > Affixes CE marking A1 Accredited in-house body or notified body >Tests on specific aspects of the product A2 > Product checks at random intervals	C. Manufacturer > Declares conformity with approved type > Affixes CE marking C1 Accredited in-house body or notified body > Tests on specific aspects of the product C2 > Product checks at random intervals	Manufacturer >Operates an approved quality system for production, final inspection and testing >Declares conformity with approved type >Affixes CE marking D1 Declares conformity with essential requirements > Affixes CE marking Notified Body > Approves the QS > Carries out surveillance of the QS	Manufacturer >Operates an approved quality system for final inspection and testing >Declares conformity with approved type >Affixes CE marking E1 Declares conformity with essential requirements >Affixes CE marking Notified Body > Approves the QS > Carries out surveillance of the QS	Manufacturer > Declares conformity with approved type > Affixes CE marking F1 Declares conformity with essential requirements >Affixes CE marking Notified body > Verifies conformity with essential requirements > Issues certificate of conformity	Manufacturer > Submits product > Declares conformity > Affixes CE marking Notified body >Verifies conformity with essential requirements > Issues certificate of conformity	Manufacturer > Operates an approved QS for production, final inspection and testing > Declares conformity > Affixes CE marking Notified body > Carries out surveillance of the QS

(1) except for sub-clause 7.3 and requirements relating to customer satisfaction and continual improvement

(2) except for sub-clauses 7.1, 7.2.3, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3 and requirements relating to customer satisfaction and continual improvement

(3) except for requirements relating to customer satisfaction and continual improvement

ANNEX II
EC DECLARATION OF CONFORMITY

1. No xxxxxx (unique identification of the product)

2. Name and address of (authorised representative of the) manufacturer:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

4. Object of the declaration (identification of product allowing traceability):

5. The object of the declaration described above is in conformity with the relevant Community harmonisation legislation……

6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:

7. The notified body ... (name, number)… performed … (description of intervention)… and issued the certificate: ….

8. Additional information:

   Signed for and on behalf of:…….

   (place and date of issue)

   (name, function)(signature)