II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 13 December 1990

concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives

(90/683/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the Council adopted a resolution on 21 December 1989 concerning a global approach to conformity assessment (4);

Whereas the introduction of harmonized methods for the assessment of conformity and the adoption of a common doctrine for their implementation are likely to facilitate the adoption of future technical harmonization directives concerning the placing on the market of industrial products and thus be conducive to the completion of the internal market by 31 December 1992;

Whereas such methods should ensure that products are in full conformity with the essential requirements laid down in the technical harmonization directives, in order to provide, in particular, for the health and safety of users and consumers;

Whereas such conformity should be assured without imposing unneccessarily onerous conditions on manufacturers, and by means of clear and comprehensible procedures;

Whereas limited flexibility should be introduced as regards use of additional modules, or variations in the modules, when the specific circumstances of a particular sector or directive so warrant, but not to such a degree as to undercut the purpose of the current Decision and only when explicitly justified,

HAS DECIDED AS FOLLOWS:

Sole Article

The procedures for conformity assessment which are to be used in the technical harmonization directives relating to the marketing of industrial products will be chosen from among the modules listed in the Annex and in accordance with the criteria set out in this Decision and in the general guidelines in the Annex. These procedures may only depart from the modules when the specific circumstances of a particular sector or directive so warrant. Such departures from the modules must be limited in extent and must be explicitly justified in the relevant directive. The Commission will report periodically on the functioning of this Decision, and on whether conformity assessment procedures are working satisfactorily or need to be modified.

Done at Brussels, 13 December 1990.

For the Council

The President

P. ROMITA

(1) OJ No C 231, 8. 9. 1989, p. 3.
(2) OJ No C 149, 18. 6. 1990, p. 162 and Decision of 21 November 1990 (not yet published in the Official Journal).
(3) OJ No C 112, 7. 5. 1990, p. 4.
(4) OJ No C 10, 16. 1. 1990, p. 1.

ANNEX

CONFORMITY ASSESSMENT PROCEDURES IN THE TECHNICAL HARMONIZATION DIRECTIVES

I. GENERAL GUIDELINES

The principal guidelines for the use of conformity assessment procedures in technical harmonization directives are the following:

(a) the essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers;

(b) conformity assessment can be subdivided into modules which relate to the design phase of products and to their production phase;

(c) as a general rule a product should be subject to both phases before being able to be placed on the market if the results are positive (*);

(d) there are a variety of modules which cover the two phases in a variety of ways. The directives shall set the range of possible choices which can be considered by the Council to give the public authorities the high level of safety they seek, for a given product or product sector;

(e) in setting the range of possible choices open to the manufacturer, the directives, will take into consideration, in particular, such issues as the appropriateness of the modules to the type of products, the nature of the risks involved, the economic infrastructures of the given sector (e.g. existence or non-existence of third parties), the types and importance of production, etc. The factors that have been taken into account must be explicitly spelled out by the Commission in these directives;

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

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

(g) the directives should avoid imposing unnecessarily modules which would be too onerous relative to the objectives of the directive concerned;

(h) notified bodies should be encouraged to apply the modules without unnecessary burden for the economic operators. The Commission, in cooperation with the Member States, shall ensure that close cooperation is organized between the notified bodies in order to ensure consistent technical application of the modules;

(i) in order to protect the manufacturers, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessment of conformity. Legal protection of confidential information shall be required;

(j) whenever directives provide the manufacturer with the possibility of using modules based on quality assurance techniques, the manufacturer must also be able to have recourse to a combination of modules not using quality assurance, and *vice versa,* except where compliance with the requirements laid down by the directives requires the exclusive application of a certain procedure;

(k) for the purposes of operating the modules, Member States shall notify on their own responsibility bodies under their jurisdiction which they have chosen from the technically competent bodies complying with the requirements of the directives. This responsibility involves the obligation for the Member States to ensure that the notified bodies permanently have the technical qualifications required by the directives and that the latter keep their competent national authorities informed of the performance of their tasks. Where a Member State withdraws its notification of a body, it shall take appropriate steps to ensure that the dossiers are processed by another notified body to ensure continuity;

(l) in addition, with regard to conformity assessment, the sub-contracting of work shall be subject to certain conditions guaranteeing;

— the competence of the establishment operating as sub-contractor, on the basis of conformity with series EN 45 000 standards, and the capability of the Member State that has notified the sub-contracting body to ensure effective monitoring of such compliance,

(*) The specific directives may provide for different arrangements.

— the ability of the body notified to exercise effective responsibility for the work carried out under sub-contract;

(m) notified bodies which can prove their conformity with harmonized standards (EN 45 000 series), by submitting an accreditation certificate or other documentary evidence, shall be presumed to conform to the requirements of the directives. Member States having notified bodies unable to prove their conformity with the harmonized standards (EN 45 000 series) may be requested to provide the Commission with the appropriate supporting documents on the basis of which notification was carried out;

(n) a list of notified bodies shall be published by the Commission in the *Official Journal of the European Communities* and constantly updated.

II. MODULES FOR CONFORMITY ASSESSMENT

Explanatory notes

Specific directives may allow the CE mark to be affixed to the packaging or the accompanying documentation, instead of to the product itself.

The declaration of conformity or the certificate of conformity (whichever of the two applies in the directive concerned) shall cover either individual or several products and shall either accompany the product(s) covered or be kept by the manufacturer. The appropriate solution for the directive concerned will be specified.

References to articles refer to the standard paragraphs of Annex II.B to the Council resolution of 7 May 1985 (OJ No C 136, 4. 6. 1985, p. 1), which have become standard articles in the 'new approach' directives.

The development of computerized communication of certificates and other documents issued by notified bodies is envisaged within INSIS.

Specific directives may use modules A, C and H with additional provisions containing supplementary requirements which figure in the boxes in the modules.

Module C is designed to be used in combination with module B (EC type examination). Modules D, E and F will also normally be used in combination with module B; however, in special cases (for example, when dealing with certain products of very simple design and construction) they may be used on their own.

Module A (internal production control)

1. This module describes the procedure whereby the manufacturer or his authorized representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the products concerned satisfy the requirements of the directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity.

2. The manufacturer shall establish the technical documentation described in paragraph 3 and he or his authorized representative established with the Community shall keep it for a period ending at least 10 years (*) after the last product has been manufactured at the disposal of the relevant national authorities for inspection purposes.

   Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

3. Technical documentation shall enable the conformity of the product with the requirements of the directive to be assessed. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the product (**).

(*) The specific directives may alter this period.

(**) The content of the technical documentation shall be laid down directive by directive in accordance with the products concerned.
For example, the documentation shall 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 standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in Article 5 have not been applied,
— results of design calculations made, examinations carried out, etc.,
— test reports.

4. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity with the technical documentation.

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

Module Aa

This module consists of module A, plus the following supplementary requirements:

For each 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 (*). The tests shall be carried out on the responsibility of a notified body chosen by the manufacturer.

On the responsibility of the notified body, the manufacturer shall affix the former's identification symbol during the manufacturing process.

(*) If this option is adopted in a specific directive, the products concerned and the tests to be carried out must be specified.

or:

A notified body chosen by the manufacturer shall carry out or have carried out product checks at random intervals. An adequate sample of the final products, taken on site by the notified body, shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, shall be carried out to check the conformity of the product with the relevant requirements of the directive.

In those cases where one or more of the products checked do not conform the notified body shall take appropriate measures.

The product checking shall include the following aspects:

(Relevant aspects shall be specified here such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etc.)

On the responsibility of the notified body, the manufacturer shall affix the former's identification symbol during the manufacturing process.

Module B (EC type-examination)

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of the directive that apply to it.

2. The application for the EC type-examination shall be lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

   The application shall include:

   — the name and address of the manufacturer and, if the application is lodge by the authorized representative, his name and address in addition,

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

   — the technical documentation, as described in point 3.

   The applicant shall place at the disposal of the notified body a specimen, repesentative of the production envisaged and hereinafter called "type" (*). The notified body may request further specimens if needed for carrying out the test programme.

(*) A type may cover several versions of the product provided that the differences betwen the versions do not affect the level of safety and the other requirements concerning the performance of the product.

3. The technical documentation shall enable the conformity of the product with the requirements of the directive to be assessed. It shall, as far as relevant for such assessment, cover the design, manufacture and operation of the product (*).

4. The notified body shall:

4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as the components which have been designed without applying the relevant provisions of those standards;

4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in Article 5 have not been applied, the solutions adopted by the manufacturer meet the essential requirements of the Directive;

4.3. perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;

4.4. agree with the applicant the location where the examinations and necessary tests shall be carried out.

5. Where the type meets the provisions of the directive, the notified body shall issue an EC type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination, conditions for its validity and the necessary data for identification of the approved type (**).

A list of the relevant of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

If the manufacturer is denied a type certification, the notified body shall provide detailed reasons for such denial.

Provision shall be made for an appeals procedure.

6. The applicant shall inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved product which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC type-examination certificate.

7. Each notified body shall communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn (***).

8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The annexes to the certificates shall be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorized representative shall keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least 10 years (***) after the last product has been manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

(*) The content of the technical documentation shall be laid down directive by directive in accordance with the products concerned.
For example, the documentation shall 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 standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in Article 5 have not been applied,
— results of design calculations made, examinations carried out, etc.,
— test reports.

(**) The specific directives may provide for the certificate to have a period of validity.

(***) The specific directives may provide for different arrangements.

(****) The specific directives may alter this period.

Module C (conformity to type)

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative established within the Community 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 directive that applies to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured products with the type as described in the EC type-examination certificate and with the requirements of the directive that apply to them.

3. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years (*) after the last product has been manufactured.

   Where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community market.

Possible supplementary requirements:

For each 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 (*). The tests shall be carried out on the responsibility of a notified body, chosen by the manufacturer.

On the responsibility of the notified body, the manufacturer shall affix the former's identification symbol during the manufacturing process.

(*) If this option is adopted in a specific directive, the products concerned and the tests to be carried out must be specified.

or:

A notified body chosen by the manufacturer shall carry out or have carried out product checks at random intervals. An adequate sample of the final products, taken on site by the notified body, shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, shall be carried out to check the conformity of production with the relevant requirements of the directive. In those cases where one or more of the products checked do not conform, the notified body shall take appropriate measures.

The product checking shall include the following aspects:

(Relevant aspects shall be specified here such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etc.)

On the responsibility of the notified body, the manufacturer shall affix the former's identification symbol during the manufacturing process.

Module D (**), (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 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 directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity. The EC mark shall be accompanied by the identification symbol of the notified body responsible for EC monitoring as specified in point 4.

2. The manufacturer shall operate an approved quality system for production, final product inspection and testing as specified in paragraph 3 and shall be subject to monitoring as specified in point 4.

(*) The specific directives may alter this period.

(**) Where this module is used without module B:
- points 2 and 3 of module A must be added between points 1 and 2 in order to incorporate the need for technical documentation,
- the words in square brackets must be deleted.

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:

— all relevant information for the product category envisaged,

— the documentation concerning the quality system,

— if applicable, 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 directive 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 and adequate description of:

— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,

— the 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 to monitor 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 quality systems that implement the relevant harmonized standard (*).

The auditing team shall have at least one member with experience of evaluation in the product technology concerned. The evaluation procedure shall include an inspection visit to the manufacturer's premises.

The decision shall be notified to the manufactuer. 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 out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufactuer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It shall notify its decision to the manufacturer. 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 allow the notified body entrance for inspection purposes to the locations of manufacture, inspection and 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.

(*) This harmonized standard will be EN 29 002, supplemented, if necessary, to take into account the specific nature of the products for which it is implemented.

4.3. The notified body shall periodically (*) carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out, or cause to be carried out, tests to verify that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer shall, for a period ending at least 10 years (**) after the last product has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of point 3.1,

— the updating referred to in the second paragraph of point 3.4,

— the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.

6. Each notified body shall give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (***).

Module E (****) (product quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 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 directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity. The CE mark shall be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.

2. The manufacturer shall operate an approved quality system for final product inspection and testing as specified in paragraph 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 for the products concerned, with a notified body of his choice.

The application shall include:

— all relevant information for the product category envisaged,

— the quality system's documentation,

— if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.

3.2. Under the quality system, each product shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the directive. 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 ensure a common understanding of the quality programmes, plans, manuals and records.

It shall contain in particular and adequate description of:

— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,

— the examinations and tests that will be carried out after manufacture,

— the means to monitor the effective operation of the quality system,

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

(*) In the specific directives, the frequency may be specified.
(**) The specific directives may alter this period.
(***) The specific directives may provide for different arrangements.
(****) When this module is used without module B:
— points 2 and 3 of module A must be added between points 1 and 2 in order to incorporate the need for technical documentation,
— the words in square brackets must be deleted.

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 quality systems that implement the relevant harmonized standard (*).

The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The assessment procedure shall include an assessment visit to the manufacturer's premises.

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 discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorized representative shall keep the notified body which has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It shall notify its decision to the manufacturer. 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 allow the notified body entrance for inspection purposes to the locations of inspection, testing and storage and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the technical 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 periodically (**) carry out audits to ensure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it shall provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer shall, for a period ending at least 10 years (***) after the last product has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the third indent of point 3.1,

— the updating referred to in the second paragraph of point 3.4,

— the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (****).

Module F (*****) (product verification)

1. This module describes the procedure whereby a manufacturer or his authorized representative established within the Community checks and attests that the products subject 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 directive that apply to them.

(*) This harmonized standard will be EN 29 003, supplemented if necessary to allow for the specific features of the products for which it is implemented.
(**) The intervals between audits may be specified in the specific directives.
(***) The specific directives may alter this period.
(****) The specific directives may provide for different arrangements.
(*****) Where this module is used without module B:
— it must be supplemented by points 2 and 3 of module A (between points 1 and 2), so as to introduce the need for technical documentation,
— the next in square brackets must be deleted.

2. The manufacturer shall take all measures necessary in order that the manufacturing process ensures conformity of the products [with the type as described in the EC type-examination certificate and] with the requirements of the directive that apply to them. He shall affix the CE mark to each product and shall draw up a declaration of conformity.

3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the product with the requirements of the directive either by examination and testing of every product as specified in point 4 or by examination and testing of products on a statistical basis, as specified in point 5, at the choice of the manufacturer (*).

3a. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years (**) after the last product has been manufactured.

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

4.1. All products shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to verify their conformity with [the type as described in the EC-type examination certificate and] the requirements of the directive that apply to them.

4.2. The notified body shall affix or cause to be affixed, its identification symbol to each approved product and draw up a written certificate of conformity relating to the tests carried out.

4.3. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

5. *Statistical verification*

5.1. The manufacturer shall present his products in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.

5.2. All products shall be available for verification in the form of homogeneous lots. A random sample shall be drawn from each lot. Products in a sample shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, shall be carried out to ensure their conformity with the requirements of the directive which apply to them and to determine whether the lot is accepted or rejected.

5.3. The statistical procedure shall use the following elements:

(Relevant elements shall be specified here such as, for example, the statistical method to be applied, the sampling plan with its operational characteristics, etc.)

5.4. In the case of accepted lots, the notified body shall affix, or cause to be affixed, its identification symbol to each product and shall draw up a written certificate of conformity relating to the tests carried out. All products in the lot may be put on the market except those products from the sample which were found not to be in conformity.

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

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

5.5. The manufacturer or his authorized representative shall ensure that he is able to supply the notified body's certificates of conformity on request.

Module G (unit verification)

1. This module describes the procedure whereby the manufacturer ensures and declares that the product concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of the directive that apply to it. The manufacturer shall affix the CE mark to the product and draw up a declaration of conformity.

2. The notified body shall examine the individual product and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, to ensure its conformity with the relevant requirements of the directive.

(*) The manufacturer's discretion may be limited in the specific directives.
(**) The specific directives may alter this period.

The notified body shall affix, or cause to be affixed, its identification symbol on the approved product and shall draw up a certificate of conformity concerning the tests carried out.

3. The aim of the technical documentation is to enable conformity with the requirements of the directive to be assessed and the design, manufacture and operation of the product to be understood (*).

Module H (full quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned satisfy the requirements of the directive that apply to them. The manufacturer shall affix the CE mark to each product and draw up a written declaration of conformity. The CE mark shall be accompanied by the identification symbol of the notified body responsible for the surveillance as specified in point 4.

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing 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.

   The application shall include:

   — all relevant information for the product category envisaged,

   — the quality system's documentation.

   3.2. The quality system shall ensure compliance of the products with the requirements of the directive 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 ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

   It shall contain in particular an adequate description of:

   — the quality objectives and the organizational 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 standards referred to in Article 5 will not be applied in full, the means that will be used to ensure that the essential requirements of the directive 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 to monitor the achievement of the required design and product quality and the effective operation of the quality system.

(*) The content of the technical documentation shall be laid down directive by directive in accordance with the products concerned. As an example, the documentation shall 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 standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in Article 5 have not been applied,
— results of design calculations made, examinations carried out, etc.,
— test reports.

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 compliance with these requirements in respect of quality systems that implement the relevant harmonized standard (*).

The auditing team shall have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

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 out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body shall evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

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

4. *EC 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 allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection and 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 periodically (**) carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it shall provide the manufacturer with a visit report and, if a test has been caried out, with a test report.

5. The manufacturer shall, for a period ending at least 10 years (***) after the last product has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of the second subparagraph of point 3.1,

— the updating referred to in the second subparagraph of point 3.4,

— the decisions and reports from the notified body which are referred to in the final subparagraph of point 3.4, points 4.3 and 4.4.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (****).

(*) This harmonized standard shall be EN 29 001, completed if necessary to take into consideration the specificity of the products for which it is implemented.
(**) In the specific directives, the frequency may be specified.
(***) The specific directives may alter this period.
(****) The specific directives may provide for different arrangements.

Possible supplementary requirements:

Design examination

1. The manufacturer shall lodge an application for examination of the design with a single notified body.

2. The application shall enable the design, manufacture and operation of the product to be understood, and shall enable conformity with the requirements of the directive to be assessed.

   It shall include:

   — the technical design specifications, including standards, that have been applied,

   — the necessary supporting evidence for their adequacy, in particular where the standards referred to in Article 5 have not been applied in full. This supporting evidence shall include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf.

3. The notified body shall examine the application and where the design meets the provisions of the directive that apply to it shall issue an EC design examination certificate to the applicant. The certificate shall contain the conclusions of the examination, conditions for its validity, the necessary data for identification of the approved design and, if relevant, a description of the product's functioning.

4. The applicant shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where such changes may affect the conformity with the essential requirements of the directive or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC design examination certificate.

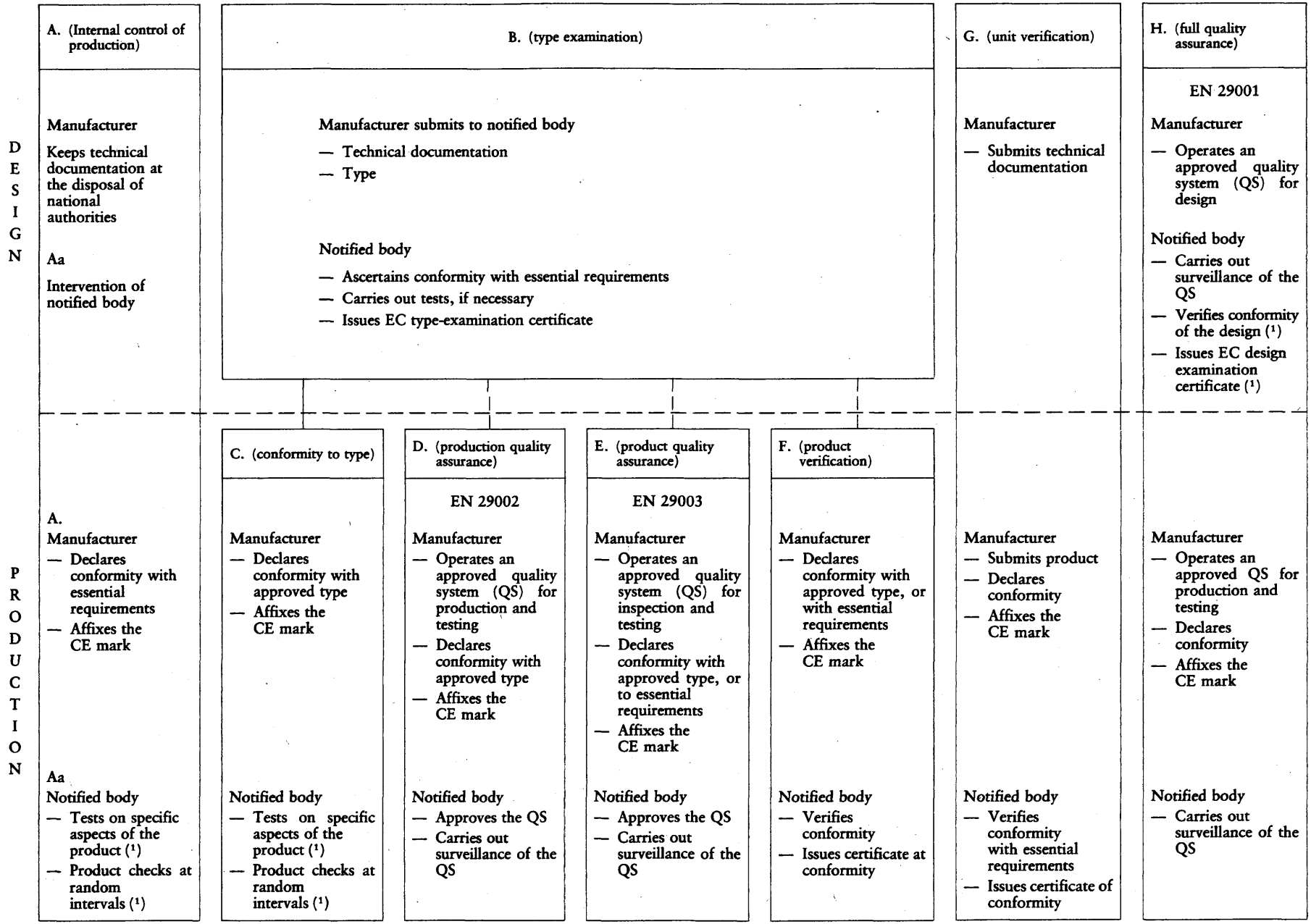
5. The notified bodies shall forward to the other notified bodies the relevant information concerning:

   — the EC design examination certificates and additions issued,

   — the EC design approvals and additional approvals withdrawn (*).

(*) The specific directives may provide for different arrangements.

CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION



(1) Supplementary requirements which may be used in specific directives.