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(Information)

COMMISSION

Ecu (1)

7 September 1989

(89/C 231/01)

Currency amount for one ecu:

Belgian and Luxembourg franc con.	43,4382	Spanish peseta	129,529
Belgian and Luxembourg franc fin.	43,5034	Portuguese escudo	173,408
German mark	2,07716	United States dollar	1,04375
Dutch guilder	2,34092	Swiss franc	1,79368
Pound sterling	0,676003	Swedish krona	6,98998
Danish krone	8,06504	Norwegian krone	7,55256
French franc	6,99781	Canadian dollar	1,23601
Italian lira	1489,32	Austrian schilling	14,6229
Irish pound	0,778161	Finnish markka	4,67599
Greek drachma	178,794	Japanese yen	153,556
		Australian dollar	1,37191
		New Zealand dollar	1,76996

The Commission has installed a telex with an automatic answering device which gives the conversion rates in a number of currencies. This service is available every day from 3.30 p.m. until 1 p.m. the following day.

Users of the service should do as follows:

— call telex number Brussels 23789;

— give their own telex code;

— type the code 'cccc' which puts the automatic system into operation resulting in the transmission of the conversion rates of the ecu;

— the transmission should not be interrupted until the end of the message, which is marked by the code 'ffff'.

Note: The Commission also has an automatic telex answering service (No 21791) providing daily data on calculation of monetary compensatory amounts for the purposes of the common agricultural policy.

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(1) Council Regulation (EEC) No 3180/78 of 18 December 1978 (OJ No L 379, 30. 12. 1978, p. 1), as amended by Regulation (EEC) No 2626/84 (OJ No L 247, 16. 9. 1984, p. 1).

Council Decision 80/1184/EEC of 18 December 1980 (Convention of Lomé) (OJ No L 349, 23. 12. 1980, p. 34).

Commission Decision No 3334/80/ECSC of 19 December 1980 (OJ No L 349, 23. 12. 1980, p. 27).

Financial Regulation of 16 December 1980 concerning the general budget of the European Communities (OJ No L 345, 20. 12. 1980, p. 23).

Council Regulation (EEC) No 3308/80 of 16 December 1980 (OJ No L 345, 20. 12. 1980, p. 1).

Decision of the Council of Governors of the European Investment Bank of 13 May 1981 (OJ No L 311, 30. 10. 1981, p. 1).

Commission communications pursuant to Council Regulation (EEC) No 4257/88 of 19 December 1988, applying generalized tariff preferences for 1989 in respect of certain industrial products originating in developing countries

(89/C 231/02)

Within the framework of the provisions of Council Regulation (EEC) No 4257/88 of 19 December 1988 (OJ No L 375, 31. 12. 1988) the Commission informs that the following quotas have been used up after the obligatory returns have been actioned:

Order No	Description	Country of origin	Quota amount (in ECU)	Date of exhaustion
10.0970	Padlocks and locks, of base metal	Hong Kong	1 314 000	16. 8. 1989
10.1053	Records, tapes and other recorded media for sound or other similarly recorded phenomena	Hong Kong	6 000 000	17. 8. 1989

Pursuant to Article 4 (1) of Council Regulation (EEC) No 4257/88 of 19 December 1988 (OJ No L 375, 31. 12. 1988) the Commission gives notice that the following fixed duty free amounts have been used up:

Order No	Description	Country of origin	Duty free amount	Date of exhaustion
10.0150	Hydroquinone (ethanediol)	China	700 000	9. 8. 1989
10.1110	Thermonic, cold cathode or photocathode valves and tubes	Hong Kong	530 000	16. 8. 1989
	Diodes, transistors, and similar semiconductor devices light emitting diodes			
	Electric integrated circuits and microassemblies			

II

(Preparatory Acts)

COMMISSION

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

COM(89) 209 final — SYN 208

(Submitted by the Commission on 15 June 1989)

(89/C 231/03)

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,

in cooperation with the European Parliament,

Having regard to the opinion of the Economic and Social Committee,

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

HAS ADOPTED THIS DECISION:

Sole Article

The modules for the various phases of 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 those listed in the Annex to this Decision and in accordance with the criteria set out therein.

ANNEX

CONFORMITY ASSESSMENT PROCEDURES IN THE TECHNICAL HARMONIZATION DIRECTIVES

I. General guidelines

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

(a) the essential objective of a conformity assessment procedure is to give to the users, consumers and public authorities, the assurance that products placed on the market conform to the various requirements expected of them as these are expressed in the provisions of the Directives;

(b) conformity assessment can be subdivided into modules which relate to the control of the design phase of products or to the control of their production phase; in certain specific cases these two functions are so inseparable they must be combined to constitute a module (e.g. modules A, G and H);

(c) as a generale rule a product should undergo a control in 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 acceptable 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;

(f) the Directives will set out the requirements governing the conditions in which the manufacturer makes his choice as to the most appropriate modules for his production;

(g) the Directives should, 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 an acceptably high level of protection, as laid down by the essential requirements; the Directives should avoid imposing unnecessary modules which would be too onerous relative to the objectives of the Directive concerned;

(h) notified bodies should be encouraged, whenever possible, to apply the modules without undue burden for the economic operators in order to ensure consistent interpretation and application of the modules. The European Organization for Testing and Certification or, in its absence, the Commission will organize close cooperation between the notified bodies;

(i) whenever Directives provide the possibility for the manufacturer to use quality assurance techniques, they must also wherever possible provide for the possibility of recourse to product certification;

(j) for the purposes of operating the various modules, Member States shall notify only competent bodies which comply with the requirements of the Directives; bodies accredited to apply the EN 45 000 series or which can produce documentary evidence that they conform to the EN 45 000 series shall be considered to conform to the requirements of the Directives. Member States which do not notify accredited bodies shall be invited to produce the documentary evidence that they conform to the requirements of the Directive;

(k) lists of notified bodies shall be published by the Commission in the OJEC and constantly updated;

(l) the CE mark (accompanied, wherever appropriate, by the identification symbol of the third party involved in the control of the production phase) shall be affixed to show that the production phase has been carried out satisfactorily only having regard to the requirements of the Directives.

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 of the Council resolution of 7 May 1985 (OJ No C 136 of 4 June 1985 p. 1), and which have become standard articles in the New Approach Directives.

The development of computerized telecommunications as a means of publication of certificates issued by notified bodies is envisaged within INSIS.

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

Modules C and D are designed to be used in combination with module B (EC type examination). Modules 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

EC DECLARATION OF CONFORMITY

1. The EEC declaration of conformity is the procedure whereby the manufacturer or his authorized representative established within the Community 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 within the Community shall keep it for a period ending at least 10 years (1) 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. The technical documentation shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of the directive.

   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 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 paragraph 2 and with the requirements of the directive that apply to them.

(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 (2). The tests shall be carried out in the presence of a notified body, chosen by the manufacturer, or by that notified body.

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 production output 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 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).

MODULE B

EC TYPE EXAMINATION

1. The EC type examination is that part of the procedure by which a notified body ascertains and attests that a specimen, representative of the production planned, meets the provisions of the directive that apply to it.

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

   The application shall include:

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

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

   — the technical documentation, as described in paragraph 3.

   The applicant shall place at the disposal of the notified body a specimen, representative of the production envisaged and hereinafter called 'type' (3). The notified body may request further specimens if needed for carrying out the test programme.

3. The technical documentation shall enable understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of the directive.

   The documentation shall contain so far as relevant for assessment:

   — a general description of the type,

   — 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 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 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 elements 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 been applied effectively;

   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.

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

6. The applicant shall keep the notified body that has issued the EC type examination certificate informed of any modification to the approved product.

   Modifications to the approved product must receive additional approval from the notified body that issued the EC type examination certificate 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 publish periodically the relevant information concerning

   — the applications for EC type examination received,

   — the EC type examination certificates and additions issued,

   — the EC type examination certificates and additions refused,

   — the EX type examination certificates and additions 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.

MODULE C

EC DECLARATION OF CONFORMITY TO TYPE

1. This declaration of conformity is that part of the procedure whereby the manufacturer 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.

2. The manufacturer shall take all measures necessary in order that the manufacturing process shall ensure 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.

(Possible supplementary requirements)

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 production output 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 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).

MODULE D

EC DECLARATION OF CONFORMITY TO TYPE (Production Quality Assurance)

1. This declaration of conformity is that part of the procedure whereby the manufacturer who satisfies the obligations of paragraph 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 EC surveillance.

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 EC surveillance as specified in paragraph 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,

— an undertaking to carry out the obligations arising from the quality system as approved,

— an undertaking to maintain the quality system as approved to ensure its continuing suitability and effectiveness,

— 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. This quality system documentation shall ensure a common understanding of the 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 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 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 paragraph 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard (4).

The assessment 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 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.

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

4. **EC surveillance**

4.1. The purpose of EC 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.

4.3. The notified body shall periodically (5) 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 full or reduced audits may be carried out by the notified body. The notified body shall provide a visit report and, if applicable, an audit report to the manufacturer.

5. Each notified body shall publish periodically the relevant information concerning the quality system approvals issued and withdrawn.

MODULE E

EC DECLARATION OF CONFORMITY (PRODUCT QUALITY ASSURANCE) (6)

1. This declaration of conformity is that part of the procedure whereby the manufacturer who satisfies the obligations of paragraph 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 EC surveillance.

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 EC surveillance as specified in paragraph 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,

— an undertaking to carry out the obligations arising from the quality system as approved,

— an undertaking to maintain the quality system as approved to ensure its continuing suitability and effectiveness,

— 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 an 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.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with these requirements in respect of quality systems that implement the relevant harmonized standard (7).

The assessment 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 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**

4.1. The purpose of EC 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 (8) 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 full or reduced audits may be carried out by the notified body. The notified body shall provide a visit report and, if applicable, an audit report to the manufacturer.

5. Each notified body shall publish periodically the relevant information concerning the quality system approvals issued and withdrawn.

MODULE F

EC VERIFICATION (6)

1. The EC verification is that part of the procedure whereby a notified body checks and attests 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.

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.

3. The EC verification may be carried out, at the choice of the manufacturer, by examination and testing of every individual product as specified in paragraph 4, or by examination and testing of the products on a statistical basis as specified in paragraph 5 (9).

4. **Verification by examination and testing of every individual 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 the CE mark to each approved product and draw up a written certificate of conformity. The CE mark shall be accompanied by the identification symbol of the notified body.

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 homogeneity of each lot produced.

5.2. If appropriate the manufacturer may affix the CE mark to each product ([10]) during the manufacturing process. The CE mark shall be accompanied by the identification symbol of the notified body responsible for the statistical verification.

5.3. 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 relevant requirements of the directive and to determine acceptance or rejection of the lot.

5.4. 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).

5.5. If a lot is accepted the notified body shall draw up a written certificate of conformity. All products in the lot may be put on the market except those products from the sample that 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.

MODULE G

EC UNIT VERIFICATION

1. The EC unit verification is the procedure whereby a notified body checks and attests that the product concerned is in conformity with the requirements of the directive that apply to it. The notified body shall affix the CE mark to the product and draw up a written certificate of conformity. The CE mark shall be accompanied by the identification symbol of the notified body.

2. The 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 to ensure its conformity with the relevant requirements of the directive.

3. Technical documentation shall be made available to the notified body and shall contain, so far as relevant for the 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.

MODULE H

EC DECLARATION OF CONFORMITY (FULL QUALITY ASSURANCE)

1. This declaration of conformity is 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 EC surveillance.

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing as specified in paragraph 3 and shall be subject to EC surveillance as specified in paragraph 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,

— an undertaking to carry out the obligations arising from the quality system as approved,

— an undertaking to maintain the quality system as approved to ensure its continuing suitability and effectiveness.

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 means to monitor 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 is satisfies the requirements referred to in paragraph 3.2. it shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonized standard ([11]).

The assessment 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 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**

4.1. The purpose of EC 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 af 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 ([12]) 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 full or reduced audits may be carried out by the notified body. The notified body shall provide a visit report and, if applicable, an audit report to the manufacturer.

5. Each notified body shall publish periodically the relevant information concerning the quality system approvals issued and withdrawn.

(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 understanding of the design, manufacture and operation of the product, and shall enable assessment of conformity with the requirements of the directive.

   Is 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 is 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 publish periodically the relevant information concerning

   — the applications for EC design examination received,

   — the EC design examination certificates and additions issued,

   — the EC design examination certificates and additions refused,

   — the EC design examination certificates and additions withdrawn.

Footnotes

(1) Specific directives may change this period.

(2) If this option is used in a specific directive the products concerned shall be specified, together with the tests to be carried out.

(3) A type may cover several product variants provided that the differences between the variants do not affect the level of safety and other performance requirements of the product.

(4) This harmonized standard shall be EN 29002, completed if necessary to take into consideration the specificity of the products for which it is implemented.

(5) In specific directives the periodicity may be specified.

(6) When this module is used without module B:

— it shall be completed (between paragraphs 1 and 2) by paragraphs 2 and 3 of module A, to introduce the need for technical documentation,

— the text in brackets shall be deleted.

(7) This harmonized standard shall be EN 29003, completed if necessary to take into consideration the specificity of the products for which it is implemented.

(8) In specific directives the periodicity may be specified.

(9) In specific directives the choice of the manufacturer may be limited.

(10) Specific directives may specify that the CE mark shall be affixed by the notified body.

(11) This harmonized standard shall be EN 29001, completed if necessary to take into consideration the specificity of the products for which it is implemented.

(12) In specific directives the periodicity may be specified.

III

(Notices)

COMMISSION

Notice of invitation to tender for the refund for the export of rye to the countries of zones I, II, III, IV, V, VI, VII, VIII, the German Democratic Republic and the Canary Islands

(89/C 231/04)

I. Subject

1. Tenders are invited for the refund for the export to third countries of rye falling within CN code 1002 00 00.

2. The total quantity in respect of which there may be fixed a maximum export refund as provided in Article 5 (1) of Commission Regulation (EEC) No 279/75 (1), as last amended by Regulation (EEC) No 2788/86 (2), is approximately 200 000 tonnes.

3. The invitation to tender will be conducted in accordance with the provisions of:

   — Council Regulation (EEC) No 2746/75 of 29 October 1975 (3),

   — Commission Regulation (EEC) No 279/75 of 4 February 1975,

   — Commission Regulation (EEC) No 2709/89 of 7 September 1989 (4).

II. Time limits

1. The period for the receipt of tenders for the first of the weekly awards will begin on 8 September 1989 and will expire at 10 a.m. on 14 September 1989.

2. For the subsequent weekly awards, the period for the receipt of tenders will expire at 10 a.m. on the Thursday of each week, except during the periods 27 October to 2 November 1989, 22 to 28 December 1989, 6 to 12 April 1990 and 18 to 24 May 1990, during which periods the invitation to tender will be suspended.

   For the second and subsequent weekly awards, the period for the receipt of tenders will begin on the first working day following the expiry of the preceding period.

3. This notice is published only for the purposes of the present invitation to tender. Until such time as it is amended or replaced, its terms will apply to each weekly award held during the period of validity of this invitation.

III. Tenders

1. Tenders must be submitted in writing and may be delivered personally against a receipt or sent by registered post or by telex, telefax or telegram, but must in any event arrive not later than the time and date indicated in heading II above at one of the following addresses:

   — Bundesanstalt für landwirtschaftliche Marktordnung (BALM), D-6000 Frankfurt am Main, Adickesallee 40 (telex 4-11475, 4-16044; telefax 1564-651),

   — Office national interprofessionnel des céréales, 21 avenue Bosquet, F-75326 Paris, Cedex 07 (telex Ofible A 27807 F; telefax 45519099),

   — Ministero per il comercio con l'estero, direzionale generale import-export, divisione II, viale Shakespeare, I-00100 Roma (telex Mincomes 61 083, 610471; telefax 5926217),

   — Hoofdproduktschap voor Akkerbouwprodukten, Stadthoudersplantsoen 12, NL-2517 JL Den Haag (telex Hovakker 32 579; telefax 461400),

   — Office belge de l'économie et de l'agriculture (OBEA) / Belgische Dienst voor Bedrijfsleven en Landbouw (BDBL), rue de Trèves 82 / Trierstraat 82, B-1040 Bruxelles/Brussel (telex Obea 24 076; 65 567, telefax 2302533),

   — Intervention Board for Agricultural Produce, Fountain House, 2 Queens Walk, UK-Reading RG1 7QW, Berks (telex 848 302; telefax 583626),

   — The Department of Agriculture and Fisheries, Cereals Division, Agriculture House, Kildare Street, IRL-Dublin 2 (telex Agri EI 5118; telefax 616263),

   — Direktoratet for Markedsordningerne, Frederiksborggade 18, DK-1360, København K (telex 15 138 DK; telefax 926948),

(1) OJ No L 31, 5. 2. 1975, p. 8.
(2) OJ No L 257, 10. 9. 1986, p. 32.
(3) OJ No L 281, 1. 11. 1975, p. 78.
(4) OJ No L 262, 8. 9. 1989, p. 15.

— Service d'économie rurale, office du blé, 113-115 route de Hollerich, L-1741 Luxembourg (telex Agrim Lux 2537; telefax 450178),

— YDAGEP, 241 Acharnon Street, GR-10446 Athens (telex 221 734 ITAG GR),

— Servicio Nacional de Productos Agrarios (SENPA) C/Beneficencia 8, Madrid 28004 (telex 41818, 23427 SENPA E; telefax 5219832, 5224387).

Tenders not submitted by telex or telegram must be enclosed in a sealed envelope marked: 'Tender under invitation to tender for the refund for the export of rye to the countries of zones I, II, III, IV, V, VI, VII, VIII, the German Democratic Republic and the Canary Islands — Confidential', itself enclosed in a further sealed envelope addressed as above.

Once submitted, no tender may be withdrawn before the Member State concerned has informed the tenderer of the result of the tender.

2. Every tender and the accompanying proof and undertaking mentioned in Article 2 (3) of Regulation (EEC) No 279/75 must be in the official language, or in one of the official languages, of the Member State of the competent authority to which it is submitted.

IV. **Security for tender**

The security for tender must be made out in favour of the competent authority concerned.

V. **Award of contracts**

The award will:

(a) give the party concerned the right to be issued, in the Member State in which the tender was submitted, with an export licence for the quantity in question indicating the export refund specified in the tender;

(b) oblige the party concerned to apply in the Member State mentioned in (a), for an export licence for that quantity.