

GENERAL AGREEMENT ON TARIFFS AND TRADE

Committee on Technical Barriers to Trade

ACTIVITIES OF REGIONAL BODIES IN THE FIELD
OF TESTING AND INSPECTION

Note by the Secretariat

1. At its meeting of 6-10 May 1985, the Committee requested the secretariat to prepare a note on the activities of regional bodies in the field of testing and inspection. The present note describes the operation of the following main systems and arrangements: CENELEC Electronic Components Committee (CECC) System (pages 1-4); the EFTA Arrangements for the Reciprocal Recognition of Tests and Inspections (pages 5-9); the Nordic Certification System of Products in Conformity with Harmonized Standards (INSTA) (pages 9-10); and the Nordic Co-operation Body for Technical Testing (NORDTEST) (pages 10-11).

2. Previous notes by the secretariat on regional standards-related activities have been circulated in the following documents:

- "Regional Standards-Related Activities" (TBT/W/30 and Corr.1 to 3) includes information on membership, publications, activities and operating rules of ASMO, ASEAN, CMEA, UN/ECE, EFTA, EPPO, OECD, ESCAP, ARSO, CEN, CENELEC, CEE/Arnhem, INSTA, PASC and COPANT and a list of other regional standards organizations.
- "Regional Standards-Related Activities" (TBT/W/42 and Add.1, Add.2 and Corr.1, Add.3, Add.4, Add.5 and Suppl.1 and Add.6) includes replies to a number of agreed questions by UN/ECE, CENELEC, INSTA, PASC, EFTA, COPANT and CEN.
- "Testing and Inspection" (TBT/W/43) includes information on the relevant activities of UN/ECE and OECD.

THE CENELEC ELECTRONIC COMPONENTS COMMITTEE (CECC) SYSTEM

A. History and composition

3. The Electronic Components Committee (CECC) was founded by CENEL (The European Committee for Electrotechnical Standardization) in 1970 on the initiative of certain European countries. A new European Committee for Electrotechnical Standardization, CENELEC, took over the prerogatives of CENEL vis-à-vis the CECC when it was set-up on 1 January 1973 to cover the extension of the European Economic Community. The legal status of CECC was changed by a decision of the CENELEC General Assembly in January 1984 which established a non-profit making entity under the German law, called "Förderverein für Elektronische Normung" (FEN) e.v. and designated the CECC

as a committee of the FEN.¹ The actual work on the harmonization of specifications etc. has been delegated by the FEN General Assembly to the CECC. An independent international body called the Electronic Components Quality Assurance Committee (ECQAC) is responsible for supervising the uniform application by its members of the quality assessment procedures of the CECC System. The joint activities of the FEN with its Committee, the CECC, together with ECQAC are called "the CECC System".

4. The objective of the FEN is to facilitate international trade by the harmonization of specifications and quality assessment procedures for electronic components and by the grant of an internationally recognized mark and/or certificate of conformity. Its basic aim is to enable electronic components produced under this System which are accepted in the country of origin, to be equally accepted in other member countries without further testing.

5. The member countries of the CECC System are Austria, Belgium, Denmark, Finland, France, Federal Republic of Germany, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom (2 member institutions).

6. The System is organized at national level as follows: a national organization established to coordinate the activity for the quality assessment of electronic components assumes four functions which are fulfilled by relevant bodies as follows: a National Authorized Institution (ONH) authorized to act as management of the System on the national level; a National Standards Organization which prepares and issues national standards, etc; a National Supervising Inspectorate (ONS) which supervises all testing and inspection necessary for the System, and the employment of the Mark, and/or Certificate, of Conformity with the country; a National Calibration Service which is responsible for the periodic verification of the measurement standards.

7. The highest authority in the CECC is the Management Committee (CD) in which all members (currently 15) are represented (one vote per member). It meets twice a year. The President and Vice-President (at the same time being the Chairman and Vice-Chairman of the FEN) are elected for an (overlapping) period of 3 years by the FEN General Assembly.

B. Membership

8. Every member of CENELEC may become a candidate for membership of the FEN with full participation in the CECC and the possibility of full or consulting participation in the ECQAC. Any decision to extend the membership of the FEN to a country which is not a member of the CENELEC, is a prerogative of the FEN who consults the CENELEC in this matter.

¹The Internal Regulations of the FEN are in the process of being drafted to reflect the modifications to the Basic Rules and the Rules of Procedures of the CECC. The final version will be voted by FEN members before its publication.

C. Access

9. Until now there has been no request for access from a supplier of a country which is not a member of CECC. In theory, an authorized inspector from a CECC member country could visit a supplier from a non-member country, if the supplier concerned would ask for it.

D. Operation

10. The principles of harmonization of specifications as well as the principles of harmonization of quality assessment are set out in the draft Internal Regulations of the FEN.

(a) Specifications

11. Specifications are prepared and approved by the CECC¹ in the following way:

12. When a member (ONH) wishes the CECC to start work in a field of activity not yet covered by an existing Working Group (WG) it shall send a written proposal to the General Secretariat. The latter shall circulate it to all ONHs not later than two months before a Management Committee (CD) meeting. If the CD then decides positively, the responsibility for the work of the new WG is delegated to an ONH which shall nominate a Chairman and Secretary and shall also provide all the necessary facilities for the work. The term of office of these two officers is not limited in the Rules of Procedure (RP). Each member ONH may nominate preferably not more than two experts as members of that WG.

13. Where the task (as approved by the CD) of a WG refers to specifications, then the WG shall be responsible for the preparation and maintenance of CECC basic, generic, sectional and blank detail specifications, and harmonization documents. They shall be based, in general, on IEC or ISO publications or drafts (the acceptance of which is considered probable). A WG may also prepare and maintain detailed specifications.

14. Once the WG has reached sufficient agreement on a draft specification, the document (in at least two of the 3 languages (French, German and English) shall be circulated by the General Secretariat to all ONH for voting (four months' rule). At the end of the voting period, the WG Chairman prepares a report on the voting (RV) and makes a proposal on the action to be taken. This document is circulated by General Secretariat to all ONH asking to comment within eight weeks. If no such comments are received the President may ratify the document and authorize the General Secretariat to publish it.

15. When more than two negative votes on the draft have been received the WG Chairman and Secretary may prepare an amendment (to be circulated under eight weeks' rule procedure), or propose in the RV an amendment which will reverse one or more negative votes (without affecting the positive ones) or refer the

¹ A list of CECC specifications is available in the secretariat for reference.

draft back to the WG. (At such a meeting the WG members shall represent their ONH). If there are no more than two ONH voting negatively, the result of the voting shall be considered as favourable.

16. An ONH may implement a CECC specification at national level by endorsing it or by publishing a national specification which is identical with the CECC specification.

(b) Quality Assessment

17. The harmonization of quality assessment procedures within the System is effected as follows: concerning approval of manufacturers, of distributors and of independent test laboratories, when a manufacturer wishes to have recognized his ability to produce and deliver components to a CECC specification, he applies to the ONH in his country for Manufacturers' Approval. The ONH then requests the relevant ONS to carry out this task in accordance with the Rules of Procedure. The manufacturer thereby appoints in his organization a Chief Inspector who shall be personally acceptable to the ONS as both technically and administratively qualified to control the inspection of the components. Similar procedures exist, mutatis mutandis, for the approval of distributors and independent test laboratories.

18. Having obtained a manufacturers' approval, the manufacturer may then apply for Qualification Approval or Capability Approval for a specified (range of) component(s). The relevant ONS verifies whether the requirements as laid down in the Rules of Procedure and specifications are met and periodically verifies that these conditions continue to be met. Components shall then be unambiguously identified by a mark, or certificate of conformity, the affixing or issue of which is under the surveillance of the ONS. It means that the components have been released in accordance with the requirements of the relevant specification.

19. Provisions are made in the Rules that a manufacturer may have his approval extended to cover a factory of his company, located in a country which does not have an approved ONS, whether this country is a CECC member country or not. These requirements generally include that the "original" factory is capable of making similar components and that the specifications clearly specify that either the primary stage of manufacture (e.g. the diffusion of semi-conductor crystals) or any specific subsequent stages (e.g. the assembly of semi-conductor crystals) may be performed in a factory other than the approved one.

EFTA ARRANGEMENTS FOR THE RECIPROCAL RECOGNITION OF TESTS AND INSPECTIONS

20. The 1968 Ministerial meeting of the European Free Trade Association (EFTA) in London decided to sponsor arrangements for mutual recognition of tests and inspections. The relevant schemes and conventions which have been drawn up by EFTA since then are, however, neither part of EFTA itself, nor dependent on the Stockholm Convention. Each is an international arrangement with an independent existence, open to all countries which have comparable testing facilities. The membership of the schemes are composed of competent testing and inspection authorities, whether or not they are government bodies, whereas the signatories of conventions are governments. Secretariat services for these arrangements are provided by EFTA.

A. The Reciprocal Recognition Schemes

(a) Reciprocal recognition of tests and inspections carried out on pressure vessels.

21. The Scheme relating to pressure vessels has been in operation since 1 January 1971 between the national authorities responsible for the administration of regulations concerning the testing, inspection and approval of pressure vessels in Austria, Denmark, Finland, Iceland, Norway, Portugal, Sweden, Switzerland and the United Kingdom.

22. The Scheme provides for reciprocal recognition of tests and inspections on pressure vessels, i.e. any static or transportable vessel for use on land which is intended to contain a fluid - liquid, steam or gas - at a pressure greater than atmospheric pressure excluding those which upon failure may cause the release of radio-activity. The provisions of the Scheme can be applied once the design of and the calculations relating to particular vessels intended for export have been found acceptable by the authority responsible for approving pressure vessels in the importing country. Then the complete range of tests required, apart from any that are normally carried out on installations, can be delegated to a testing body in the exporting country, provided that the testing body is recognized by the approval authority in the country to which the product is to be exported.

23. The list of competent testing bodies (Appendix 2 to the Scheme) which carry out activities under the Scheme in the participating countries are updated every five years.

(b) Reciprocal recognition of test and inspections carried out on ships' equipment.

24. In force since 1 January 1971, the Scheme relating to ships' equipment is in operation between the competent authorities of Denmark, Finland, the Federal Republic of Germany, Iceland, the Netherlands, Norway, Portugal, Sweden, the United Kingdom and Yugoslavia.

25. Since the entry into force of the Scheme, the participating authorities have worked to establish common requirements for any equipment for ships, that are now in force for lifeboat engines, electro-hydraulic steering gear

for passenger ships, the design and construction of lifeboat davits and winches, glass-fibre reinforced plastic lifeboats, inflatable life-rafts, lifeboat covers (canopies), non-portable fire extinguishers, compasses, pilot hoists, (performance standards), self-contained breathing apparatus for the use of firemen in ships, totally enclosed lifeboats, gangways and accommodation ladders including platforms, life-jackets, type testing of fire alarm cabinets and electrical component parts for fire alarm and detection systems. Common requirements are being drafted for other items of ships' equipment such as double compartment inflatable work vests, hydrostatic release gear, thermal protective aids and immersion suits. These will be submitted to the participating authorities for their acceptance. In addition, the existing common requirements will be amended, where necessary, to take into account the more detailed testing requirements contained in the recent amendments of the International Maritime Organization to Chapter III of the International Convention for the Safety of Human Life at Sea, which are due to come into force of 1 July 1986.

(c) Reciprocal recognition of tests and inspections carried out on gas appliances

26. The Scheme relating to gas appliances covers tests and inspections of appliances and their accessories and fitting using town gas, natural gas or liquefied petroleum gas and which are subject to approval by a national authority.

27. The ten approval bodies participating in the Scheme which is in force since 1 August 1972 are from Austria, Denmark, Finland, Iceland, Italy, Norway, Portugal, Sweden, Switzerland and the United Kingdom.

28. Although few licences have been granted under the Scheme so far, in certain cases, foreign approval bodies have accepted national test reports in full or in part on the basis of the simplified approval procedure. In an attempt to facilitate the implementation of the Scheme, the approval bodies introduced in 1979 a more flexible procedure for the recognition of testing institutions for gas appliances.

(d) Reciprocal recognition of tests carried out on agricultural machines and tractors for operational safety and ergonomics and for road traffic safety

29. Competent authorities in Austria, Denmark, Finland, Norway, Portugal, Sweden, Switzerland and the United Kingdom participate in this Scheme which has been in operation since 1 September 1972.

30. The Scheme applies to any machine, implement or vehicle for use in agriculture, horticulture or forestry and to their accessories, though not to any electrical equipment, on condition that they are subject to approval by national authorities. Information has been exchanged on changes in national safety regulations for combine harvesters and for safety cabs and frames. This information is to serve as a basis for updating the consolidated lists of national safety requirements, which provide manufacturers with information on requirements in the export markets covered by the Scheme. Furthermore, areas in which there might be a possibility of harmonizing some of the

national requirements for certain components of self-propelled working machines such as excavators, earthmoving machinery, etc. are being identified, taking into account the standards already in existence or under preparation in the International Standardization Organization (ISO) and the Economic Commission for Europe (ECE).

(e) Reciprocal recognition of tests and inspections carried out on lifting appliances

31. This Scheme came into force on 1 January 1978 and is in operation in Austria, Finland, Iceland, Norway, Sweden and Switzerland. It covers tests and inspections made before exports of all kinds of lifting, handling, loading and unloading machinery, including building cranes, harbour cranes, travelling cranes, deck cranes, lifts for passengers or goods, escalators, ski lifts, mine lifts and fork lift trucks. It does not cover tests or inspections required after the installation of the equipment.

32. In 1982, a new clause was added to the Scheme requiring testing institutions recognized under it to insure against any liability arising from their tests.

(f) Reciprocal recognition of tests and inspections carried out on heating equipment using liquid fuel

33. In force since 1 January 1978, this Scheme is in operation in Austria, Finland, Iceland, Norway, Portugal, Sweden and Switzerland.

34. It covers any appliance subject to national approval that uses liquid fuel for heating purposes and thus applies to such products as oil burners, domestic boilers, air heaters and dryers, oil stoves with flue connection, portable heaters and portable cooking and lighting appliances.

(g) Reciprocal recognition of evaluation reports on pharmaceutical products

35. The Scheme for simplifying the procedures regarding registration of pharmaceuticals came into operation in 1979 between the pharmaceutical authorities of Austria, Finland, Norway, Sweden and Switzerland.

36. Initially an ad hoc group of experts appointed by the EFTA Councils identified the differences in the various national legal provisions and observed that all the work done by a national authority in connection with the registration of a pharmaceutical product had to be repeated in every other country where the product was registered. The present Scheme provides that once a product has obtained registration in one country, the registration authorities elsewhere can receive an "evaluation report" from the authority of first registration which contains the data supplied by the manufacturer, an evaluation by the authority, and its conclusions. The authority which has asked for the report can then accept all or part of the evaluation work already done.

B. The Reciprocal Recognition Conventions

(a) Convention on the control and marking of articles of precious metals

37. The Convention came into force in 1975 and is signed by Austria, Finland, Ireland, Norway, Portugal, Sweden, Switzerland and the United Kingdom. It is open to accession by all countries having arrangements for the assay and marking of articles made of precious metals, including gold, silver and platinum, necessary to comply with the requirements of the Convention.

38. The Assay Office in the exporting country tests the fineness of the precious metal or metals used and applies the following hallmarks: the Responsibility Mark consisting of an abbreviation or a symbol which is the registered mark of the sponsor of the article, usually the manufacturer; the Fineness Mark in accordance with the set standards of the Convention; the Common Control Mark instituted by the Convention with a different shape for each of the three metals; and the Assay Office Mark identifying the office and the country where the article was tested and marked. Articles marked with these symbols are accepted by any member country of the Convention without further testing and marking. These marks have the same legal standing as national hallmarks of the Convention members.

(b) Convention for the mutual recognition of inspections in respect of the manufacture of pharmaceutical products

39. The Convention came into force in 1971. At present its membership includes Austria, Denmark, Finland, the Federal Republic of Germany, Hungary, Iceland, Ireland, Liechtenstein, Norway, Portugal, Romania, Sweden, Switzerland and the United Kingdom.

40. The scope of the Convention covers inspection of the manufacture of pharmaceutical products, defined as any medicine or similar product intended for human use which is subject to control by health legislation in the manufacturing contracting state or in the importing contracting state and any ingredient which manufacturer uses in the manufacture of such products.

41. The inspection covers the process of manufacture of pharmaceuticals including personnel, premises and facilities, equipment, hygiene and manufacturing and control procedures. The inspections for product quality specifications and production control which are carried out in the country of manufacture are recognized by the importing countries. In terms of the Convention each participating authority has the right to ask the inspectors of the exporting country for information about the general standards of manufacturing capacity in a particular firm and the specific standards of manufacture and control of a given product.

C. Reciprocal Recognition of Tests of Electrical Equipment

42. This arrangement for mutual recognition in the electrical field is not a separate agreement among participating authorities, but one which operates by means of member states (EFTA countries and the United Kingdom) taking such

steps as are necessary for its implementation. It enables a manufacturer whose electrical equipment has received a certificate from a testing station in one member state to clear his product with this certificate through the testing authority in any other member state, to the extent that any of the tests carried out in the first station are in accordance with the testing requirements of the final station.

43. The arrangement came into operation in 1969, as a transitional measure until Certification Body (CB) procedure of the International Commission on Rules for the Approval of Electrical Equipment (CEE/Arnhem) was extended to a sufficient number of harmonized CEE specifications. In 1976, the EFTA Committee of Trade Experts agreed that the arrangement should continue unchanged and recommended that national administrations should remind the competent national authorities annually of its existence.

NORDIC CERTIFICATION SYSTEM OF PRODUCTS IN CONFORMITY WITH HARMONIZED STANDARDS (INSTA)

44. Each of the national standardization bodies in the Nordic countries excluding Iceland has a national third party certification scheme on products in conformity with harmonized standards. In 1977 these bodies agreed on a mutual certification procedure which can be implemented when two or more of the bodies have harmonized standards.

A. Certification

45. The Dansk Standardiseringsrad, the Finlands Standardiseringsförbund, the Norges Standardiseringsförbund and the Sveriges Standardiseringskommission, in-charge of the national certification system, respectively, in Denmark, Finland, Norway and Sweden, approve the administration of each others certification systems as well as mutually accept the inspection and test reports drawn up by recognized testing laboratories, including those from outside the Nordic countries. This certification system is based on type inspection, approval as well as continuous, external and internal quality inspection. It can be used in connection with national certification systems or as the Nordic certification system as such in which two or more of the above national bodies take part.

46. There is a set of special rules laid down for the certification of each product. For the time being the product certification schemes are in operation for protective helmets for industry, protective footwear, safe-storage units and protective helmets for road users.

B. Marking

47. A certified product can be marked with one of the following national conformity marks which has been registered with the Nordic standardization bodies: the DS mark (Denmark), the SFS mark (Finland), NS mark (Norway) and the SIS mark (Sweden). The national marks can be combined to form a Nordic mark and is used in connection with the certification of conformity with harmonized standards which have been approved as national standards in those countries whose marks form a part of the Nordic mark used.

C. Testing

48. If a type testing has been carried out, the application must be accompanied by a report drawn up by a recognized testing laboratory and which indicates that the requirements of the standard have been met. If an application has been submitted without a report indicating that the type testing has been passed, the national standardization body will have the type testing carried out and possibly also an inspection of the firm concerned.

D. Access

49. The Nordic certification system is open to everyone. Applicants in a Nordic country taking part in a certification system in accordance with the special rules of the system submit their application to the national standardization organization. Other applicants submit their application to one of the Nordic countries, which in turn ensures acceptance in any other Nordic country taking part in the system. Out of a total number of 80 licences, 22 are non-Nordic. Some of the Nordic licensees are also representing non-Nordic producers.

NORDIC CO-OPERATION BODY FOR TECHNICAL TESTING (NORDTEST)¹

50. The NORDTEST is a regional body concerned with technical testing. It was established in 1973 by the Nordic Council of Ministers and joined in by Denmark, Finland, Iceland, Norway and Sweden.

51. The main purpose of the NORDTEST is to save resources by common Nordic work on the development of testing methods, by reducing the total number of tests carried out within the Nordic countries and by the concentration of advanced testing methods to a limited number of testing laboratories within the Nordic countries; to facilitate trade between the Nordic countries by using common testing methods and common approval of test results within the Nordic countries; to provide the government authorities in the Nordic countries with testing methods which can be used for the formulation of Nordic or national technical regulations.

52. In order to achieve these objectives the NORDTEST has the function of developing, selecting, recommending and registering joint Nordic test methods which lead to appropriate and comparable results when testing materials, products, constructions, installations, and technical system and procedures; co-ordinating a series of activities and projects between the testing organizations in the Nordic countries; assuming the responsibility for a continuous exchange of information between these organizations including a documentation service and exchange of reports; and promoting common Nordic representation in the international co-operation activities on testing.

¹See also the presentation by the representative of NORDTEST at the fourteenth meeting of the Committee (TBT/M/14, Annex).

53. A NORDTEST publication entitled "the NORDTEST Guidelines for the Acceptance of Test Results" establishes a set of fundamental requirements to be observed by the testing laboratories and their staff. The observance of these guidelines enables the authorities in the participating countries to base their approval of an imported product on the test results which are documented in the form of a test certificate from the country of origin.

54. The activities of the NORDTEST are carried out by a board, a secretariat, internordic technical groups and supervisors of projects on development of test methods.

55. The technical groups appointed by the board are responsible, respectively, for testing standards in the fields of building materials and constructions, fire, acoustics and noise; non-destructive testing; testing of equipment for heating, plumbing and sanitation: electronic apparatus and equipment, consumer goods; mechanical and chemical testing concerning work environment.

56. The duties of technical groups include registration, each within its own sector, of test and control methods which are agreed to by the participating countries and evaluating the need for new methods; taking the initiative for recommending NORDTEST-methods within the relevant sectors; proposing NORDTEST projects and designating priority for any suggestions for projects, supervising project work and evaluating the results of completed projects; encouraging the use of NORDTEST methods and promoting the exchange of experience with such methods.

57. Existing test methods in the form of international or national standards or other documents which have been selected as NORDTEST methods are included in NORDTEST Register with information regarding the sources from where the descriptions of the tests methods are available. The methods are arranged under the heading of each technical field. The register can also include test methods which are included in the Nordic standards. A method which has not been published previously or which is a newly developed method resulting from a NORDTEST project, will either be published as an original NORDTEST method or as that of the institute which has carried out the project.