COMMISSION OF THE EUROPEAN COMMUNITIES

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HIGH TECHNOLOGY

AND

PRESTANDARDISATION

(Communication from the Commission)

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I. INTRODUCTION

With the prospect of a large unified Community market on the horizon for 1992, improvements in the efficiency and the competitiveness of the entire EC industry, including SMEs, becomes a key issue if the goal is to be achieved.

Because of fast technological and economic developments, science and technological development activities have to play an important strategic role, where standardisation, including prestandardisation is one of the essential prerequisites to reach that important goal of a large European Market.

Furthermore the importance of standardisation in this context goes beyond the frontiers of the Community as the problem of standardisation for High Definition Television (HDT) illustrates.

The importance of R&D in support of standardisation has always been recognised as illustrated by the fact that the selection criteria of the Framework programme 1987-1991 quite clearly and explicitly state that the actions should be chosen with regard to their contribution to the definitions or implementation of Community policies and, among others:

- research which contributes to the achievement of the Common Market and leading, where the need is felt, to the establishment of uniform technical specifications and standards

The Single Act also stresses in art. 130F the link between research and technological development and the need to exploit fully the potentials offered by the internal market by establishing Community Standards. Quite a number of Community policies gave rise to prestandardisation issues, linked to long standing Community R&D activities like nuclear safety, protection of the environment in which the JRC plays a growing role. Moreover with the mobilisation of ambitious R&D programmes, in this context both on national levels and with ESPRIT, BRITE, RACE etc. on the Community level as well, the relationship between such programmes and the European standardisation structures and procedures is becoming of increasing importance.

The relations between R&D programmes and the Community infrastructure for standardisation have also been examined recently within the context of Eureka.

The purpose of this document is in addition to the document provided by the German Presidency:

- to point out the vital role of European standardisation in the establishment of a large European market, to show that the already existing structures and procedures of the European Standards Institutions can meet the requirements of advanced technology and promote the timely transfer of research results through the activities of standardisation and prestandardisation to industry;
- to indicate the present role of Community R&D programmes and of the Joint Research Centre in supporting prestandardisation

- to indicate the possibilities for the reinforcement of prestandardisation activities with regard to the supporting role of
 - . the existing infrastructure Commission CEN/CENELEC
 - . the Joint Research Centre and
 - . cost shared programmes.

II. PROMOTION OF EUROPEAN STANDARDISATION

Economic integration in Europe is rapidly leading to a realisation of the importance of the role that standardisation has to play, not only in preventing and removing barriers to trade but also in enabling the advantages of a large European market to be turned to better account.

In order to solve the many technical harmonisation problems, it was necessary to set up a system of European Standardisation to provide harmonised standards capable also of meeting requirements for the approximation of law if the need arises.

The European Standards Institutions CEN and CENELEC, whose members are the national institutions of the European Community and EFTA, adopted statutory rules aimed at drafting of European standards and ensuring that they are implemented at national level. Furthermore, with European prestandards (ENV.), CEN/CENELEC introduced a new type of document which allows European standardisation to accommodate to the accelerated rhythm of technological evolution, particularly in the field of new technologies. (see annexe 1)

The overall framework for the activities of European standardisation and the cooperation between CEN/CENELEC and the European Community can be characterised by the following elements:

- The Directive of the Council 83/189 (1) laying down an information procedure in the field of standards set up an institutional and procedural framework to faciliate and accelerate standardisation at European level. The procedure which is managed for the Community and the EFTA countries by CEN/CENELEC, ensures the regular distribution to national standards organisations of information on the standards activities at national, European and International level. The procedure constitutes a valuable tool for identifying trends and for programming European harmonisation of standards. The Directive established a procedure allowing the Commission after consultation of Member States through the Committee on Standards and Technical Regulations to entrust the elaboration of particular European Standards and Prestandards to CEN/CENELEC.
- A new harmonisation strategy known as the "new approach" (2) has been defined which on the basis of essential requirements adopted by the Community legislator, assigns more directly to standards institutions the responsibility for the technical tasks falling to them in the field of harmonisation.

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- (1) Council Directive of 28 March 1983 laying down procedure for the provision of information in the field of technical standards and regulations (83/189/EEC) OJ L 109 of 16 April 1983.
- (2) Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards (85/C 136/O1) OJ C 136 of 4 June 1985

This new environment has therefore led to reconsider the standardisation process, not to reject standardisation which is needed more than ever, but to ensure that the structures and procedures are adapted to the requirements. Within such a context, prestandardisation which is part of the standardisation process, allows the consensus to be initiated at an early stage. It provides a prospective phase to consolidate the credibility of a proposal before its adoption.

b) Adaptation of European standardisation to advanced technology

The European prestandards (ENVs) constitute a useful instrument for launching prestandardisation activities at a very early stage, even at the phase of development of new products. European prestandards can be adopted easily and rapidly to take account of technological development due to the fact that they offer a series of procedural or status advantages and flexibilities (they are of an optional and transitional nature and limited to a period of 3 years, with the possibility to be prolonged once for 2 other years). Once the technology has reached a sufficient degree of stability, the prestandards should be converted into ordinary European Standards.

According to CEN/CENELEC Common Rules for standards work European prestandards (1) can be developed either by a technical body of CEN/CENELEC or, on the basis of an appropriate reference document from another body, such as a research centre or a professional federation adopted through the CEN/CENLEC voting procedure.

In essence it may be said that for prestandardisation related to high technology development

- there is no need for additional procedural and institutional provisions,
- there may well be a problem of management (workload and cost for increased prestandardisation activities) which the Community would have to address.

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(1) see enclosure 1: Preparation of European Prestandards (ENV) i.e. point 7 of CEN/CENELEC Common Rules for standards work / Edition 1; January 1988.

Contracts were concluded between the Commission and CEN/CENELEC as well as between EFTA and the aforementioned organisations. By this means, financial contributions can be granted for the work of European standardisation and prestandardisation in given areas. This is especially the case where the setting up of European standards is necessary in order to implement a Community policy e.g. in view of completing the Internal Market or of Community Policy in the field of information technology and telecommunications.

III. STANDARDISATION AND ADVANCED TECHNOLOGY

a) The need for prestandardisation

The importance of standardisation became apparent with the industrial development of the 19th century. obvious examples being an agreement on the railway gauge and the requirement for safety devices preventing the explosion of the steam vessels.

During many decades standardisation could be efficiently achieved by ensuring that good practices were progressively agreed and codified. Many of the standardisation procedures still take due account of such concrete needs.

The technological evolution has brought new requirements which correspond to radical changes.

- In many areas standards need to be agreed "ex ante" because of the complexity of systems which cannot be defined without prior agreement on the architectural rules. The use of advanced technology to exchange text or to control a manufacturing process requires some conventions on the organisation of such systems and illustrate this phenomenon.
- Any lack of agreement at the early stage leads to the implementation of diverging solutions and seriously hampers the chance to converge at a later stage; each party camps on the provisional solution and nobody is keen to scrap the existing investment.
- The complexity of the standards developed in advance justifies the need for verifying the practibility of the proposed solution. The natural distrust for a standard only available on paper has to be compensated by the credibility to be gained during the implementation and thus often requires a prospective stage which precedes the formal adoption of a standard.
- Many proposals for standards involve costly R & D work and consensus might require clarification of the intellectual or industrial property rights.
- Conversely, the results of R & D projects might not be properly exploited if their transfer to standardisation is not adequately organised to promote the right degree of consensus for a wider use of innovative concepts.

IV. THE SUPPORTIVE ROLE OF R & D

It is necessary to identify ways and means by which national Community and other international activities such as Eureka can support the establishment of standards at the earliest possible stage. This is particularly the case in high-technology areas such as:

- information technology
- communication technology
- public transportation technology
- environmental research and technology
- industrial production technologies (e.g. computer integrated manufacturing)
- advanced materials, such as advanced ceramics or composite materials
- optical engineering including lasers
- biotechnology and food technology
- membrane technology
- fracture mechanics technology

It was already stated that the existing institutions should be put into a position to fulfill the growing requests resulting from prestandardisation initiatives and that new structures should certainly not be created. However the Commission has identified a number of issues similar in nature to those in the Presidency paper and which need to be further developed.

Community Activity

In the frame of European Community R&D programmes activities, work related to prestandardisation has gained quite some momentum over the years—and there is considerable—development potential with regard to corresponding JRC activities as well as cost-shared actions.

With regard to cost-shared actions, prestandardisation activities in a larger sense are linked to the following programmes where CEN/CENELEC for the time being, have become active enly in-a few given areas (see annexe 2; but all programmes involving transfrontier co-operation can encourage standardisation).

Information Technologies and Telecommunications (ESPRIT and RACE)

The Commission has given a considerable number of standardisation mandates already to CEN/CENELEC for a number of subjects. Most of these activities have been based on available results of International work. The Community and EFTA give financial support for these activities through the arrangements outlined above. The aim of this support is to speed up prestandardisation and to allow full participation of competent experts.

Standardisation in information technology and telecommunications is a good example of the enterprise of the European standards institutions which have succeeded in adapting existing structures and procedures to an environment as specific as new technology.

The ESPRIT and RACE programmes are based on collaborative R&D, and some of the projects can play a significant role in paving the way to standards. The Commission encourages, eventually by the use of contractural clauses, the transfer of the results to the standardisation bodies, in a form which is suitable as a contribution to the relevant working groups.

The experience gained with the ESPRIT program has shown that many projects have already had a significant impact on the development of standards (office document architecture, advanced manufacturing technology) and this might be amplified with the ESPRIT II projects.

The challenge of RACE in the field of wide band communication is linked to the interaction between the design of wide band networks, the availability of new types of terminals and the provision of new services. Achieving a balance between so many parameters illustrates the need for a prospective stage which fits well with the concept of prestandardisation and which indicates that in such advanced fields no European contribution to world wide standardisation will achieve credibility if not backed up by a minimum of solid R & D work.

The same reasoning applies to the High definition television (HDTV) which is now calling for an efficient synergy between the initiatives and measures proposed by the Commission and the R & D efforts of EUREKA.

Community Bureau of Reference

The BCR deals essentially with improvement of measurements and many of its activities are related to existing standards when the laboratories face measurement difficulties.

The priorities selected for the programme are directly related to the present and immediate needs of harmonisation in view of the completion of the internal market. For example many topics already identified for future work concern the quality of products of agriculture and industrial commodities such as glass, textiles, metals, for which disputes due to measurements should be avoided.

If proposals are received for measurements related to high technology, they will be given special attention. The results of projects that could be undertaken for high technology measurements will be put at the disposal of CEN/CENELEC for prestandardisation.

<u>Nuclear Safety, Management and Disposal of Radioactive Waste, and Radioprotection</u>

Standards-related activity is being undertaken in the following areas:

- . Codes and standards for Fast Breeder Reactors
- . Safety of water cooled reactors
- . Activities with the European Safety and Reliability Association (FSRA)
- . Quality assurance and quality control in particular for alpha waste
- . Medical Diagnostic radiology
- . Dosimetry

Joint Research Centre

With regard to direct action, prestandardisation related activities are linked to a series of actions in the Joint Research Centre (JRC).

The JRC has an established position in prenormative R&D, both in the nuclear and the non nuclear field and as a contribution to the broad objectives of improving safety, the protection of the environment and improving the competitive basis of the European industry. Some illustrative examples are the following from the on-going work at the JRC establishments:

- prenormative R&D and metrology in the nuclear field (Geel and Karlsruhe Establishments)
- supportive R&D in relation to EC air pollution directives (Ispra establishment)
- . prenormative R&D for photovoltaics (Ispra Establishment)
- non-destructive evaluation techniques for heavy steel sections (PISC/Ispra establishment)
- . Prenormative R&D on high temperature materials (special alloys and ceramics/Petten establishment)

It is evident that all programmes involving transfrontier co-operation encourage standardisation and this aspect will even be more emphasised in future, already in the preparation of the new Brite-Euram programme. There has been an initiative to insist more on standards supportive R&D in general and more specifically for membranes and high tech materials, of which due account will be taken.

Another example is that interests are also voiced for prenormative and normative R&D in the field of "In vitro evaluation of the toxicity and pharmacological activity of molecules" and the Medical and Health Programme (prestandardisation for medical equipment).

In the context of <u>Eureka</u>, the Commission has launched a campaign aiming to make Eureka participants more aware of standardisation matters.

CEN/CENELEC organised on 3 March 88 on behalf of the Commission a seminar at which Eureka participants and standardisers were—brought together in order to explain how research results can be put into the standards-making process at a very early stage.

V. REINFORCING THE SUPPORTIVE ROLE OF R&D FOR PRESTANDARDISATION

The Commission has already insisted on the role played by standardisation in contributing to the achievement of a true internal market and in promoting a better exploitation of the results obtained for the various R&D programmes.

The Community has already acquired a long experience in this area which corresponds to the priorities of the Treaty.

The necessary structures and procedures to deal with prestandardisation are already available in Europe and the recent adaptions performed by the European standardisation bodies show that the requirements of new technology can be easily accommodated.

There is however a need, as indicated by the Memorandum to strengthen the use of the existing procedures in the field of R&D to enhance the support of prestandardisation activities.

A first essential step would be to carry out a survey of current or proposed R&D which has implications for pre-standardisation activity at national level in order to have a clearer picture of the areas in which there is potential interest in such R&D activities. As mentioned above, the Commission has very little information about what is going on at national level in this context, and the Member States should undertake to provide further information.

As for the promotion of use of existing structures and procedures for prestandardisation, one could envisage to propose that the following measures be undertaken immediately:

- (a) Early notification of the standardisation activities through national and European standard bodies should take account of the prestandardisation activities with a view to informing all interested parties through a wider circulation of the relevant information.
- (b) In national and Community R&D programmes one should use the contracts concluded to promote closer links between research work and prestandardisation, such as, for example, encouraging early notification of R&D results which might be appropriate for prestandardisation activity and establish for larger projects the nomination of a standardisation officer having both the insight into the project substance and into the standardisation structures and procedures.
- (c) Reinforce in cooperation with CEN/CENELEC the researchers' awareness of the importance of prestandardisation in accelerating the industrial development of new technologies.

This factual input - to be reviewed regularly - will contribute to develop a more and more consistent policy for optimising the feed-in from R&D programmes into prestandardisation and the early identification of needs for R&D support in national and Community R&D Programmes.

It could be envisaged to present a second and more complete report to the Council on this subject before the end of 1988. In this context it would also be desirable to draw on information provided by the Member States and by the Commission's industrial advisory committees. Into this report could be included recommendations about how to strengthen the supportive role of both cost-shared actions and of the Joint Research Centre.



Part 2: Common Rules for standards work

2ème partie:
Règles Communes
pour les travaux
de normalisation

Teil 2: Gemeinsame Regeln für die Normungsarbeit

PREPARATION OF EUROPEAN PRESTANDARDS (ENVI

7.1 <u>General</u>

// I fundered Prestandards (INV) may be established as a suspective standards for provisional application in technical fields where the immovation rate is high (eg Information Technology) or when there is an urgent need for guidance and primarily where aspects of safety for persons and goods are not involved.

They may be prepared in two ways :

a) through a technical body of CEN/CENELEC (either Technical Committee or working group).

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- b) through a questionnaire and voting procedure, based on any appropriate reference document.
- 7.1.2 The decision to prepare an ENV shall be made by the Technical Board or other body empowered by the General Assembly to make such a decisions.
- 7.1.3 Each ENV shall include a note or explanation of its status as a prospective standard for provisional application.

7.2 <u>Preparation by a technical body</u>

- 7.2.1 Delegations to technical bodies preparing ENV shall be briefed in order to take into account the views of all interests concerned in the individual countries represented by CEN/CENELEC members.
- 7.2.2 The technical body may vote only on the basis of documents which have been circulated to all CEN/CENELEC members at least two months prior to the meeting.
- 7.2.3 The technical body considers the comments received and establishes the final version of the ENV which is put to the vote in accordance with 5.1.4 at the same meeting; only delegations present may vote.
- 7.2.4 If approved, the ENV is immediately made available to the members by the Secretary General with the addition of an ENV title page giving all the necessary information.

7.3 Preparation through questionnaire procedure and voting

- 1.3.1 When an ENV is intended to be approved through a questionnaire and voting procedure, the distribution as prENV of the appropriate reference document to the members is made by the Secretary General.
- 1.3.2 Members are granted a <u>three</u> months term for consultation on national level and voting in accordance with 5.1.4.
- 7.3.3 Votes received are assessed by the Secretary General in consultation, if necessary, with the Technical Board or other body responsible. If approved for all members (see 5.1.5.1) or for members from EC countries (see 5.1.5.2), the ENV is immediately made available to the members by the Secretary General with the addition of an ENV title page giving all the necessary information.
- 7.3.4 If the ENV is not approved, the Technical Board or other body responsible may set up without delay if necessary by correspondence a technical body which will work according to 7.2.3.

7.4 Rejection

If in case of 7.2.3 (or 7.3.4 and subsequent action according to 7.2.3) the ENV is not approved, the President of CEN/CENELEC shall decide on further actions.

7.5 <u>Languages</u>

It is permissible to approve an ENV even if the text is first available in one of the official languages of CEN/CENELEC only, provided that it can be expected that users of the ENV are able to understand the text written in that language.

In any case, missing official language versions shall be established as quickly as possible in the usual way, if necessary through Comité de Lecture procedure (see 4.7).

7.6 <u>Implementation</u>

7.6.1 Members shall make the ENV available at national level in an appropriate form promptly and announce its existence in the same way as for EN/HD.

NOTE: Implementation of the ENV on national level may take the form, for example, of "Norme Expérimentale" in France, "Draft for Development" in the United Kingdom and "Vornorm" in Germany.

7.6.2 Existing conflicting national standards may be kept in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

7.7 Lifetime

The life of an ENV is first limited to three years. After two years the Secretary General shall take action by requesting members to send in comments on that ENV within six months. The comments received will be transmitted to the Technical Board for further action as follows:

- conversion into an EN after formal vote:

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- extension of the life of the ENV for another two years (once only); or
- replacement by a revised ENV approved in accordance with 7.2 or 7.3; or
- withdrawal of the ENV:

or

- assignment to a technical body of the task of helping the Technical Board to reach any of the decisions listed above.

Mandates given by the Commission to CEN/CENELEC for prestandardisation

Current CEN/CENELEC activities within the field of Information Technology and related areas.

Supervised by ITSTC (Information Technology Steering Committee) 1. (with CEN/CENELEC/CEPT representation)

- 1.1 File transfer Telematics Message Handling Terminal Support Remote Database Access Transaction Processing System Management
- 1.2 Document Transfer Formats

Data Stream Formats

Directories

1.3 Graphic Character Repetoires

Control Functions

1.4 ISDN

Telephonic Circuit Packet Switched Network Digital Data Circuit Local Area Networks

- 1.5 Relay Functions
- 1.6 Automatic Manufacturing Techniques (AMT) Architecture AMT Standard Parts Library AMT Mechanical Standards

2. Supervised by CEN

- 2.1 Programming Languages
- 2.2 Computer Graphics
- 2.3 Magnetic support media
- 2.4 Identification and banking cards
- 2.5 Operating systems (Unix)
- 2.6 Trade Data Interchange
- 2.7 CD-ROM

3. Supervised by CENELEC

- 3.1 Electrical installations of buildings3.2 Automatic controls for household appliances
- 3.3 Safety of telecommunications equipment
- 3.4 Electronic entertainment and educational systems for household and similar use.
- 3.5 Mains communication systems
- 3.6 MAC receiving equipment
- 3.7 ISPB, telecommunications equipment on customer premises
- 3.8 Radio interference
- 3.9 Electronics compatibility (EMC)
- 3.10 Cables and links for telecom purposes
- 3.11 Coaxial cables and fiber optics cables
- 3.12 Safety of telecommunications equipment
- 3.13 Mobile radio equipment
- 3.14 Alarm systems