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COMMUNICATION FROM THE COMMISSION
TO THE COUNCIL AND THE EUROPEAN PARLIAMENT
ON THE BROADER USE OF STANDARDIZATION IN
COMMUNITY POLICY

This Communication has been drawn up under the terms of the Strategic Programme for the Internal Market.

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COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND PARLIAMENT ON THE BROADER USE OF STANDARDIZATION IN COMMUNITY POLICY.

I. Introduction.

I.1 The purpose of this Communication

This Communication fulfils the undertaking given in the Strategic Programme to come forward with a report on the broader use of standardization in Community policy, for forwarding to the Council and the European Parliament. It is aimed at providing an overview of the existing position regarding the use of standards in the context of the policies of the European Union, and an outline of intentions for development of the role of standardization in the immediate future. It indicates possible future lines of development for the further application of standards in the short and medium term, and discusses both classical and newly developed applications of standardization.

Note: This Communication does not cover the results of the current review of ICT Standardization Policy. The corresponding analysis will be presented to the Council and the Parliament in a separate document.

I.2 The political context

The progressive setting up of a strong European standardization infrastructure and the establishment of clear rules for the functioning of European standardization have made possible a major role for European standardization in the development of the European regulatory system. This can be seen particularly in the context of the "New Approach", which, based on a clear separation of competences and responsibilities between the legislator and economic operators, marked a turning point in the development of Community regulatory policy.

In consequence, during recent years, the centre of gravity of standardization activities has shifted from the national level to the European level, and today by far most new activities concern European and international standards.

Given the importance of European standardization, the Commission published in January 1991 a **Green Paper on the development of European Standardization**.¹ This paper gave rise to an extensive debate, the results of which were summarised in the **Communication from the Commission on Standardization in the European Economy** of 16 December 1991.² On the basis of this Communication, the Council adopted, on 18 June 1992 a **Resolution**, in which it emphasized the strategic importance of standardization, confirmed a series of principles underlying European standardization,

1. COM (90) 456 final (OJEC n° C20 of 28.1.1991).

2. 92/C 96/02 (OJEC n° C96 of 15.4.1992)

encouraged the use of European standards as an instrument of economic and industrial integration, and advocated a wider use of European standards in Community policy.³

European standardization as it has developed plays an enabling role in European integration, and European Union initiatives for the development of European standardization contribute to the European economy while avoiding the unnecessarily stifling of economic initiative due to excessive regulation. This fits into the context of the intentions of the **Maastricht Treaty on European Union** and of a series of statements made in various Community policy documents, dealing with the need to diversify instruments used in implementing Community policy, the need to involve the social and economic partners in a more coherent way in implementing Community policy, and the role of standards in specific areas.

The **Sutherland Report on the Operation of the Internal Market after 1992** suggested, as its first recommendation, the need for the Community to base its proposals for legislation on a wide-ranging analysis of its political, social and economic impact, comparing the advantages and disadvantages of intervention and of non-intervention. It went on to stress the need to develop a policy towards the choice of market regulation techniques based on their appropriateness for particular objectives.

I.3 Standards as an alternative to regulation

In its response to the Sutherland Report, the Commission referred, on these points, to its **Communication** to the Council and the European Parliament **on the principle of subsidiarity** of 27 October 1992.⁴ In relation to effectiveness and proportionality of action taken, the Commission announced that it would ensure that arrangements for taking legislative action were consistent and coherent with the objectives being pursued, in the interests of maximum effectiveness and an appropriate level of intensity. Among the instruments that can so be used, it mentioned recourse to non-compulsory instruments such as standardization.

Such a use of standardization could, in principle, replace regulatory action with voluntary standardization action in sectors of Community activity. Since it is based on consensus, and relies on acceptance of the results by those who will use them, standardization follows the principle of subsidiarity to a high degree.

In certain areas, for example in innovative technological sectors, the European Union is already taking action to promote standards as a direct support to its policies, rather than drawing up regulatory instruments with more or less mandatory force. Existing sectors in which such action is being taken are described in more detail in section II. It is envisaged, in line with the Communication, that future proposals for action in the regulatory sphere will be examined with a view to determining the extent to which voluntary action is more appropriate.

³ 92/C 173/01 (OJEC n° C173 of 9.07.1992)

⁴ SEC (92) 1990 final of 27.10.1992

1.4 The role of standardization in European Quality Policy

In its White Paper "Growth, Competitiveness and Employment⁵" and in its Strategic Programme "Making the most of the Internal Market⁶", the Commission has identified the need for a European quality policy as a means of increasing competitiveness and of improving the environment for enterprises.

In such a policy, standardization is a major tool, not only for product quality but also for Quality Management matters. In this context, the quality systems standards, the EN 29000 series, and the conformity assessment standards (the EN 45000 series of standards) are particularly worthy of note. These series of standards have major significance for the operation of the notified certification bodies within the context of the New Approach; furthermore, they make a substantial contribution to the development of quality in the European market place. Indeed, in some sectors these standards may be said to have a greater impact than product standardization.

The Council Resolution on the role of standardization in the European economy quoted above includes an invitation to the European standards organisations to continue discussions on a harmonized expression of conformity with European standards. The existence of such a mark would have the advantage of providing a common means of identifying products in conformity with European standards, which would provide manufacturers with a recognisable Europe-wide means of demonstrating compliance, and give purchasers a clear indication of the quality of products.

1.5. The role and limits of standardization

Standardization is a mechanism by which interested parties (such as industry, workers and consumers, contributing through their organizations in an appropriate way) establish, on the basis of a consensus, by means of an open and transparent procedure, in the framework of recognized standards organizations, technical specifications which are adopted as standards after a public enquiry, and with which compliance is in principle voluntary.

Standards are not limited to the design of a particular product for the purpose of reducing the number of different solutions to the same technical problems or to ensure that one product works with another. The coverage of standards extends to many other types of requirement, including the performance (as opposed to the design) of products, properties of materials, defined levels of protection against risks, for example protective enclosures, systems of classification, methods of test, the operation of equipment or systems, such as systems of quality assurance, definitions of terms, quantities, units and symbols and their presentation and use, etc.

⁵ Com (93) 700 07.12.93; Bulletin of the European Communities, Supplement 6/93

⁶ Com (93) 632 final of 22.12.1993

Standardization is an important and powerful instrument of market transparency, through actions by interested parties themselves on a wide range of issues, and it should for this reason be fully supported as an instrument of economic integration and self-regulation.

There are, however, a number of legitimate "public policy" concerns relating to safety, health, consumer protection, environmental protection, interoperability and interconnection and so on, where regulation indeed cannot be left to interested parties and in which the public authorities must assume responsibility. Even where this is so, however, there should be no *a priori* exclusion of a role for interested parties in support of legislation. Standardization offers a mechanism for using such support, and the possibility of making use of standardization in such areas should be considered.

The Commission is not unaware of the fact that questions are being raised concerning the capacity of the European standards organizations to deal with requests for standards for wider use. Do the standards organizations provide a mechanism for consensus building in all areas, or is their competence in fact limited to traditional areas and the direct interest of industry? Does the existence of national standardization in a particular area (for example, in foodstuffs) guarantee that European standardization will be successful? Can the standards bodies organize the participation of interested parties in all areas so as to produce standards effectively, and so as to give them the requisite acceptability and legitimacy? Are standards organizations prevented from delivering standards in good time for the implementation of policies by the very need for procedures of voluntary participation, openness and public enquiry that gives them their legitimacy for recourse by the legislator? Are standards the only alternative instrument to which the legislator can have recourse? Does the development of standards pre-empt decisions that the legislator must take, in particular with regard to levels of risks that may be judged intolerable by the society as a whole?

In attempting to find answers to these questions, it is necessary to take into consideration the fact that standards benefit from a particular position because they have a clearly defined status in the Union and in its Member States, and they are based on a long tradition. This confers particular advantages to standardization with respect to other instruments of voluntary application. The standards organizations have however a responsibility to ensure that the system operates efficiently and without undue bureaucracy.

Standards should not limit the freedom of the market place by excluding products - particularly innovative products - that do not conform to them. They should not be misused to preserve or create a dominant market position to the detriment of free competition by formalising in an officially recognised document the solution adopted by a single major supplier unless appropriate measures are taken to make the relevant technology available to other interested suppliers. The standardization system should not be overloaded by a possible further use of standards.

Nor should it be used to confer an undue advantage to certain interested parties by bypassing the process of democratic decision-making and creating *de facto* market conditions which will be extremely difficult for the legislator to reverse due to the severe economic penalties that might then have to be incurred. This calls for full transparency.

among standards organisations, their constituent parties, the authorities and the Community institutions, allowing authorities to indicate the conditions, under which development of standards is undesirable or inappropriate in particular as regards the formulation and implementation of Community policy.

Furthermore, standardization, and particularly the recent change in emphasis from the national level to the European level, introduces adjustment costs for business which are not necessarily always outweighed by the positive effects, such as the reduction of trade barriers or the introduction of economies of scale. This is particularly the case for SMEs who are largely effectively excluded from the standards making process. The first provisional results of a Euromanagement pilot action in this area indicate that SMEs, because of their lack of resources, have difficulties in finding out or understanding what is going on within the standards making bodies, and have little way of directly influencing the standards process. Adjustment costs are disproportionately felt by SMEs, particularly those SMEs that are not selling across national boundaries.

Finally, the implementation of the policies of the Union should benefit from the use of standards as opposed to other types of instruments, such as voluntary agreements, technical approvals, calls for technology, and so on.

1.6. A turning point for European standardization

Over the last ten years European Standardization has undergone dramatic developments. Over the same period, European standardization has become adapted from primarily a means of being harmonizing national practices to a mechanism for drawing up standards at European level *de novo* in areas that may not have been previously standardized, for the elimination of barriers to trade caused by the existence of varying national rules or standards, and of providing support for European legislation.

This development creates challenges as to the development of new standards, which go beyond the development of "traditional" standardization incorporating design details, and of meeting the requirements of broad legislative programmes. However, since these anticipative standardization activities (as, for example, in the case of information technology and telecommunications) have been experimented with for about 10 years, a review is necessary so as further to "tune" them to the real needs of markets and political directions.

Today, about one third of the European standardization activities is covered by mandates issued by the Union. The development of mandated standardization work may have been considered by industry in the past to be a constraint or a top-down approach. However, over recent years great improvements have been made in setting up a dialogue between public authorities and the European standards organisations. Standardizers are now invited to meet the requirements of the regulatory framework, whilst they are left flexibility necessary to draw up programmes that will be effective taking into account the voluntary nature of standardization.

The development of European standardization has also been beneficial for international standardization. International standards, once transposed as European standards, are implemented in a uniform way throughout Europe. Furthermore, arrangements for close and extensive cooperation have been put in place between the European and international bodies. At the same time, the Union has emphasised the importance of international standardization in the Council Communication on Standardization in the European Economy mentioned above.

European operators are increasingly required to take account of the results of European standardization. They are making a significant contribution to the process of elaboration of standards, but need to be aware that it is in their interests to enhance their participation in areas where the absence of standards forms a barrier to the development to the European market.

European standardization is now reaching a turning point. It is approaching the end of a transitional period in which it has evolved from a small structure of peripheral importance to its present position of being a major force in the structure of technical development. This marks a key point in the development of European technical integration. At this stage, however, European standardization has not yet achieved a critical mass of standards, by comparison with the existing collections of national standards, and difficulties may yet arise until this critical mass has been reached.

The evidence of the need to adapt and the fact that standardization today is critically being viewed, indicate, however, that developments have been taking place and that the European standardization system is progressively assuming its proper role in Europe.

II. The use of standards in support of Community policy

Standards exist in their own right, and even though they are voluntary, they play an important role. The legislator can however call upon standardization as a support for its legislative activities or policy. The conditions under which standards are used, will be determined by the legislator, and they may be different from one area to the other. The use of standards under the New Approach to Technical Harmonization and Standards⁷, and in support of Community policy in public procurement, is now well established. In other areas, however, such as transport, environmental policy, energy, food quality, and safety at the work place, the use of standardization is rather new and still needs clarification as to the conditions and potential of the use of standardization. The aim of this communication is to contribute to such clarification.

II.1 The New Approach.

The "New Approach to Technical Harmonization and Standards", adopted in 1985⁸, represents an established way of using standardization in support of the process of

⁷ 85/C 136/01 (OJ No. C136 of 4 June 1989)

⁸ Council Resolution 85/C136/02 (OJ no C 136 of 4 July 1985).

Community technical legislation. Under the New Approach, the European standards bodies are asked to draw up, under mandate from the Commission, standards intended as a means of providing presumption of conformity with essential safety requirements set out in New Approach Directives. Use of the standards remains voluntary; other methods of achieving compliance with the terms of a Directive are always available to suppliers.

As of December 1993, there are thirteen Directives in force that make use of the New Approach, covering a broad spread of applications from consumer products to pressure vessels and machinery.

When the New Approach was first used, standardization mandates tended to be applied with the intention of providing specific standards to answer specific needs identified in the relevant Directive. Increasingly, however, the emphasis is changing towards the drawing up of coherent programmes by means of programming mandates, usually addressed jointly to the European standardization organizations, and calling for the drawing up of programmes of standards that will meet the global needs of the relevant Community legislation.

Standards mandated under New Approach Directives are now coming into force. Substantial work however remains to be completed, and it will be a significant task of the standards bodies to ensure that the standards, mandated in support of the legislative programme are brought to timely completion. Furthermore, although the legislative programme, foreseen by the White Paper of 1985⁹ for the completion of the Internal Market is largely complete, further legislation for the development of the common market is under active consideration, for example in pressure equipment and precious metals. The work still to be undertaken remains extensive, as will be seen from the current work programmes of CEN, CENELEC and ETSI.

II.2 Public Procurement

Since 1977, reference to standards has been used as an instrument in the opening up of public procurement in the European Union. There is a significant difference in the application of standards in this policy area compared to that of the New Approach: reference to European standards where they exist is made obligatory by the terms of the various **Public Procurement Directives** in tender documents issued by contracting authorities. This is true for all European standards whether they are covered by a mandate or not, and whether they are New Approach standards or not. The base texts of legislation are now in place for this area at European level.

The importance of standards for this aspect of Community policy is recognised by the issue of mandates to the standards bodies in certain key sectors, with the expectation of a substantial future development of standards in relevant areas. So far, mandates primarily for public procurement purposes, or with significant public procurement aspects, have been issued or proposed in the fields of electricity generation; oil and gas exploration;

transmission and distribution of gas; railway equipment; air traffic control equipment; equipment for ports and airports; and computer aided acquisition and logistic support. Also in untraditional areas such as attestation of conformity with EC procurement rules and qualification of construction enterprises initiatives have been taken. Standardizers have undertaken important activities in these areas which are still underway. Other mandates, though not primarily intended in support of Community public procurement policy, such as New Approach, are nonetheless relevant as a result of the provision in the Public Procurement Directives that reference to European standards is mandatory in contracting documents where such standards exist.

Standards will not open the public procurement market unless they have room to operate. Since legislation must obviously prevail over standards where the two are in conflict, there must be a consensus, at the level of the Member States' administrations, to allow standards to operate in sectors that were formerly heavily nationally regulated, in the interest of the benefits that will accrue from a larger market and the integration of European industry. This requires a willingness in principle to open up procurement markets that may have been kept protected for reasons of national policy, and also a willingness where necessary to deregulate, i.e., to withdraw mandatory national requirements in favour of voluntary European ones. This implies that when programmes of standards to open the public procurement market are drawn up, existing programmes should not be taken over without consideration in detail; the usefulness of each item for the intended purpose should be specifically considered in the light of the fundamental objectives of Community public procurement policy.

The Commission must therefore encourage deregulation at national level in favour of the use of European instruments of technical harmonization, particularly voluntary instruments such as standards. At the same time, if actions by the Member States in applying national technical rules to specifications used in public procurement are found, when examined by the Commission, to have the effect of closing the public procurement market, for example by protecting the position of national suppliers, such actions will need to be met with a vigorous enforcement response.

Another important aspect of standardization in support of public procurement policies, is the area of electronic commerce. The development of new advanced applications for facilitating exchange of contract information, must not lead to the creation of new barriers to trade. The situation has been given extra momentum through the US National Information infrastructure project and the publication of the "Bangemann Report: Europe and the Global Information Society" on what Commission activities in this area are currently rapidly expanding.

A particular aspect of standardization in public procurement is the support of interoperability within the concept of trans-European networks introduced into Community policy by Title XII of the Treaty on European Union. This aspect is discussed in II.10 below.

II.3 Information Technology and Telecommunications

Experience in this sector

Although initiated earlier, European policy for standardization in information technology and telecommunications was given momentum by the Council Decision on Standardisation in the field of information technology and telecommunications of 22 December, 1986¹⁰ which lays down basic principles of the primacy of global standardisation and the necessity for harmonised application of standards to ensure the interoperability of systems and the ability to exchange information.

The implementation of the policy has had to face several constraints typical of this area : the complexity of the subject and the pace of advance of technology; the pervasive nature of information technology, which calls for flexible and interoperable solutions; the role of industry both as manufacturers and user, since European and international industrial groupings have promoted convergence and harmonised application of international standards at world level; the international dimension of the IT sector, and the overlapping of responsibility among the different European standardization bodies.

European initiatives since 1985 have aimed at achieving the stated policy objectives and at overcoming the difficulties. This has increased the degree of openness, effectiveness and co-operation, but it has become evident that further adaptation is necessary.

IT&T Standardization is here given a particularly extensive treatment because urgent and significant improvements in the effectiveness of standardization is regarded as crucial to meeting the challenges posed by the global information society.

Major achievements

Major results have been achieved in opening-up the IT standardization system to direct participation of industry and users, by the establishment of the European Workshop for Open Systems which covers the international co-ordination requirements of the IT and telecommunications sectors.

Change has been radical in the telecommunications sector, now that, with the setting up of ETSI, true European standards with transparency in elaboration, public enquiry, and adoption by weighted national voting are coming into use. Furthermore, ETSI has been responsible for a substantial contribution in the regulatory domain where standards have been needed to form the technical basis for regulation under the Telecommunications Terminal Equipment Directive¹¹. Co-ordination between the European standards organisations has been achieved through the setting-up of the Information Technology Steering Committee (ITSTC).

¹⁰ 87/95/EEC (OJ No. L 36 of 7 February, 1987)

¹¹ 91/263/EEC of 29 April, 1991 (OJ No. L 128 of 23 April, 1991)

A matter for satisfaction is the penetration of IT standardization into several economic sectors which have agreed plans and initiated development of IT standards for their specific applications. Concrete examples of such areas are electronic identification and payment systems; the distribution of standardized electronic messages; medical informatics; road transport telematics; libraries; the storage of geographical data; and postal services.

As well as supporting the development of standards, the Commission has recognised this need by support for the application of standards. Particular examples of this support are the Conformance Testing Programme (CTS) - a measure unique in the world for the enforcement of rigour and discipline in standards implementation. A further example is the European Procurement Handbook for Open Systems (EPHOS), which provides guidance for those involved in public procurement on standards and specifications in the field of information technology and communications.

Difficulties in this area

Although the concept of interoperability through standards has become widely accepted, products based on recognised standards have often been displaced by successful products in the market whose technology is based either on public or on private specifications ("de facto standards"). Such specifications may be satisfactory from the technical point of view but create a multiplicity of solutions and the risk of "islands of incompatibility" resulting from differing technical solutions chosen by each community.

Four major problems appear to be matters for concern. Firstly, the present standardization system may not have the capacity to keep pace with technological evolution and to deliver the required specifications on time and with the appropriate level of detail. Secondly, specifications need to be implemented with enough discipline for the avoidance of divergence and for the enabling of interoperability. Thirdly, products conforming to standards are not always available. Finally, purchasers, both public and private face difficulties in referring to standards for buying equipment and building systems that are truly interoperable.

Changes have occurred in the technological domain so that the role, or at any rate the mechanisms, of standardization require review to keep up with them.

The Report on the "Global Information Society"

A Task Force set up on the initiative of Commissioner Bangemann has recently issued a Report, "Europe and the Global Information Society: Recommendations to the European Council"¹² on issues to do with information technology and telecommunications. While recognising that the standards institutes have an honourable record in producing standards, the report expresses concern regarding the fitness for purpose of the European standardization process in information technology, in particular regarding the lack of interoperability and the extent - judged to be insufficient - to which the setting of priorities is determined in the market.

¹² 26 May, 1994; presented to the meeting of the Council held at Corfu in June 1994

There are calls for action at the level of operators, the European standards bodies, and the Union.

In order that information technology standardization might respond to market needs, there is a call for a mechanism for the drawing up by market operators of specification requirements for specific application objectives, such requirements being applied as input to the competent standards body. Furthermore, it is considered that priorities should be based upon market requirements, and that publicly available specifications, originated in the market, should be identified with a view to their rapid transformation into standards through "fast track" procedures. Where the market is considered not to be providing acceptable technical solutions for the achievement of one of the EU's objectives in this area, the Report calls for the development of a mechanism to call for the selection or generation of new technologies.

Particular stress is laid on the need for interoperability, essential to the infrastructure of an information-based society. The interconnection of networks and interoperability of services are recommended as primary Union objectives, and as a consequence the establishment of specifications for global interoperability is regarded as a priority area for the standardisers. Finally, it is recommended that the process of European standardization be reviewed in order to increase its speed and responsiveness to markets.

The next step

The prospect of a global information society gives new opportunities and challenges to the role and mechanisms of standardization, and such challenges cannot be faced by a system that suffers from the weaknesses mentioned above. The Commission therefore believes that re-focusing IT standardization policy is a primary concern, and has opened a debate on the different aspects of standardization policy. To this end, a Workshop was organised in November 1994¹³ at which the European Commission sought recommendations from social, industrial and economic partners on the reshaping of IT standardization policy so as better to serve the social and economic objectives of the Union and the needs of the global information society.

With this preparatory work the Commission intends to review ICT Standardization Policy and to communicate the results to the Council and the Parliament.

The question of access to Intellectual Property Rights included in standards and other interfaces required for the purposes of interconnection and interoperability has to be considered further by the Commission.

Future policy options

The Commission has a responsibility for the definition of the standardization policy for the European Union but it is not in its capacity to solve the problems which affect standardization

¹³ European towards the Global Information Society. 'How to choose the right ICT standardisation policy'. Workshop organised by the European Commission 28-30 November, 1994 at Genval, Belgium.

in the context of the development of the information society. Although, in addition to its policy-making role, the Commission can influence and support the evolution of the system as user, customer, regulator, arbiter, sponsor and facilitator, main initiatives remain under the responsibility of other players. The Report on the Global Information Society mentioned above makes the distinction in roles quite clear.

The standardization policy of the Union should favour the application of international and European standards. Preference to standards should be given whenever they provide an efficient solution to technical problems. The capacity for delivering timely and accurate standards is of the utmost importance for the provision of information infrastructure, and represents a major challenge to the standardization system.

Conflicting standards risk creating islands of incompatibility, and should be discouraged. When they cannot be avoided, a sufficient level of interoperability among them should be a requirement. Coherence in maintaining the international alignment in IT standardization should be maintained so as to promote world wide interoperability.

II.4 Biotechnology.

Biotechnology comprises a series of techniques which are finding application in a number of industrial sectors and in agriculture.

Three Directives have been approved that relate directly to biotechnology: on the **contained use of genetically modified micro-organisms**¹⁴, on the **deliberate release into the environment of genetically modified organisms**¹⁵, and on the **protection of workers from notes related to exposure to biological agents at work** (seventh individual Directive within the meaning of Article 16 (1) of Directive 89/39/EEC)¹⁶. Furthermore, products such as foodstuffs, pharmaceutical products and agriculture, which may well be derived from biotechnology are also covered by specific product related legislation.

In the Communication from the Commission on **promoting the competitive environment for the industrial activities based on biotechnology within the Community**,¹⁷ following the principles of subsidiarity and Community policy on the use of standardization, the Commission considers it appropriate to make use of the resources of industry and to mandate CEN to draw up standards to complement Community legislation.

A standardization mandate has therefore been given to CEN covering relevant aspects of standardization in biotechnology. Standards will define the technical specifications, codes and methods of analysis which form the necessary technical complement to legislation.

14 90/219/EEC of 23 April 1990 (OJ L 117 of 8 May 1990, p.1°)

15 90/220/EEC of 23 April 1990 (OJ L 117 of 8 May 1990, p.15)

16 90/679/EEC of 26 November 1990 OJ L 177 of 5 July 1991, p.22)

17 SEC(91)629 final of 19 April 1991

Reliance on standards for these technical questions will contribute to the use of the latest technology in support of Community legislation. Standardization will also serve to facilitate compliance with legal requirements. Furthermore, due to the trans-sectoral nature of biotechnology the establishment of common standards will reinforce the industrial base and improve competitiveness. Thus a programme of standards has been drawn up by CEN covering both regulated areas and those not covered by specific Community legislation.

II.5 Advanced Materials

Investment in the development of advanced materials has been significant, and the Union has, through its industrial and materials technology research support programmes and through activities in the Joint Research Centre, made a substantial contribution to the field.

An example of Union policy in this area is given by advanced ceramic materials, in which area it has been recognised by the Commission that standards are an appropriate means of supporting the development and bringing into use of such new materials. Standardization in this area promotes innovation, the application of the technology and the development of a market for products using advanced ceramics.

Accordingly, in January 1989, CEN and CENELEC were given a mandatè to draw up a programme of standards in this area. CEN and CENELEC have replied with a joint programme in fulfilment of the mandate. A further standardization mandate will cover all aspects of advanced industrial ceramic materials covering all types of advanced ceramic materials.

Similarly, ECISS, the European Committee for Iron and Steel Standardization, is developing standards under mandates related to steel, in order to answer needs in specific areas, such as pressure equipment.

II.6 Foodstuffs

The Commission's orientations on foodstuff legislation have been laid down in two Commission Communications to the Council and Parliament: "**The completion of the internal market, Community legislation concerning foodstuffs**"¹⁸ and "**The free movement of foodstuffs within the Community**,"¹⁹ or, furthermore, as regards geographical indications and designations of origin, or certificates of specific character for agricultural products and foodstuffs in recent Council regulations. A Conference on Food Quality in the Internal Market organised in June 1993 allowed the Commission to recall these orientations:

¹⁸ Com (85) 603 final

¹⁹ C271/03 of 24.10.89 (O.J. C271 of 24.10.1989, p.3)

The Commission considers that standardization activities can facilitate the implementation of European Union policy on foodstuffs. This is true in particular for methods of analysis or sampling, good hygienic practices, technical specifications, specifications related to names under which products are sold and standards on quality based on objective criteria.

Standardization is now being undertaken in different areas; recent mandates cover the detection of irradiated foodstuffs, and the wide area of methods of analysis for materials in contact with foodstuffs.

In order to create transparency and to develop further initiatives, if need be, the Commission will establish a report analyzing existing non-mandated standardization activities in the food sector, in order to identify patterns and possible gaps in these activities as well as the reasons for them. CEN will be associated with the study. In the light of the study, the Commission will examine whether there is a need for Community mandates for standards.

II.7 Health and safety at the work place

As a result of the discussion which was launched in some Member States on the use of standards in relation to Article 118A of the EEC Treaty and in a reaction to the Council Resolution of 18 June 1992 on the role of standardization in the European economy, the services of the Commission have been working towards a global position on the matter in a Memorandum on the role of standardization in relation to directives adopted on the basis of Article 118A of the EEC Treaty. After the conclusion of all currently ongoing consultations, the Commission will issue a final version of the Memorandum.

In its present form, the Memorandum analyses the use of standards as a tool in relation to the legislative approach in Article 118A which gives Member States the freedom to maintain or introduce more stringent measures than the minimum requirements provided for by Union legislation. The Memorandum recognises that this right of Member States cannot be interfered with by standardization. It finds that Article 118A Directives can be supported by European standardization to improve general communication and comprehension of what is expected to be accomplished in practice, and to ensure that health and safety at work standards are comparable.

The Memorandum considers that a dialogue between the social partners, the Commission, Member States and the standards organizations is an important prerequisite to optimize efforts and suggests clear consultation procedures to be established within the existing framework of consultative committees, such as e.g. the Advisory Committee on Safety, Hygiene and Health Protection at Work.²⁰

²⁰ Council Decision on the setting up of an Advisory Committee on Safety, Hygiene and Health Protection at Work 74/325/EEC OJ L 185 09.07.74

The Memorandum states that the European Standards Bodies should find appropriate means of adopting the results of standardization activities related to Article 118A Directives, to allow the specific characteristics of such Directives to be taken into consideration.

The Commission may, following consultation of relevant committees, issue mandates indicating the legal and political framework within which standards are to be developed so as to be in line with policies pursued by public authorities Community wide. Such mandates should define the scope for standardization and the issues where the legislator is intervening or has the intention to intervene.

II.8 Energy

The energy sector was one of the first in which standardization mandates were given (1984); this in a sector where Community legislation did not then exist. The first mandates concerned petrol products for which standardization ensures free movement. In other energy sectors harmonization of rules and technical standardization will be a significant means of eliminating technical barriers to trade.

The global approach to standardization in the energy field, proposed by the Commission²¹ and approved by the Energy Council on 30 November 1992, distinguishes two types of standardization mandate to CEN and CENELEC; those linked to legislation and those not explicitly required by legislation (independent mandates).

Where a standard is not sufficient of itself to guarantee free movement, legislation becomes necessary. Nevertheless, the approach of independent standards will be used wherever possible due to its flexibility and in order to avoid an excess of regulation.

Among mandates linked to legislation is that related to the efficiency of hot water boilers, necessary to the application of the "New Approach" Directive 92/42/EEC, adopted by the Council on 21 May 1992,²² on the same subject. The aim of the Directive is to improve energy efficiency. The mandates related to the Directives applying Council Directive 92/75/EEC on the labelling of domestic appliances also fell into this category. In this area, the system set in place by the Directive covers the types of apparatus offering adequate scope for the improvement of energy efficiency.

Where there is no legislative development, independent mandates call for standardization. This is so for transport equipment and installations, and for the distribution of energy where a standardization programme is foreseen under a joint mandate to CEN and CENELEC.

The use of standards is necessary to attain the objectives of the European Union in areas such as trans-European networks, with the aim of ensuring interoperability; public

21 SEC (92) 724 final of 9 June 1992

22 92/42/EEC of 21 May 1992 (OJ N° L 107 of 28 June 1992)

procurement, where investment is particularly significant; free circulation of energy products; the environment, relating to the objectives of the Rio Conference; the protection of consumers and workers and energy efficiency.

The improvement of energy efficiency is linked to the fundamental objectives of energy policy concerning:

- The improvement of industrial competitiveness;
- The reduction of the dependence of the European Union on imports of fuel;
- The impact of energy consumption on the environment.

The field covered by energy efficiency is considerable, extending from the application of advanced technology to the remote control of appliances to improvements in the efficiency of energy-using apparatus such as internal-combustion engines and machines.

The Commission foresees that energy efficiency will be included in essential requirements applicable to apparatus using energy. This will allow products related to existing New Approach Directives to be covered, and will reduce the need for legislation in accordance with the concerns expressed by the Council and the Commission.

Similarly, in the past, the Council has given full support to Commission proposals for specific initiatives, such as the ALTENER programme, promoting alternative energy sources, where it has committed itself fully to support actions by the European standards organisations in these areas.

II.9 Environment

In the Fifth Action Programme on the Environment, "**Towards Sustainability**"²³, the Commission stated that in order to bring about substantial changes in current trends and practices, and to involve all sectors of society, in a spirit of shared responsibility, a broader mix of instruments needs to be developed and applied.

In line with this, the Commission issued its **Communication on Industrial competitiveness and protection of the environment**²⁴, in which it is recognised that the development of a Community approach to achieving integration of the requirements for competitiveness and the environment requires the implementation of a strategy based on a coordinated recourse to a variety of instruments, within the fields of both environmental and industrial policy. It added that regulatory requirements alone do not provide the incentive to continue to improve environmental performance. Means other than legislation are required and, in implementing regulatory requirements, a degree of flexibility must be met.

23 Com (92) 23 final of 27.3.1992

24 SEC (92) 23 final of 27.3.1992

In its Resolution on the same question, the Council subscribes to these ideas, stressing that alternative approaches should always be examined as an option to achieve the most appropriate mix of instruments.

As regards standardizers, a formal consultation document on environmental standardization was issued in 1993, and a conference organized in June 1993 in a reply to requests by the Council and the Commission to bring all interested parties together to discuss a common strategy on environmental standardization.

The Commission stated at the conference that the importance of environmental concern is now acknowledged at Community level. Although at first sight the role for industrial standards can appear less obvious, the implementation of Community Directives and Regulations require the development at Community level of standard test methods, pollution measurement methods, pollution control methods, equipment, products and processes.

A certain amount of work is already under way as result of mandates from the Commission to CEN. A significant part of this work has to do with measurement methods, for example for the analysis of dangerous substances in the aqueous environment, or for methods of calibration for automatic systems of measurement of atmospheric pollution.

Environmental management is another significant domain in which the use of standards is being developed. In this case, Regulation 93/1836/EEC of 29 June 1993, allowing voluntary participation by companies in the industrial sector in a **Community Eco-management and Audit scheme** ²⁵, invites companies to establish and implement an environmental policy aimed at continuous improvement in environmental performance. Third party validation is carried out by independent accredited verifiers. Standards for environment management systems and audits can be recognised by the Commission as meeting the corresponding requirements of the regulation. In order to avoid the proliferation of potentially contradictory standards a mandate has been given to CEN to develop single standards to be introduced across the Community.

A proposed Directive on packaging and packaging waste, in line with the Union's waste management strategy, calls for the use of standards, both with the aim of giving presumption of conformity with essential requirements on the composition of packaging and the re-usable and recoverable, including recyclable, nature of packaging, and with the aim of supporting the Union's environmental protection objectives. A mandate for the drawing up of a programme of standards has been issued in this area.

The flow of work is evolving gradually and the expected future demand from the Commission (discharges into air and water, revision of waste water directive, the need for a common European approach to life cycle assessment) will make standardization increasingly significant in the future within this policy area.

The role of standards in the implementation of environmental regulation is not however, yet fully appreciated in all political and environmental circles. The European standards bodies should therefore be active in developing the level of transparency and promotion which will gain the necessary political acceptance.

It is suggested that the Commission and CEN, together with other bodies where appropriate should carry out an annual review in the sector. This review would monitor current mandated activities, and set priorities in the field of direct standardization; the review will take account of results from research activities executed under the Fourth Framework programme of EC activities in research, technological development and demonstration (JRC actions and actions under the shared-cost action programmes). It would also include discussion of an indicative listing of the indirect standardization implications of Union environmental legislative proposals, and would include an evaluation of activities carried out by standards bodies on their behalf.

II.10 Trans-European networks

The creation of European networks is a relatively new policy area and of increasing importance. Apart from a few exceptions (e.g. telecommunication), interoperability as such has not until now been dealt with in Community legislation or related mandated standardization activities. Standardization, whether mandated or market led, has, however, an effect on interoperability and standardization of all elements related to interconnection will constitute a natural basis for networks. Although standardization is defining an essential aspect of networks, it is in itself not capable of setting up European networks. More specific and directed action by the Commission may be needed in order to ensure interoperability through common technical specifications, in European standards or legislation.

Two cases exist in which interoperability is already qualified as an essential legal requirement. These are the Directive on **telecommunications terminal equipment**²⁶ (which is part of a wider set of Directives) and the Directive on **interoperability for high speed trains**.²⁷

Particularly important are standardization activities mandated for Public Procurement, notably in the "excluded sectors". Although interoperability is not the specific purpose of these mandated activities, in reality the common specifications provide an important basis for it. Mandates (standardization or programming) exist for the areas of water, oil (exploitation, extraction, shipping), gas (exploitation, transmission and distribution), electricity (characteristics, production, transport and distribution), railways, air transport, port infrastructures, waterways and other terminal equipment.

Standardization activities in the IT area are creating the necessary tools for data exchange, introduction of new media and therefore for interoperability in all areas.

²⁶ 91/236/EEC of 29.04.1991 (OJ N° L128 of 23.04.1991)

²⁷ COM(94)107 of 15.04.1994

Examples are work on bank cards, barcodes, healthcare informatics, and the activities carried out by CEN - EWOS (European Workshop for Open Systems) on communication protocols for data exchange, etc. European standards adopted under some New Approach Directives for industrial equipment may have an effect on interoperability.

Also outside the mandated area, standardization is an important potential contribution to the realisation of networks. For various reasons, however, essential elements for networks may remain outside the standardization area. First, standardization is a voluntary process, based on consensus, and only if market operators find an interest in drafting and using standards will they invest in it. Second, where regulatory and national administrative environments exist, standardization can only operate within these limits, and such limits may exist for essential elements of European networks. Third, the historical context of existing national networks may make the elaboration of European standards complicated and time-consuming, and it may not be excluded that up to now protection of interests may have limited the room for standardization.

The creation of European networks makes it necessary for action to be undertaken by public authorities to ensure common technical specifications. As the emphasis must be laid on specifications agreed by market operators themselves, European standardization is the most appropriate tool. It will be necessary to analyse the extent to which existing standardization activities, either mandated by the Commission or undertaken at the initiative of the standardization bodies themselves, contribute to the development of trans-European networks. New mandates should then be entrusted to CEN/CENELEC/ETSI for examination of the scope and potential for standardization related to interoperability. The Commission should seek to create space for standardization, either by proposing, where necessary, an agreed regulatory framework at Community level, or by asking the Member States, in discussing the conditions for standardization mandates, for a commitment to deregulate in favour of mandated standardization activities.

II.11 Protection of consumers

Following earlier Community measures for consumer protection, the Treaty on European Union²⁸ introduced a strengthened policy in favour of consumers, aiming to achieve a high level of protection. This policy, insofar it consists of measures based upon Article 100A of the Treaty concerning the achievement of the internal market and specific measures in support of measures taken by Member States with a view to protecting the health, safety, economic interests and awareness of consumers, opens an area of Union policy where there is an important potential for standards, either in their own right or as support to regulation.

Standards can be used as a means of consumer protection - for example, by allowing manufacturers to make products interchangeable or interoperable with those of other

manufacturers, or to make claims regarding the quality of their product (although standards cannot form the basis for all actions undertaken for the purpose of consumer protection: in some parts of this policy area mandatory regulation is clearly necessary). Actions for consumer protection should arise from genuine needs of consumers, and standardization has the capacity to reduce any tendency to unnecessary legislation.

III. Standardization and research.

The Council Resolution already referred to on the role of European standardization in the European economy²⁹ stresses the importance of strengthening the links between research and development activities and standardization. The **Fourth Framework Programme (1994-1998) of EC activities in research, technological development and demonstration**³⁰ enhances European research activity in this area in that it includes, in the Industrial Technologies strand, a specific programme of research linked with standards, measurement and testing. Among other objectives, this programme will cover research necessary to accelerate the establishment of European directives and standards for the reinforcement of the single market and the realisation of other Community policies, especially those dealing with health and security.

Other research programmes, for example, in information and communications technologies, will also have a clear bearing on standardization as a contribution towards bringing research results effectively into the European market place.

In certain areas, particularly in IT and telecommunications, there is already some experience of the transfer of research results, for example related to the RACE, ESPRIT and related programmes.

In information technology extensive research and development has paved the way for the establishment of standards in several domains. Examples are open distributed processing, the compression of information for the transmission of images, open document architecture, file transfer, and computer graphics interfaces.

The new Specific Programme for Information Technologies includes pilot systems validating the implementation of the proposed standards, and further research towards proposals for standardization in other areas such as multi-media storage and transmission, effective user access to global information sources and the interoperability of systems.

Above all the new Specific Programme is aimed at contributing fully to the provision of the essential underlying technology components required for the progressive implementation of the Global Information Society. Related prenormative activities will act on the principles of the Council Decision referenced earlier in this communication, which identified the primacy of global standardization and the necessity for the

²⁹ 92/C 173/01 of 18.06.1992 (OJ N° C 173/1 of 9.7.1992)

³⁰ Decision of the Council and the Parliament N° 110/EC of 26.04.94 (OJ N° L 126 of 18.05.94)

harmonization of standards so as to ensure the interoperability of systems and the ability to exchange information.

A dual link between standards and research may be identified. Standards can contribute to the value of research results by presenting innovative technology in a form appropriate for use by industry, and by identifying common solutions for the practical use of such research. On the other hand, standardizers may themselves have a need for research, for example when the process of elaboration of a standard reveals the need for research in order that the ultimate standard should have a sound scientific basis, for example where a property is to be standardized but the method of determining its value is not yet fully developed.

At the same time, standardization has the capacity to provide a link between research and legislation. The strengths of standardization - consensus, experience in drawing up technical requirements, and openness of the process - can build on innovation to provide documents usable and available for legislation. The links between standardization and regulation are well developed in certain areas (and their extension is the subject of discussion elsewhere in this document) and these links provide a path for standards based on innovation to exploit innovation for the purposes of European regulation.

The standardizers have recognised the importance of research, and have set up a working group to deal with the issue. This group is in the process of examining the needs of the standardizers, sector by sector, for standards-related research, and will report once its investigation and analysis is complete.

One factor that is already emerging is that standardizers are evolving detailed research requirements based on needs that arise from the tasks of drawing up standards; the result of this is that prenormative research will need to be closely aligned with the needs of standardizers if the results are to have optimal benefit. Thus there will need to be close and continuous cooperation between all interested parties - standardizers, researchers, and regulatory authorities - in drawing up prenormative research programmes and close direction of the activities carried out under such programmes to ensure that they meet the needs of the standardizers. It has already been recognised that in several cases significant delays have been caused because of the absence of appropriate test methods, when the need for normative research has been underestimated or even neglected entirely.

There is a need to maintain a careful balance in the relationships between standards and research. Standardization helps research results to come to the market; but the development of technology - and thus European support for technology-driven research - can be a cause of instability in the technological environment, causing the blockage in the development of standards as standardizers await developments in the state of the art.

Additionally the normative dimension of the Community RTD policy constitutes an important element of the Community contribution to the development of European Standardization.

IV. Standardization in relation to other organizations at global or European level

A standard is a technical specification distinguished from other types of specifications by a number of characteristics. In particular it should be adopted by a recognized standards body, indicated, as far as the Union is concerned, in Directive 83/189/EEC, established by a consensus of all those interested by means of a transparent process taking account of public consultation. It must be publicly available, and is of voluntary application.

European standardization is closely linked to international standardization, and it is therefore important to consider this link with international standardization.

Some international bodies make technical specifications that resemble standards in form, but which are not, because they do not fulfil all the above requirements. In the context of this Communication it is important to consider these specifications as well, and to indicate their relation to European standardization. Specifications adopted by such organizations do indeed not qualify as standards and produce no effect where Community law refers to standards.

In the same way, where Community policies have a significant relationship with the activities of such bodies, there is a need for Community action to take account of these activities, in order to avoid conflicts between specifications, wasted or duplicated work, and the inadvertent erection of regulatory or other barriers to trade in instances where the international or European body has regulatory competence in its specific domain.

IV.1 World-wide standardization bodies

The world-wide standards organizations ISO and IEC have a close working relationship with the corresponding European bodies.

Agreements between world and European bodies enable the transfer of work between international and European standardization to be carried out in both directions. The transfer of international work to the European level is significant since it improves efficiency by eliminating duplication of works, avoids the development of European solutions that differ from those accepted at a wider level, and ensures that the world solution is implemented uniformly throughout Europe.

In practice, CENELEC uses the international standards drawn up by the corresponding international body, the IEC, as a normal basis for its own work. In the same way, CENELEC will at a normal rule verify whether mandated activities can be carried out at international level.

CEN takes account of international work in ISO and may, under the terms of the agreement between the two bodies, make use of ISO standards as a basis for European standards. In areas where this is considered appropriate, the process can operate in the other sense, i.e., work originating at the European level may be carried out at the level of ISO.

International standards require a broader consensus than European ones, and thus the relative advantages of European and international standardization have to be carefully compared. The Commission fully supports the transfer of European standardization work to the world level. It is expected however, that the ultimate international standard will be of high quality, delivered on time and used outside Europe as well as within it. Finally, the European body should remain accountable vis-à-vis the Union.

Examples of the existence of such close cooperation in mandated domains are to be found in the areas of pleasure craft, eco-management, and oil and gas exploration, production and distribution.

IV.2 Regional and world-wide bodies with sectoral competence

A number of public organizations at international and European level have specific technical needs related to their particular fields of operation, and draw up technical specifications in support of their own particular objectives. An example is NATO, which has a need to co-ordinate supplies of all kinds, and draws up technical specifications for use by the forces of all its member states.

Certain organizations at European or international level, but outside the framework of the Community, may have specific responsibilities for regulation or the setting of technical specifications in their areas of competence: for example the European Organization for the Safety of Air Navigation (Eurocontrol). The International Telecommunications Union (ITU) should be mentioned in this context; it is a body under the auspices of the United Nations that makes technical specifications in the area of telecommunications, including radio communications; in the telecommunications domain, the specifications issued by ITU (Recommendations) generally cover the technical field corresponding to that covered by ETSI at European level.

NATO

The North Atlantic Treaty Organization (NATO) elaborates technical specifications (called Standardization Agreements or STANAGs) for equipment used by the armed forces and associated bodies of its member states. There is an implication for public procurement policy since although Article 223 (b) of the EC treaty provides that the EC Member States may take measures to protect the essential interests of their security related to the trade in or production of arms, munitions and war material, it is also provided that such measures may not adversely affect the conditions of competition in the common market regarding products not intended for specifically military purposes. The implication of the latter provision is that Community public procurement legislation applies in the case of procurement of products by national defence entities of any products except those of specifically military application.

As a first step, the Commission has issued a mandate to CEN, CENELEC and ETSI for the drawing up of a programme of standards, in cooperation with NATO, related to

computer aided acquisition and logistic support (CALs), that is, a computerised system of acquisition and supply of materials to NATO forces and other bodies. It is expected that the elaboration of appropriate European standards will integrate CALs into the European standardization system with a consequent advantage not only to procurement entities but also to European industry. NATO is setting up an office to deal with questions of technical standards, and further cooperation is envisaged with the technical activities of NATO.

In its own interest, industry is cooperating actively in the development of CALs; at the European level industrialists have responded to the challenge by setting up a European CALs Industry Group (EUCIG) which unites all the industrial players with an interest in the computer aided procurement process. This group is participating actively in the programming task.

CEPT

Until the formation of ETSI, the Conference of European Post and Telecommunications Administrations CEPT was responsible for the elaboration of Recommendations giving technical requirements in the telecommunications area. This work has been transformed into standardization in ETSI; CEPT has now become an organization of post and telecommunications regulatory organizations in a number of European states (not limited to the Community and EFTA countries). CEPT has significant responsibility in the area of radio frequency regulation through the European Radiocommunications Committee, a sub-group of CEPT.

Eurocontrol

Eurocontrol elaborates technical specifications ("Eurocontrol standards") for adoption by the aviation authorities of its Member States (again, these differ from the Member States of the Community) for equipment and procedures for air traffic control. A Directive on the definition and use of compatible specifications for the procurement of air traffic management equipment and systems³¹ has been elaborated under the Community's transport policy, particularly that of harmonization and integration of air traffic control with the aim of relieving the strain on air transport due to congestion. This Directive calls upon the Commission to identify "Eurocontrol standards" to be made mandatory under Community law (it should be noted that "Eurocontrol standards", despite their name, are technical specifications, not standards, since they are drawn up otherwise than by consensus and are of mandatory, not voluntary, application).

The Directive permits the Commission to give standardization mandates to the European standards bodies to complement the process of implementing Eurocontrol standards. As a first step, a mandate has been issued to CEN, CENELEC and ETSI for the drawing up of a programme of standards in this area, in close cooperation with Eurocontrol. With

31 93/65/EEC of 19 July 1993

the active participation of Eurocontrol, this activity is helping to define the relative areas of competence of Eurocontrol and the standards bodies in order to develop the necessary structure for the best use of resources in this sector. The ultimate standards will serve to complement the specifications drawn up by Eurocontrol, to provide a complete technical framework for air traffic control at the European level.

Other organizations

A few more examples may be given (the list is not exhaustive). The United Nations Economic Commission for Europe (UNECE) draws up rules for terrestrial transport, which have an implication for future EC transport policy. Similarly, Community legislation in the maritime area must take due account of the rules laid down by the International Maritime Organization IMO and, also in this sector, internationally recognised societies for marine classification. Regulatory bodies at global level also exist for air transport (ICAO).

V. Conclusions.

Standardization is an important factor in self-regulation, which because of its specific status, should be fully supported by the public authorities. It also has the capacity to be an effective, rapid, generally acceptable and easily used complement to legislation - and sometimes an effective substitute for mandatory regulation. The quantity of European standards has increased considerably in recent years, and has enabled the particular role of European standardization to become established.

In line with the Council Resolution already mentioned, the use of standardization should be encouraged and, where appropriate, the principle of referring to European standards in Union legislation should be used. These policy objectives should be implemented taking into consideration the potential, and the limits, of standardization referred to in this Communication. Where recourse to standardization is envisaged, certain conditions should be met, relating to the following issues:

- (i) efficiency: ESOs must be capable of meeting the demand for European standards from industry and from authorities. This implies delivering standards which meet such requests as regards the substance and as regards timescales for adoption; in the Strategic Programme the Commission has announced a review of how European standardization can be financed in the medium term, and will take as a basis the infrastructure needed to meet the requirements of the expected demand both from industry and public authorities for standards.
- (ii) European dimension: the European dimension of activities carried out by European standards organizations and their added value would be lost if their European origin were denied at national level. This implies a uniform, clearly visible identification of the European character of the standard as transposed at national level and a genuinely European marking of conformity with ENs.

- (iii) acceptability: European standardization must be fully and wholeheartedly accepted as an instrument of Community policy; this implies full transparency in continuing activities, easy access to European standards and full access for interested parties to the standardization process.
- (iv) need: There should be a continuing assessment of the need for European Standards in particular areas and for the standards making process itself to be made increasingly transparent and objective. Working links should be established with business organisations with the aim of understanding their concerns and objectives towards standardization policy within the Union.
- (v) technical appropriateness: Standards should support the integration of the market, but should not act as an obstacle to innovation. Standardization must not limit the development of innovative products by setting out in excessive detail the technical solution to be adopted for particular products, but instead should wherever possible be based on test methods and specifications of performance.

The Commission recognises that the European standards organizations have adopted significant measures to meet these requirements. Significant improvements have been made and new measures are continuously being implemented.

The need for such action remains, however, important for the future, and the further improvement of European standardization as support for European Union policy must be based on a close co-operation and dialogue between the European authorities and the standards organizations in a spirit of partnership.

For the Commission this means a need

- To examine areas in which standardization can contribute to the development of subsidiarity by substituting mandatory regulation with voluntary instruments;
- To ensure that legislative proposals take appropriate account of the advantages offered by extended recourse to standardization, in order to lighten the load of regulation, to improve economy in the use of resources, and in particular to obtain coherence and conformity with the recommendations of the Sutherland Report.
- To establish working links with the standards organizations at a stage as early as is possible in new policy areas. In this context, the two-step approach of programming mandates followed by standardization mandates must be encouraged.
- To treat the European standards organizations as forming a unique system, in which the individual components take all necessary measures to organize optimal allocation of work, by giving common mandates and requesting common positions in answer to such mandates.
- To leave the necessary flexibility to the standards organizations to fulfil, given the voluntary character of the process, their tasks, by giving open mandates on the

basis of which standards organizations define, in the light of their own competences and responsibilities, the standards programme needed to meet the requests contained in the mandate;

- To recognise the importance of considering necessary normative research during the process of establishing the individual standardization programmes.
- To highlight, and further to advance, the importance of promoting and using standards, thus creating the incentive for participation in the standardization process; and in particular to highlight and promote the use of standards in support of the improvement of quality;
- To indicate its priorities in cases where recourse to standardization is liable to compromise progress in existing areas or to overload the system.
- To consider how to take account of the particular concerns of SMEs within the recently announced proposals for an integrated programme in favour of SMEs and the craft sector and the financial initiatives within the Structural Funds.

Standardizers, on the other hand, should

- Be aware of the new dimension in standardization carried out in support of Union policy; in contrast to standardization decided at the initiative of economic operators, where individual standards are made to meet specific demands, mandates will call for the elaboration of coherent programmes of standardization covering broad areas. This implies understanding and awareness of the political and legal framework, programming, priority setting, proper and careful management of programmes and willingness to adapt to this kind of requirement.
- Develop, wherever possible, standards based on performance characteristics and testing methods rather than particular technical specifications for products, and be prepared to elaborate standards, such as performance standards, test methods, procedures and innovative standards in areas such as quality systems, which go beyond traditional product standards, since these last would result in a continuation of an Old Approach-like harmonization at the level of standardization.
- Provide full transparency on progress in mandated areas, and systematically monitor delays and their causes.
- Promote the concept of European standardization among economic operators and other existing or potential users.
- When receiving mandates from the Commission and drafting standardization programmes, consider at an early stage the necessary normative research to be undertaken and reflect this in the planning of the programme, and develop suitable procedures for the current updating of normative research needs and priorities.

- Take appropriate action to improve the participation of representatives in the process of elaboration of standards, so as better to reflect the needs of legitimate interests such as consumers, trade unions and other groups dealing with the safety of workers and representatives of environmental groups.

Industry should review the nature of its participation in standardization activities, and in particular should ensure that its representatives are appropriate to the importance of the task.

On this basis, the Commission will, in close cooperation with the Member States in the framework of Directive 83/189/EEC, and in consultation with the European standards organizations, consider the issue of further mandates for the areas mentioned above for the development of European standards.

The Commission invites the Council and the Parliament to take note of the information contained in this Communication and to endorse its orientations.