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**European Policy Principles on International Standardisation**

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## INTRODUCTION

The Commission was asked by the Council to develop Guidelines for a European Standardisation Policy in the International Context by June 2001 <sup>(1)</sup>.

The standards making process is considered a voluntary activity carried out by and for the interested parties themselves. Albeit not playing an active role in the production of standards itself, the Commission deals with standardisation in relation with many Community policies, in particular with the Single market and Community external trade. The role standards can play for market access and free movement of goods, and their potential for deregulation and for ensuring a high level of protection has been discerned by the Community more than 15 years ago when the New Approach to technical harmonisation and standardisation was introduced <sup>(2)</sup>.

Trade in goods must also comply with the WTO Agreement on Technical Barriers to Trade which deals to a significant extent with international standards. Hence, the Commission retains a European policy on international standards, and more specifically on their use in regulation. Important elements of this policy have been set out in the 1996 Communication from the Commission on the Community External Trade Policy in the fields of Standards and Conformity Assessment <sup>(3)</sup>. However, the use of standards in more and more fields makes it desirable to offer further clarification and guidance on this topic.

This paper sets out in a single document a number of established policy principles on international standardisation and on the use of international standards in Community policies, in the light of the advantages offered by international standards, notably their potential to facilitate trade in goods <sup>(4)</sup>. The paper also recognises the limitations of standardisation. Standards cannot replace governmental responsibility to safeguard a high level of protection concerning health, safety and the environment as stipulated by the Treaty establishing the European Community. On top of that, the international standardisation process is lengthy, does sometimes not achieve a sufficiently balanced consensus among the stakeholders and does not always meet the level of protection deemed appropriate by the Community. Nonetheless, voluntary standards can reduce the need for regulation and government intervention.

The Commission will continue to make use of standardisation in the execution of existing policies and will give due consideration to them when developing new policy initiatives <sup>(5)</sup>. This paper may serve as a point of reference to Member States and the parties involved in or dealing with international standardisation, notably the parties engaged in the European and national standards bodies. It can be of use to interested parties in the EC and EFTA member states and in the candidate countries for accession to the EC. And it may serve as a reference document for contacts with third countries and in relation with technical assistance projects supported by the Community.

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<sup>(1)</sup> OJ C 141 of 19.5.2000, Council resolution on the role of standardisation in Europe.

<sup>(2)</sup> OJ C 136 of 4.6.1985.

<sup>(3)</sup> COM(1996) 564 final of 13.11.1996.

<sup>(4)</sup> This document is not dealing with sanitary and phytosanitary measures.

<sup>(5)</sup> Cf. COM(1995) 412 final of 30.10.1995.

## I. STANDARDS MATTER

1. Standards significantly matter to enterprises, consumers and governments. For businesses standards help to create a common trading language. They ensure that parts produced across borders are compatible and that networks are interoperable, they reduce costs for manufacturing and warehousing. For consumers, standards reduce the costs they generally face when deciding for options, such as time and efforts they devote to their search. Standards generally reduce the costs of uncertainty, in particular when relating to functional properties as they facilitate comparisons. For governments, standards offer an opportunity for deregulation and improved governance as they help to reduce the level of regulatory detail to the essential requirements needed to attain legitimate objectives such as the protection of health, safety and the environment. Standards help to reduce the risk of being locked into a specific technology and promote the dissemination of know-how.
2. Increased trade is linked with economic development and, in many ways, leads to more convergence between trading partners. Had it not been for its capacity to facilitate exchange and access to markets, to improve the quality and safety of products and services, and to disseminate knowledge, technology and business practices, standardisation would not have become a crucial element in European economic integration and world trade. Beyond the role standards play for the functioning of the internal market and for contributing to the protection of public interest, they are also an important element in the Community's enlargement process and in external trade agreements.
3. Standardisation is a voluntary process and for no matter which subject, this process has to be open and transparent, and result in a consensus amongst stakeholders. International standardisation is carried out by a number of societal stakeholders who reconcile their positions nationally and internationally. **Europe has an interest in international standardisation because of its potential to eliminate technical barriers to trade and to increase market access for all. International standardisation also offers the possibility to promote and disseminate technologies on a par basis with others.**
4. But to reap the full benefits of international standardisation, it is important to take some basic requirements into account and to balance the interests not only of industry, but also consumer concerns, health and safety considerations, environment aspects and concerns of small and medium sized enterprises (SMEs). It may also be beneficial to consider the interface of standards and regulations, respectively the scope for standardisation and regulatory activity and the procedures chosen to demonstrate conformity with legal requirements and/or standards.
5. **In Europe, there are, for most areas of the economy, well-established principles for the standards developing process and for the bodies accountable for this process. The principle of openness aims at ensuring that a broad range of societal interests, including consumer and environmental interests, are represented in the standardisation process.** In addition, these principles ensure, among other aspects, that all interested parties can participate in the work and that standards neither impede competition, nor hinder progress and technological innovation. European stakeholders also strive for coherent standards, preferably one standard, based on the international one.

## II. TRADE, INTEGRATION AND CONVERGENCE: PRIORITY FOR INTERNATIONAL STANDARDS

6. Today, standards, also when used in relation to legislation, are a cornerstone of the functioning of the European Single Market. They are one of the basic elements in a system including, amongst others, conformity assessment procedures and market surveillance. The interoperability, accuracy, and acceptance of measurements are also fundamental for meaningful standards, in particular where these have influence on the transparency of economical transactions, health and safety. The European system has contributed to economic integration and has helped to attain other policy objectives set out in the Treaty.
7. Whilst the character of the European Single Market and its political will to build it may be unique, it may be beneficial for third countries to understand and work with European principles. Especially, countries engaged in efforts to set up or review a standardisation system and its possible links with regulation may take an interest in European principles, as well as regions which want to further integrate.
8. In the international context, it should be noted that the way regulatory authorities use standards in technical regulation has also become an important element with regard to trade facilitation. The WTO Agreement on Technical Barriers to Trade (WTO TBT Agreement) obliges WTO members to use existing international standards as a basis for their technical regulations, except when such international standards would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued. In some industrial sectors (and often for historic reasons), recommendations or other deliverables from intergovernmental organisations are also considered as international standards. Such bodies are generally referred to as standardising bodies and their work tends to be used as a basis for harmonisation of legislation.
9. European stakeholders are interested in collaborating with their trading partners to facilitate market access and economic integration through the use of international standards and the creation of standards-receptive economic and legal conditions. Generally, regional or national standards should be aligned to the greatest possible extent to international standards, but the value of national and regional standards as stepping-stones to international standardisation should also be recognised. It is also considered helpful to have explanations from authorities for deviations from international standards as foreseen under the WTO TBT Agreement. **To avoid confusion and uncertainty amongst trading partners and to increase transparency, it is necessary to withdraw conflicting national standards from the collections of the national standards bodies as soon as regional or international standards are available, provided legitimate regulatory requirements permit.**
10. There is, however, widespread concern among the public on the appropriateness, use and limitations of international standards for political and ethical reasons or due to cultural diversity. Therefore it should be noted that, under the WTO TBT Agreement, each WTO member has the sovereign right to define the level of protection it deems appropriate to meet legitimate objectives, subject to the requirement that they are not applied in an arbitrary or discriminatory manner. Whilst international standards may be seen as beneficial in some instances, they may be perceived as little advantageous or even as threats in others. Different national standards or not having a recognised

standard at all could also reflect differences in risk perception, individual tastes or distinctive markets. **If regulatory authorities decide to make recourse to international standards, it is important that they can make use of standards from standards bodies which can be held accountable for establishing consensus between all national positions and interested parties.**

### **III. INTERNATIONAL, EUROPEAN AND NATIONAL STANDARDISATION COMPLEMENT EACH OTHER**

11. **Internationally traded goods need international standards whenever possible.** However, under certain circumstances, international standards may be ineffective or inappropriate, for instance, because of an insufficient level of protection or regional or local differences. National standardisation is therefore considered to complement the international standardisation process while European standardisation provides coherence for free circulation on the European market or to meet European harmonisation and other public interests. National standardisation takes account of national and local particularities including geographic, cultural and linguistic characteristics; it strengthens the capacity of the European and international standardisation process to reach out to local interests, and it helps to ensure a wide participation of stakeholders. **It can be of particular value to consult between stakeholders nationally and represent national positions independently in the international context. For that purpose, it is important that the national standardisation systems allow for effective participation by all interested parties, and that national positions are coherent with European policies and legislation, if existing.**
12. In view of the amount of financial, technical and human resources required for effective participation in international standardisation, stakeholders, in particular representatives of environment, consumer and employees' interest and SMEs are interested in an efficient allocation of their resources. This is also the case for countries with a lack of technical expertise and financial resources to participate in international standardisation. To this end, stakeholders may wish to consider allocating resources for representation in international work in a targeted manner so that domestic priorities or societal concerns are reflected properly. An exchange of information and co-operation with other participants in international standardisation - active or observing - may facilitate priority setting and allocation of resources. If the relevant standards were to be used in relation with public policy or legislation, public authorities should consider support to ensure that all societal interests are represented at all levels of the international standardisation process.

### **IV. THE WTO ACCEPTED PRINCIPLES FOR INTERNATIONAL STANDARDISATION**

13. **To have one applied standard and one accepted test for each product, process or service is a trade-facilitating objective.** This principle is commonly promoted by enterprises operating at a global scale, but it offers also benefits for small and medium sized enterprises. It seeks to reduce the costs a manufacturer of a product has to face for goods being re-designed and re-tested when entering foreign markets. Such a principle is beneficial for consumers provided that the one applied standard takes their interests into account and/or meets legal requirements concerning legitimate regulatory objectives such as the protection of human health and the

environment. Consequently, such standards ought to respect some basic requirements.

14. **International standards have a maximum effect in trade facilitation when they are part of a single and coherent set of standards. If international standards are used in relation to technical regulations as promoted by the WTO TBT Agreement, international standards bodies need to have a clearly defined constituency.** If standards bodies were to produce simultaneously international and regional or national standards, some partiality, incoherence and conflict in the set of international standards could arise. Such a situation would be confusing for businesses, users and public authorities, and the latter would risk creating regulatory barriers if using conflicting international standards as a basis for technical regulation.
15. To this end, WTO members adopted a set of principles to clarify and strengthen the concept of international standards under the TBT Agreement <sup>(6)</sup>. The WTO accepted principles are:

**Transparency.**

All essential information regarding work planning, work under progress and final results should be made easily accessible to all interested parties and throughout all stages of standards development. Appropriate time and opportunities for written comments should be provided.

**Openness.**

Any interested national member should be provided with meaningful opportunities to participate in standards development.

**Impartiality and consensus.**

The standards development process should be conducted in a non-discriminatory way and should not give privilege to, or favour the interests of, a particular supplier or country. Conflicting arguments must be reconciled to satisfy all national members.

**Effectiveness and relevance.**

The international standards development process should take account of market needs, scientific and technological development. It should also consider regulatory needs and pay due respect to consumer concerns, and concerns relating to the health and safety of workers and the protection of the environment.

**Coherence.**

The standards development process should result in a coherent set of international standards that do not conflict with each other. International standards bodies should co-operate and co-ordinate with each other to avoid conflicting international standards.

**Development dimension.**

International standardisation should take the constraints on developing countries to effectively participate in standards development into consideration. Provisions for capacity building and technical assistance within international standards bodies should also be considered.

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<sup>(6)</sup> WTO/G/TBT/9 of 10 November 2000, and Annex 4 thereof.

16. The principles adopted in relation with the WTO TBT are in line with Europe's thinking on international standards, and they are consistent with the basic principles respected by the European standards bodies and their national members. However, from a European perspective, not only the standards development process, but also the constitution of the bodies developing international standards plays an important role if public authorities were to use international standards as a basis for regulation. **The WTO principles taken as a whole ensure that international standardising bodies are open to participation by national standards bodies and produce international standards that do not conflict with each other.** Another important element is the participation of all stakeholders including environmental and consumer interests in international standardisation.
17. Whilst there is an emphasis on contributing to global convergence by elaborating and using coherent international standards, this is sometimes difficult in fast moving technology sectors. In such sectors, there are a number of initiatives outside the scope of international standards bodies which are intended to contribute to global convergence in an early phase of standards development, however, and pending a possible further elaboration and adoption in international standards bodies. This is notably the case in the telecom and information technologies field. To contemplate such situations, the European Telecommunications Standards Institute (ETSI), for instance, has set up liaison committees with other regional associations to ensure common understanding on specific developments concerning telecom standardisation. In addition, extended use of the mechanism in ETSI known as the "Partnership Project" has been applied to develop specifications at the earliest moment in new emerging technological areas requiring stabilisation at global level. **Some sectors, in particular fast moving technology sectors, may benefit from an early phase standards development outside international standards bodies and it is important that, if required, such work could be channelled into international standards bodies.** However, further reflection on the standards making process is needed in view of the fast pace of technology evolution in some sectors.

## V. STANDARDS CAN OFFER A POTENTIAL FOR DEREGULATION

18. When legislation is needed to protect legitimate public objectives, regulatory authorities may have an interest to concentrate on the setting of public policy objectives and to keep the necessary mandatory regulation slim, stable and technology neutral, allowing for innovation. This may be achieved by leaving detailed technical work leading to compliance with legal requirements to private sector standards bodies. **The voluntary use of standards in regulation requires a clear definition of each party's roles and competencies.** Where objectives are set out by legislation, standards can offer solutions for compliance with essential legal requirements. The voluntary standardisation process, however, cannot duplicate or replace governmental responsibility for the protection of fundamental public interest such as the protection of human health and safety and the environment. **Voluntary standards can reduce the need for regulation, respectively government intervention.** This is notably the case in the telecom and information technologies sectors where open standards aiming at achieving interoperability can play an important role to ensure that the benefits of competition can be maximised for consumers, reducing the risk that they become locked into a specific technology.

19. The strive for deregulation and trade facilitation at global level has triggered conceptual thinking and discussion in a number of international and intergovernmental fora in order to achieve a common understanding on good regulatory practice and to closer align regulations and standards. The variety of means considered range from agreement on equivalency of standards, alignment on international standards to international harmonisation of regulations. The identification of common regulatory objectives is often the starting point for a regulatory dialogue which can help to approximate legal requirements, if fundamental cultural and societal concerns permit and if the level of protection defined by each country is comparable.
20. The use of international standards as a basis for technical regulations offers a presumption of conformity with international trade rules, notably with WTO rules. However, countries have the right to go beyond the level of protection defined by international standards in order to achieve the desired level of protection at the domestic level, provided the respective measures are not arbitrary and do not discriminate. An important element in these efforts is to provide information on existing regulations and standards in order to explore commonalities. European initiatives are also directed to build common understanding of best regulatory practice with trading partners. **The European side can share with third countries and other regions more than 15 years experience on its New Approach to technical harmonisation and standardisation which was a significant step in the implementation of the Single Market in Europe.**

## **VI. STRIVING FOR MORE EFFICIENCY AND ACCOUNTABILITY IN INTERNATIONAL STANDARDISATION**

21. The use of deliverables from single standards developing organisations or other specifications promoted by private consortia meets the requirements of industry in some sectors, allowing direct representation by industry. This approach is of relevance in areas with fast moving technology or in cases with no environment, health and safety aspects or other public interest in standardisation. Therefore, it co-exists along the more formal approach where standards from international standards bodies offer consensus via national member bodies. It is important to ensure that national positions balance the interests of all concerned parties, including economic, social, health and safety concerns, environmental aspects and, if needed, respond to regulatory concerns through participation of regulators in all phases of standards development.
22. To obtain efficiency in international standards development and effective responses to sectoral needs, a large spectrum of standards developing organisations should be avoided. Furthermore, attaining these objectives does not reduce the need for a coherent set of international standards reflecting the consensus of all national members. **Within international standards bodies, measures to improve their efficiency should further be deployed. However, striving for more efficiency should not conflict with accountability which is considered important if standards were used as a basis for legislation.** While the standardisation process should be stepped up to become more efficient, it must not fail to be open for participation by all interested parties and to strike a balance of national interests, considering the constraints of developing countries.

23. Sectoral characteristics are mirrored at the international level by the fact that, in addition to the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC), other specialised standardisation bodies exist. Most of them are intergovernmental organisations. The International Telecommunication Union (ITU) elaborates recommendations that, in some cases, have binding status and/or regulatory implications, notably in the ITU-R sector, but also to a lesser extent in the ITU-T sector.
24. When converging technologies blur the boundaries between sectors, bodies with similar rules are well positioned to respond by setting up joint groups, for instance. Generally, there are groups for sectoral focus in standardisation bodies such as technical committees or workshops, and they bring the relevant stakeholders together. These groups operate on a common platform and share procedures and principles for consensus. This ensures consistency and coherence and allows easily a combination of efforts in cross-sectoral matters without having to set up additional organisational structures. **It may be beneficial to channel standards, specifications and other deliverables into the international standardisation process that have reached a certain consensus outside international standards bodies.** In such cases, it is essential to define criteria for a coherent integration into the existing set of international standards and for an impartial maintenance of such standards. In other cases, research aimed at solving technical problems that impede the drafting and implementation of international standards may be needed. Such research should address the most pressing problems on a consistent world-wide basis, and avoid duplication.
25. Co-operative agreements do already exist between international and regional or national standards organisations. The Vienna and Dresden Agreements between ISO and CEN, respectively the IEC and the European Committee for Electrotechnical Standardisation (CENELEC) are useful examples how to enable for input, to avoid double work or to speed up standardisation work. These agreements provide, if wished, for development in one body and approval, by parallel voting, in both. These arrangements provide at the international scale for early information and the possibility to provide comments. Another example for a co-operative agreement is the one between the ITU and ETSI. With regard to the co-operation between international and regional or national standards bodies, it is important that the maintenance of the international standard is considered first with the international standards body who may decide whether or not to delegate the maintenance responsibility to the originating body.
26. **Co-operative arrangements with international standards bodies offer a systematic framework to take over international standards and/or to contribute to the international standards making process.** In some specific cases where international standards are not considered appropriate, for instance, when they do not meet regulatory requirements for European legitimate objectives, or in those areas where international standards do not yet exist, the European standards community may deviate from international work. In such instances, the co-operative agreements need to provide a framework to indicate and justify such deviations in a transparent way. Other regional or national standards bodies may also find it beneficial for their constituency to set up transparent agreements for co-operation with the respective international standards body.

## VII. CREATE AWARENESS AND ENABLE THIRD COUNTRIES TO JOIN FORCES

27. The EC and its Member States provide considerable technical assistance to third countries to help them aligning their technical regulations, standards and conformity assessment structures and procedures as well as the quality of their products and services to European and international requirements. The type of assistance provided is decided on a case-by-case basis, taking into account the situation and the development level of the recipient country. The decision about priority areas for assistance in the various countries is generally made jointly by the donor and the recipient.
28. **The Community generally supports, in line with its political objectives, the development of a (preferably regional) infrastructure for standardisation. The EC also promotes the creation of legal and economic conditions which facilitate trade and which are receptive to the use of voluntary consensus standards.** Typical assistance areas are: if needed, regional integration, the harmonisation of legislation and technical regulations, standardisation and conformity assessment infrastructures, effective participation in regional or international standards bodies, and questions concerning marking issues and market surveillance systems. The EC supports also research projects that contribute to standardisation and harmonisation of technical regulations.
29. A more efficient implementation of the WTO TBT agreement is another goal pursued in the EC's technical assistance activities. **Special attention is also directed to trading partners having an interest in using European standards directly - be it in the absence of appropriate international standards or for other reasons such as regional integration or close liaison with Europe.**

## VIII. AN OPEN INVITATION

30. Increasing the effectiveness of international standardisation, building on the synergies that can be created by standards-receptive economic and legal conditions as well as the support of third countries in international standardisation require communication and co-ordination between all relevant stakeholders to avoid overlap and duplication. Hence, **European actors should communicate with each other to ensure mutual understanding and positions in respect of legal requirements or in support of policies of the EC. While representing their own constituencies in specific discussions, European actors are invited to follow the principles set out in this paper which, taken together, define the European policy in relation to international standardisation.**