
International
standards for the
elimination of
barriers to trade



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an analysis of the agreements and of the discussion of standardization policy

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International standards for the elimination of barriers to trade – an analysis of the agreements and of the discussion of standardization policy

The Commission for Occupational Health and Safety and Standardization (KAN) was founded in 1994 to assert German interests in OH&S matters, especially with regard to European standardization. KAN is composed of representatives of the social partners, the federal state and the Laender, the Hauptverband der gewerblichen Berufsgenossenschaften (HVBG, Federation of the Statutory Accident Insurance Institutions of the Industrial Sector) and the German Standards Institute (DIN). One of KAN's tasks is to focus the public interests in the field of occupational health and safety and to exert influence on current and future standardization projects by delivering opinions on specific subjects.

KAN procures studies and expert opinions in order to analyse occupational health and safety aspects in standardization and to reveal deficiencies or erroneous developments in standardization work.

With the signing of the WTO Agreement⁸ on 1 January 1995, the European Union also acceded to the TBT Agreement⁹. WTO members undertake to base their technical regulations upon the relevant international standards, and thus ascribe considerable importance to international standardization. The priority accorded, in the Vienna and Dresden agreements concluded between ISO/CEN and IEC/CENELEC, to international standards for products and processes in preference to European standards is thus also brought to bear on a political level. Since the TBT Agreement was concluded, it has played an important role in the topical discussion of standardization policy by the Internal Market Council and the European Commission.

In addition to requirements for products and processes, international standards may also contain provisions governing the working environment within companies, for example codes of practice for employees and employers. The German institutions responsible for health and safety at the workplace, and the social partners, who together agree upon standardization issues within the Commission for Occupational Health and

⁸ "Agreement Establishing the World Trade Organization (WTO)", 15 April 1994, OJ EC, L 336, 1994, pp. 3-10.

⁹ "Agreement on Technical Barriers to Trade", OJ EC, L 336, 1994, pp. 86-99.

This report

Safety and Standardization (KAN), support the principle of preference being given to international standards. It is feared, however, that where such international standards are incorporated into the European body of standards, provisions will arise which compete with provisions by the Member States transposing the directives pursuant to Article 137 of the EC Treaty. The scope embodied within the EC Treaty for national authorities to regulate the requirements concerning the working environment within companies must not, in the view of the parties represented in KAN, be restricted by international agreements or international standards.

It is also feared that it may not prove possible to maintain the level of protection which exists in Europe as standardization activity is internationalized. One means by which this might be avoided would be the supplementing of the TBT Agreement by essential safety requirements on the European "New Approach" model. The parties represented in KAN wish the development of international essential safety requirements for products to be based upon a high level of protec-

tion, in accordance with the European model.

The present legal opinion, which was drawn up on behalf of KAN, is intended as a basis for discussion of these essential aspects at national, European and international level. It addressed the following subjects:

1. What areas of policy of the EC Treaty are affected by the TBT agreement? Is the list of articles from the EC Treaty in the Council Decision adopted on 22 December 1994¹⁰ exhaustive?
2. In what policy areas of the EC Treaty affected by the TBT Agreement are technical regulations supported by standards?
3. Does the TBT Agreement also apply to measures concerning the working environment within companies, which in the EU fall within the scope of EC Directives pursuant to Article 137 of the EC Treaty?
4. Can it be inferred, from the provision that the TBT Agreement refers not only

¹⁰ "Council Decision 94/800/EC, adopted on 22 December 1994, concerning the conclusion of agreements within the framework of the multilateral negotiations of the Uruguay Round (1986-1994) in the name of the European Community with reference to the areas falling within its competence", OJ EC L 336, 1994, pp. 1-2.

¹¹ Prof. Dr. Müller-Graff: Normung und Welthandelsrecht – Verpflichtungen aus dem Übereinkommen über technische Handelshemmnisse, paper delivered at the CEN 1997 General Meeting, Vienna.

to products but also to production methods, that the work process for manufacture of a product must also be taken into consideration?¹¹ Do requirements upon the manufacturer's in-plant organization (e.g. management standards relating to quality, environmental protection and occupational health and safety) thus fall within the scope of the TBT Agreement?

5. Do international agreements other than the TBT Agreement exist which affect the relationship between EU legislation and international standards?

6. To what extent has the concept¹² of drafting international essential safety requirements according to the European "New Approach" model been taken up by European and international organizations (TABD, OECD, UN/ECE, etc.)?

7. What stage has been reached by discussion of the definition of "international standard"?

KAN wishes to thank the author for conducting the project and submitting the report. Thanks also go to the experts for their critical supervision and support during the evaluation of the study:

[For list of experts, see p. 7.]

The full text of the study is available in English and German at <http://www.kan.de>.

In addition to the results summarized below, it contains, in Annex A, a comparative survey of organizations which draft international standards.

Annex B contains a total of 12 tables concerning the supporting of technical regulations by standards in Community law outside the scope of the New Approach. The present project is the first attempt to produce such a record, which is intended to be complete and up-to-date, for the full body of Community law and for the current proposals for Community legislation.

¹² See "Feedback report Global Trade" from the conference held in Berlin by the European Commission and EFTA on 15-17 March 1999.

Summary of the study

1. What areas of policy of the EC Treaty are affected by the TBT agreement? Is the list of the articles of the EC Treaty in the Council Decision adopted on 22 December 1994 exhaustive?

The legal bases stated in Council Decision 94/800/EC of 22 December 1994 do not identify Article 113 of the EC Treaty (now Article 133 of the EC Treaty) as the sole applicable legal basis for the trade policy conducted by the Community alone. The following areas are also mentioned: principles of agricultural policy, restriction of the right of establishment, mutual recognition of diplomas and certificates, transport, indirect taxation, the Single Market, and supplementary powers of the Council for unanticipated cases¹³. The list contains no provisions establishing competence for Community measures in the area of occupational health and safety, environmental protection, consumer protection, and health protection¹⁴.

Of itself, this list does not enable conclusions to be drawn concerning the scope of the content of the TBT (Technical Barriers to Trade) Agreement and the obligations assumed under it by the EC and

its member states. According to its wording and the practice of its application, however, the TBT Agreement extends to all products, whether they be produced industrially, by artisans, or agriculturally. The TBT Agreement thus affects all areas of policy of the EC Treaty relevant to products, with the exception of the purchasing specifications for production or consumption issued by government departments, which are expressly excluded by the TBT Agreement, and the sanitary and phytosanitary measures described in Annex A of the SPS Agreement.

The implications – of particular interest to KAN – of this for regulations governing the health and safety of workers at work which are subject to Article 137 of the EC Treaty (formerly Article 118a of the EC Treaty) must be clarified in relation to the terms “technical regulation” and “standard” (see section 3 below).

The information available does not reveal the extent to which the notified technical regulations are regulations relating to production conditions and processes and the conditions of use of the product (process regulation) in addition to those concerning characteristics inherent to the product (product regulation).

¹³ Articles 43, 54, 57, 66, 75, 84 Para. 2, Article 99, 100, 100a and 235 of the EC Treaty.

¹⁴ For example Article 118a of the EC Treaty (now Article 137), Article 130s of the EC Treaty (now Article 175), Article 129a of the EC Treaty (now Article 153), Article 129 of the EC Treaty (now Article 152).

2. In what policy areas of the EC Treaty affected by the TBT Agreement are technical regulations supported by standards?

The chief area in which Community legislation makes reference to technical standards are the Single Market New Approach directives in the area of technical harmonization and standardization. This core area has been addressed comprehensively on the web site maintained jointly by the European Commission, the European Free Trade Association (EFTA) Secretariat and the European standardization organizations CEN, CENELEC and ETSI (<http://www.newapproach.org/>). A third (33.4%) of the harmonized European standards within the New Approach are identical to international standards developed by ISO or IEC; a further 13.2% adopt international standards with modifications.

Numerous Community acts outside the New Approach to technical harmonization and standardization also contain references to technical standards. These include the areas of public procurement or information technology, for example. The present project is the first attempt to record these references which claims to be complete and up to date for the full body of current Community law and for the current proposals for Community legal instruments.

The identified references to standards differ fundamentally from the regulatory mechanism of the New Approach to technical harmonization and standardization. Whereas in the latter case, all product characteristics relevant to distribution of the products are regulated in numerous harmonized standards for support of the essential requirements for a category of products, references to standards outside the scope of the New Approach generally serve to add information on specific aspects of product requirements of greater or lesser detail which are specified in Community legislation itself. Consequently, the standards overwhelmingly concern the definition of measurement and test methods. Some standards are also referred to for precise identification of products, in particular in the area of customs duty and import/export.

At no stage in the evaluation was the scale of product safety or threshold values for environmental impact or, for example, noise pollution of technical products found to be undefined without the reference made to technical standards. Rather, technical standards are without exception employed to define criteria for, or reliably assess, observance of the product requirements specified by the Community's legislative organs themselves.

Detailed analysis revealed that references to standards are evidently not always

Summary of the study

applied in a co-ordinated fashion within the European Community. The rigid reference to standards, common for a long time in Community law, gives rise in particular to numerous consequential problems, for example in the absence of updating.

3. Does the TBT Agreement also apply to measures governing the in-plant working environment, which in the EU fall within the scope of EC Directives pursuant to Article 137 of the EC Treaty?

In its definition of the terms "technical regulation" and "standard", the TBT Agreement encompasses only processes and production methods which have a direct bearing upon the product characteristics, i.e. which are reflected in the product as it is distributed.

A distinction between processes or production methods according to whether they are demonstrably reflected in the product corresponds largely to the distinction prevailing in Community law. Product-related occupational health and safety is governed in directives pursuant to Article 95 of the EC Treaty. Directives pursuant to Article 137 of the EC Treaty govern production- or company-related occupational health or safety, which in turn provides member states with scope for the implementation of higher stand-

ards of protection provided such standards do not impair the freedom of movement of distributable products and plant. Clear assignment to one category or the other may be difficult in some cases.

Even where international product standards exist, the TBT Agreement initiates no mechanism for adoption of such standards in corresponding technical regulations and regional or national standards. Rather, Articles 2.2 and 2.4 of the TBT Agreement and Item F of the Code of Good Practice for the Preparation, Adoption and Application of Standards contain numerous reservations and alleviatory measures. International standards serve only as a basis for national technical regulations; they must be effective and appropriate means for the fulfilment of the legitimate objectives pursued. The objectives which may legitimately be pursued in the drafting of national technical regulations include, under the heading of protection of the safety and health of human beings, occupational health and safety. The legitimate objectives listed are not exhaustive.

This characterizes the wide scope of political responsibility which is not affected by the TBT Agreement.

The WTO arbitration case concerning the French asbestos ban shows for the

first time what scope the WTO rules leave the members for a policy of occupational health and safety geared to high standards of protection. The Appellate Body particularly emphasized the right of a WTO member to specify the required level of protection of human health. The consequences for less scandalous cases have yet to be established.

The concept of integration of national and European standardization activity into the international context has not yet been given adequate consideration with regard to its consequences for the status of standardization regarding the health and safety of workers at work, which is governed by Article 137 of the EC Treaty.

If the current principle governing standardization within the area of the health and safety of workers at work is to be maintained, this viewpoint must also be advocated at international level. Legitimization must however extend substantially beyond the particular arrangements governing the relationship between product-related and production or application-related occupational health and safety in the EC Treaty.

In Europe, the perspective on the role of standardization in the area of the health and safety of workers at work has as a

substantial objective that of maintaining the high standards which have been developed and are applied in the individual countries and by bodies representing employers and employees. This basic position and objective cannot be assumed to apply automatically to the international level.

Rather than pursuing at international level the EC's concept of consciously not standardizing aspects of the health and safety of workers at work, forms of standardization activity must be provided for which enable the developed industrial nations with established OH&S systems to retain their scope, whilst at the same time permitting them to transfer expertise and technology in this area to developing countries. The concept of separation of the process and production measures (PPMs) into those which are reflected in the product (product-related) and those which are not (non-product-related) has been developed particularly convincingly in an OECD study, and its consequences formulated.

The International Labour Organization (ILO) is the appropriate organization for international co-ordination in the area of social and in-plant occupational health and safety. It is without equal in fulfilling important functions in the area of social occupational health and safety and in representing a joint forum for

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governments, trade unions and employers' representatives, for both developing and industrial countries. Its work is geared especially to particularly vulnerable occupational groups, and to particularly serious impacts. Precisely because of the procedures governing the drafting of its regulations, however, it is less suited to the need for rapid adaptation in the area of engineered occupational health and safety.

For product-inherent technical occupational health and safety, however, technical standards are without alternative: The international standards organizations' body of technical standards is sufficiently detailed, relevant and up to date with regard to the technical requirements upon products. It also meets the strictest requirements upon mutual coherence of the individual provisions, and is also subject to continual updating.

4. Can it be inferred, from the provision that the TBT Agreement refers not only to products but also to production methods, that the work process for manufacture of a product must also be taken into consideration? Do requirements upon the manufacturer's in-plant organization (e.g. management standards relating to quality, environmental protection and occupational health

and safety) thus fall within the scope of the TBT Agreement?

Requirements upon in-plant aspects do not fall within the scope of the TBT Agreement. As OH&S management standards deal solely with requirements upon in-plant aspects, they likewise do not fall within the scope of the TBT Agreement.

Furthermore, a common element of all management standards is that owing to the deliberately ubiquitous nature of their scope of application in production and service enterprises and in administration environments of all types, they permit no specific provisions relating to the inherent characteristics of products. Management standards governing quality and environmental protection do not therefore fall within the scope of the TBT Agreement.

5. Do international agreements other than the TBT Agreement exist which affect the relationship between EU legislation and international standards?

In addition to the TBT Agreement, two further WTO agreements exist for the Community which affect the relationship between EC legislation and international standards, namely the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), and the Government Procurement Agreement.

Mention is made only briefly of the complex relationship between international agreements, EC directives, national legislation and a wealth of technical standards in the area of dangerous goods transport.

The relationship between Community legislation governing motor vehicles and parts and the drafting of technical regulations under the aegis of the United Nations Economic Commission for Europe (UN/ECE) is particularly close. The "Parallel Agreement" recently created the basis for global technical co-operation under the aegis of the UN/ECE for a sector which has for many years been governed by a detailed body of technical regulations under national responsibility.

6. To what extent has the concept of drafting international essential safety requirements according to the European "New Approach" model been taken up by European and international organizations (TABD, OECD, UN/ECE, etc.)?

The Organisation for Economic Co-operation and Development (OECD), the UN/ECE and the Transatlantic Business Dialogue (TABD) have presented proposals for the linking of binding technical regulations of individual states with international standards. The UN/ECE and the TABD have also developed models for

this purpose in which essential requirements can be established at international level as terms of reference for international standardization committees according to the model of the New Approach to technical harmonization and standardization.

The international model developed by the UN/ECE for good regulatory practice involving the use of international standards adopts almost all relevant elements of the New Approach. This model assigns important co-ordination tasks to the UN/ECE. The specifically new slant of this approach is that it does not contain a model purporting to be global, but is based upon initiatives by countries wishing to co-operate within certain product sectors. Whereas the TBT Agreement is based upon the assumption that suitable international standards may well be available to serve as a basis for national technical regulations, the UN/ECE model assumes, as does the New Approach of the European Community, that agreement upon jointly formulated Common Regulatory Objectives (CROs) will result in a need for further international standards to be drafted.

The TABD is one of the pioneers of the concept of establishing essential requirements on a sector-by-sector basis at a global level as a binding orientation framework for international standardiza-

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tion activity. In recent years, however, the TABD has made less effort to gain acceptance of its idea of transferring the New Approach to technical harmonization and standardization to the international level, and to the formulation and clarification of the conditions necessary for this transfer, and has instead attempted to influence the definition of technical requirements in specific product sectors. The TABD emphasizes the reference of technical regulations to international standards which have been brought about by market forces.

Conversely, the European Union's New Approach is based upon the premise that the national regulators responsible for the protection of elementary legal rights formulate the key constraints for standardization activity through the essential requirements, and thus put a statutory framework in place.

The proposal that international essential safety requirements be formulated on the European "New Approach" model would have to take the following aspects into account:

- The formulation of essential requirements at international level represents adoption of only one key element from the New Approach to technical harmonization and standardization. The efficacy and legitimacy of the

New Approach, however, is attributable to the careful co-ordination of a number of elements. Besides the specification of statutory essential requirements, these elements include the issuing of standardization mandates by the European Commission, close co-ordination between the technical committees and the Commission by New Approach Consultants, the facility for the raising of formal objections, safeguard procedures, and co-ordination of the activities of certification bodies and market surveillance authorities.

- The formulation of essential requirements remains, with good reason, the prerogative of the legislative bodies holding political responsibility. What party might assume this task at international level, and by means of what instruments, remains unclear.

The present structure of the WTO fails to meet the requirements for political control of the framework of international standardization. To date, no corresponding proposals have been submitted for preparation of a new World Trade Conference or under the auspices of the WTO Committee on Technical Barriers to Trade.

The international model of the UN/ECE entrusts the control of such a framework for specific product sectors

to the groups of countries indicating a wish to co-operate. In the author's view, however, the UN/ECE cannot be considered for a global co-ordination function.

A study of the extent to which elements of the New Approach have already been implemented at international level in certain sectors (e.g. electrical products) lay outside the scope of the present report.

7. What stage has been reached by discussion of the definition of "international standard"?

Discussion of the definition of an "international standard" reached a substantial conclusion in November 2000 with submission of the Second Triennial Report on Application of the TBT Agreement. The WTO Committee on Technical Barriers to Trade adopted a decision con-

cerning the principles to be observed in the development of international standards, guides and recommendations, namely those of transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and consideration of the needs of developing countries.

The decisive commitment of the EU to the criteria of coherence and singularity was supported by the argument that reference in technical regulations to international standards would be a suitable means to the elimination of barriers to trade only if a situation did not exist in which competing international standards were available for selection. The criteria of coherence and singularity are reflected in the approved document however only in the substantially weakened form of co-operation and avoidance of duplicated activity.

Recommendations resulting from the study

1. Recommendations to DIN

KAN requests that DIN make the report available to the international and European standards committees and to the national mirror committees of international committees.

KAN requests that, in the interests of consistent application of the WTO/TBT Agreement, DIN promote:

- observance of a clear distinction between standards containing requirements which influence product characteristics and those which do not in the drafting of standards at international level;
- the embodiment of this distinction in the guidance documents (e.g. ISO/IEC directives) more explicitly than has previously been the case.

2. Recommendations to the Federal Ministry of Labour and Social Affairs (BMA), and to employers' and employees' representatives

KAN requests that the BMA, or the Federal government, and employers' and employees' representatives adopt the following position with regard to organizations which attempt to find an arrangement at international level corresponding to the New Approach (e.g. WTO, OECD, UN/ECE):

- Such arrangements should not make reference to standards placing requirements upon the health and safety of workers at work.
- A mandate for drafting of standards to "support the safety, health and environmental protection objectives" to non-governmental standards organizations must be issued subject to political control of the terms of reference, in order to prevent the scope of the tasks assigned from being exceeded.
- In order for the mandating of tasks as described above to gain in effectiveness and legitimacy, a number of elements must be carefully co-ordinated. These include the definition of legally binding essential requirements, where applicable the issuing of defined standardization mandates, a certain level of quality assurance of the standards, official recognition of standards which meet all necessary conditions, safeguard clauses, and co-ordination of the activities of certification bodies and market surveillance authorities.
- Unambiguity and consistency must be essential elements of the international body of standards.

3. Recommendations to the KAN Secretariat

KAN instructs the KAN Secretariat to assess whether

- the OECD concept for processes and production methods (PPMs) in the area of environmental protection can be applied to occupational health and safety. The objective of this assessment is to identify clear criteria for production methods by which methods which influence product characteristics can be distinguished from those which do not;
- the findings of a study performed by Hilf and Reuss into the constitutional requirements upon international standardization in food law can be exploited for the area of occupational health and safety.

International standards for the elimination of barriers to trade

Part 2: Full text of the study



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**International standards for the elimination of barriers to trade –
an analysis of the agreements and of the discussion of
standardization policy**

**Report
commissioned by the Commission for Occupational Health and Safety
and Standardization (KAN)**

Josef Falke

Bremen, October 2001

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Index of abbreviations

AENOR	Asociación Española de Normalización y Certificación
AFNOR	Association Française de Normalisation
ANEC	Association Normalisation Européenne pour les Consommateurs, <i>European Association for the Coordination of Consumer Representation in Standardization</i>
ANSI	American National Standards Institute
API	American Petroleum Institute
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
BAT	Best Available Techniques
BGH	Bundesgerichtshof <i>German Federal Supreme Court</i>
BMA	Bundesministerium für Arbeit und Sozialordnung <i>German Federal Ministry of Labour and Social Affairs</i>
BREF	Best Available Techniques Reference Documents
BSI	British Standards Institution
CAC	FAO/WHO Codex Alimentarius Commission
CCITT	International Telegraph and Telephone Consultative Committee
CEN	Comité Européen de Normalisation, <i>European Committee for Standardization</i>
CENELEC	Comité Européen de Normalisation Electrotechnique, <i>European Committee for Electrotechnical Standardization</i>
CEPT	Conférence Européenne des Administrations des Postes et des Télécommunications, <i>European Conference of Postal and Telecommunications Administrations</i>
CISPR	Comité International Spécial des Perturbations Radioélectriques, <i>International Special Committee on Radio Interference</i>
DIN	Deutsches Institut für Normung e.V.
DIS	Draft International Standard
ECAC	European Civil Aviation Conference
ECE	Economic Commission for Europe
ECMA	European Computer Manufacturers Association
EEB	European Environmental Bureau
EFTA	European Free Trade Association
EN	European Standard
EOTC	European Organisation for Testing and Certification
EPS	European Pre-standard
ETS	European Telecommunications Standards
ETSI	European Telecommunications Standards Institute
EuZW	Europäische Zeitschrift für Wirtschaftsrecht
FAO	Food and Agriculture Organization of the United Nations
FDIS	Final Draft International Standard

GATT	General Agreement on Tariffs and Trade
GPA	Agreement on Government Procurement
HD	Harmonization Document
ICAO	International Civil Aviation Organization
ICS	International Classification for Standards
ICSCA	Industry Co-operation on Standards and Conformity Assessment
IEC	International Electrotechnical Commission
I-ETS	Interim European Telecommunications Standard
IFAN	International Federation of Standards Users
ILO	International Labour Organization
IMO	International Maritime Organization
ISO	International Organization for Standardization
ITU	International Telecommunication Union
JISC	Japanese Industrial Standards Committee
JWT	Journal of World Trade
KAN	Kommission Arbeitsschutz und Normung <i>Commission for Occupational Health and Safety and Standardization</i>
MEPC	Marine Environment Protection Committee
MRA	Mutual Recognition Agreement
MSC	Maritime Safety Commission
NIST	National Institute of Standards and Technology
NNI	Nederlands Normalisatie-Instituut
NSAI	National Standards Authority of Ireland
OECD	Organization for Economic Co-operation and Development
OIE	Office International des Epizooties <i>World Organization for Animal Health</i>
OIML	International Organization of Legal Metrology
OJ	Official Journal of the European Communities
OSH	Occupational Safety and Health
PPM, PPMs	Process and Production Method(s)
prEN	project EN
SABE	Strategic Advisory Body on Environment
SFS	Finnish Standards Association
SPS Agreement	Agreement on Sanitary and Phytosanitary Measures
TABD	Transatlantic Business Dialogue
TBT Agreement	Agreement on Technical Barriers to Trade
TSI	Technical Specifications for Interoperability
TUTB	European Trade Union Technical Bureau for Health and Safety
UBA	Umweltbundesamt <i>German Federal Department of the Environment</i>
UN/ECE	United Nations, Economic Commission for Europe
UNI	Ente Nazionale Italiano di Unificazione
UNICE	Union des Industries de la Communauté Européenne, <i>Union of Industrial and Employers' Confederations of Europe</i>

UVV	Unfallverhütungsvorschrift <i>German accident prevention regulation</i>
WHO	World Health Organization
WP.6	UN/ECE Working Party on Harmonization and Standardization Policies
WP.29	UN/ECE World Forum for Harmonization of Vehicle Regulations
WSSN	World Standards Services Network
WTO	World Trade Organization
ZLR	Zeitschrift für das gesamte Lebensmittelrecht

1. Scope of the TBT Agreement

Question: *What areas of policy of the EC Treaty are affected by the TBT agreement? Is the list of the articles of the EC Treaty in the Council Decision adopted on 22 December 1994 exhaustive?*

a) Council Decision 94/800/EC adopted on 22 December 1994

Council Decision 94/800/EC, adopted on 22 December 1994, concerning the conclusion of agreements within the framework of the multilateral negotiations of the Uruguay Round (1986-1994) in the name of the European Community with reference to the areas¹ falling within its competence has the purpose of approving, in the name of the European Community, the complete and far-reaching package of multilateral agreements which the Commission had negotiated on behalf of the European Community and its member states and the complete adoption of which is linked to membership of the WTO in accordance with Article XIV (1) of the WTO Agreement². This also includes the Agreement on Technical Barriers to Trade³, which will be referred to henceforth as the TBT Agreement⁴.

The decision not only identifies Article 113 of the EC Treaty (now Article 133 of the EC Treaty) as the applicable legal basis for the trade policy conducted by the Community alone, but also refers to numerous other provisions, namely Articles 43, 54, 57, 66, 75, Article 84 (2) and Articles 99, 100, 100a and 235 of the EC Treaty. The reasons given are that parts of the obligations entered into in full affect Community regulations which were adopted on the basis of the articles stated.⁵ This list does not for example include those provisions which form the basis of Community measures in the area of occupational health and safety (Article 137 of the EC Treaty, formerly Article 118a), environmental protection (Article 175 of the EC Treaty, formerly Article 130s), consumer protection (Article 153 of the EC Treaty, formerly Article 129a) and health protection (Article 152 of the EC Treaty, formerly Article 129) outside the sweeping basis for provisions of relevance to the Single Market (Article 95 of the EC Treaty, formerly Article 100a). Can the conclusion be drawn that the total package of agreements contains no regulation affecting aspects of occupational health and safety, environmental, consumer or health protection, without central reference to the Single Market?

The appropriate legal basis to be selected has been the source of numerous legal disputes between the European Parliament and the Council and between the European Commission and the Council. Regulatory matter has repeatedly arisen which could not be assigned clearly to any given legal basis. The legal basis selected, however, also determines the decision-making procedure, i.e. the required majorities and the forms of involvement taken by the various institutions. The selection must be based upon objective circumstances which can be verified by a court. Where more than one legal basis may be considered for the object and purpose of a regulatory provision, the focus of regulation and the characterizing substance of

1 OJ 23.12.94 L 336, 1 f.

2 Agreement establishing the World Trade Organization, 15 April 1994, reproduced in OJ 23.12.94 L 336, 3-10.

3 OJ 23.12.94 L 336, 86-99.

4 General information on the TBT Agreement, Sykes, Alan O., *Product Standards for Internationally Integrated Goods Markets*, Washington 1995, 63-86; Senti, Richard, *WTO: System und Funktionsweise der Welthandelsordnung*, Zürich 2000, 521-533; Müller-Graff, Peter-Christian, *Die Maßstäbe des Übereinkommens über technische Handelshemmnisse (ÜTH) als Bauelemente eines Weltmarktrechts*, in: idem (ed.), *Die Europäische Gemeinschaft in der Welthandelsorganisation. Globalisierung und Weltmarktrecht als Herausforderung für Europa*, Baden-Baden 2000, 111-130.

5 8th recital of Decision 94/800/EC.

a measure are the deciding factors. In cases of doubt, preference is to be given to the legal basis which makes provision for stronger powers of co-operation of the European Parliament. The characterizing aspects regulated by the numerous agreements within the “complete WTO package” have been formulated in the list of rules governing competence contained in Council Decision 94/800/EC. Despite the far-reaching preamble of the WTO Agreement⁶, the individual agreements contain no body of provisions which have occupational health and safety, environmental protection, consumer protection or health protection as their central objective. The corresponding rules of Community law governing competence need not therefore be stated. The possibility of individual agreements containing provisions which are of relevance to the stated policies of protection is not necessarily thereby excluded, however.

b) Survey of the content of the TBT Agreement

International agreements are interpreted solely according to their content, and not according to their many ratification texts in their various forms.

The scope of the TBT Agreement covers all goods, including industrial products and agricultural produce (Article 1.3). Only purchasing specifications drafted by official bodies for production or consumption by official bodies (Article 1.4)⁷ and sanitary and phytosanitary measures described in Annex A of Agreement on Sanitary and Phytosanitary Measures⁸ (Article 1.5) are expressly excluded. The preliminary remarks in Annex 1 of the TBT Agreement state explicitly that services are excluded from the scope of the agreement. Goods are subject to the agreement irrespective of the political purpose of a regulation governing them.

The TBT Agreement is intended to prevent requirements based upon welfare considerations and which govern the marketability of products, whether in the form of binding technical regulations or in the form of standards serving as recommendations, or which govern conformity assessment procedures, from acting as unjustified barriers to trade. It thus introduces provisions governing legitimacy, notification and prioritization (Articles 2 to 4) for the development, adoption and application of technical regulations and standards, and makes comprehensive provisions governing conformity assessment procedures (Articles 5 to 9).

Certain provisions of the TBT Agreement indicate that the Agreement also extends to provisions governing products with a bearing upon occupational health and safety, health protection, environmental protection and consumer protection.

- The preamble expressly recognizes⁹ “that no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable

6 Which states: “Recognising that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development...”

7 Which fall within the scope of the plurilateral Agreement on Public Procurement of 15 April 1994, OJ 23.12.94 L 336, 273-289.

8 Reproduced in OJ 23.12.94 L 336, 40-50.

9 6th recital.

discrimination between countries where the same conditions prevail or a disguised restriction on international trade, and are otherwise in accordance with the provisions of this Agreement”.

- According to Sentence 2 of Article 2.2, technical regulations should not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. The assessment of potential hazards is to be based *inter alia* upon the available scientific and technical information, related production technology, or intended end uses of the products (Sentence 4 of 2.2). Sentence 3 of Article 2.2 recognizes, in a non-exhaustive list, the requirements of national security, the prevention of deceptive practices, and protection of human health and safety, animal and plant life and health, and the environment as justified objectives. In order to minimize the restrictive effect upon trade of technical regulations, Article 2.3 states that they may not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.
- Where technical regulations are required and relevant international standards exist or their completion is imminent, WTO members must use them, or the relevant parts of them, as a basis for their technical regulations, except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued (Article 2.4).
- Where a technical regulation may have a significant effect on trade of other WTO members, it must be justified at the request of another Member in terms of the above provisions (Sentence 1 of Article 2.5). Whenever a technical regulation is prepared, adopted or applied for one of the objectives¹⁰ explicitly mentioned in Article 2.2, and is in accordance with relevant international standards, it is to be rebuttably presumed not to create an unnecessary obstacle to international trade (Sentence 2 of Article 2.5).
- Should a relevant international standard not exist or the technical content of a proposed technical regulation deviate substantially from the technical content of relevant international standards, a notification process must be followed and the other WTO members provided with opportunity to comment (Article 2.9). A prior notification process need not be followed where urgent problems of safety, health, environmental protection or national security arise or threaten to arise (Article 2.19).

In accordance with the code of good practice for the preparation, adoption and application of standards contained in Annex 3 of the TBT Agreement (referred to below as the Code of Good Practice), the national standards organizations¹¹ are subject to regulations corresponding in some cases to the provisions stated:

- Where international standards exist or their completion is imminent, the standardizing body shall use them, or the relevant parts of them, as a basis for the standards it develops, except where such international standards or relevant parts would be ineffective or inappropriate, for instance, because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems (Item F of the

¹⁰ Article 2.5, Sentence 2 mentions the objectives expressly stated in Article 2.2, although legitimate objectives of protection are stated there only by way of example, and are not listed exhaustively.

¹¹ In February 2001, 124 standards organizations on the territory of 85 WTO members had accepted the standards code, including 55 governmental and 60 non-governmental bodies. The signatories include all national standards organizations of the EU member states, together with CEN, CENELEC and ETSI as the sole regional standards organizations. Cf. the revised list of the Secretariat of the WTO Committee on Technical Barriers to Trade, G/TBT/CS/2/Rev.7, 8th February 2001.

Code of Good Practice). The reasons why international standards may represent an unsuitable basis for national (or regional) standardization projects are indicated only by way of example, and not exhaustively. In contrast to Sentence 3 of Article 2.2 of the TBT Agreement, no legitimate objectives are stated.

- A period of at least 60 days must be allowed prior to adoption of a standard in order to provide interested parties on the territory of a member of the WTO with the opportunity to submit comments on the draft standard. This period may be shortened in cases where urgent problems concerning safety, health or the environment arise or threaten to arise (Item L, Sentences 1 and 2 of the Code of Good Practice).

Equivalent provisions apply to conformity assessment procedures.

- In cases where a positive assurance is required that conformity assessment procedures conform to technical regulations or standards, and relevant recommendations issued by international standardizing bodies exist or their completion is imminent, they or the relevant parts of them must be used as a basis for the conformity assessment procedures, except where such recommendations or relevant parts are inappropriate for the Members concerned, for, *inter alia*, such reasons as: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; or fundamental technological or infrastructure problems (Article 5.4 of the TBT Agreement).
- Should a relevant international conformity assessment procedure not exist or the technical content of a proposed conformity assessment procedure not be accordance with the technical content of relevant international standards, and the process potentially have a considerable effect upon trade conducted by other WTO members, a notification process must be followed and the other WTO members provided with opportunity to comment (Article 5.6). A prior notification process need not be followed where urgent problems of safety, health, environmental protection or national security arise or threaten to arise (Article 5.7).

c) The practice of notification in accordance with the TBT Agreement

The annual reviews for 1995 to 2000 on the Implementation and Operation of the TBT Agreement¹² classify the objectives stated for the notification of technical regulations and conformity assessment procedures. Notification is performed by means of a form¹³; a detailed description of the reasons justifying the intended measures is neither required nor usual.

Table 1 contains a list of the reasons stated in the notifications in the years 1995 to 2000. In a total of 3,547 recorded notifications, the protection of human health or safety was stated in over a third (36.7%); a proportion of these reasons which cannot be further identified represents reasons relating to occupational health and safety. Further reasons frequently stated concern quality requirements (12.8 %), harmonization with new national legislation or technical progress (11.8 %), consumer protection and protection against deceptive practices (11.2 %), environmental protection (9.6 %), and other harmonization requirements which were not further specified (8.3 %). The grounds stated for technical regulations seldom made reference to requirements of national security (0.7%), the protection of animal or plant life or health (1.1%), reduced costs and increased productivity (1.8%), or the reduction or elimination of barriers to trade (3.4%). The documented information on the notifications does not provide any indication of the extent to which the notified technical regulations concern those relating to production conditions and processes and the conditions of use (*process regulation*) in addition to those concerning the characteristics inherent to the product (*product regulation*).

A dispute of relevance to occupational health and safety is worthy of mention: in January 2001, Belgium notified the draft of a law permitting manufacturers to apply a mark to their products should their production arrangements comply with the relevant regulations of the International Labour Organization.¹⁴ This label is intended to enable purchasers of products and services to consider the observance of basic standards governing working practices as a purchasing criterion. The ASEAN countries¹⁵ and also Egypt, Hong Kong, Brazil, India, Canada, Argentina and Pakistan objected particularly strongly to this proposal¹⁶, arguing that it would represent arbitrary discrimination against developing countries, and would represent an impermissible confounding of issues of occupational health and safety, for which the ILO is exclusively responsible at international level, and aspects of world trade.

12 The Committee on Technical Barriers to Trade publishes Annual Reviews of the Implementation and Operation of the Agreement; for the years 1995 to 1999, these are the documents G/TBT/3, GTBT/4, G/TBT/6, G/TBT/7, G/TBT/8 and G/TBT/10.

13 Cf. Decisions and Recommendations on Procedures for Notification and Information Exchange, reproduced as Annex 3 of the Second Triennial Review, G/TBT/9, 18-23.

14 G/TBT/N/BEL/2, 16 January 2001.

15 ASEAN Concerns regarding the proposed Belgian Law for the Promotion of Socially Responsible Production. Submission by the ASEAN Countries, G/TBT/W/159, 28 May 2001.

16 Cf. specifically G/TBT/M/23, Minutes 9-18.

Table 2 shows the notifications received in the years 1995 to 2000, classified according to the procedure categories provided for in the TBT Agreement. By far the greatest proportion of the notifications (88.6%) concerned technical regulations issued by a national government department within the normal period of notice in accordance with Article 2.9. Only in one case out of twenty (5.1%) was recourse made to the shorter period of notice with reference to an urgent need for action to avoid potential harm in accordance with Articles 2.10 or 5.7. Only 8.5% of notifications refer to conformity assessment procedures. Notifications by local bodies are virtually insignificant.

Table 1: Breakdown of the reasons given in the notification of technical regulations and conformity assessment procedures in accordance with the TBT Agreement in the years 1995 to 2000

Reasons stated in the notification *	1995	1996	1997	1998	1999	2000	Total	
							Absolute	In %
Interests of national security	2	0	22	0	1	0	25	0.7
Consumer protection and protection against deception	20	57	111	72	77	59	396	11.2
Protection of human health or safety	122	127	347	241	212	254	1.303	36.7
Protection of the life or health of animals or plants	5	2	14	5	4	10	40	1.1
Environmental protection	37	51	89	61	46	58	342	9.6
Quality requirements	94	96	165	13	26	61	455	12.8
Harmonization	46	46	47	33	50	74	296	8.3
Harmonization with national legislation or technical progress	15	99	70	92	62	80	418	11.8
Reduction or avoidance of barriers to trade	31	23	30	12	12	13	121	3.4
Cost reduction and productivity increases	0	13	33	8	5	6	65	1.8
Other reasons	11	1	5	108	173	43	341	9.6
Total number of notifications	365	460	794	648	669	611	3.547	100.0

* More than one reason may be stated for a notification.

Source: Compiled from the annual reports on application of the Agreement on Technical Barriers to Trade for the years 1995 to 1999 (G/TBT/3, G/TBT/4, G/TBT/6, G/TBT/7, G/TBT/8, G/TBT/10).

Table 2: Breakdown of the notifications of technical regulations and conformity assessment procedures by procedure type in accordance with the TBT Agreement in the years 1995 to 2000

Procedure type *	1995	1996	1997	1998	1999	2000	Total	
							Absolute	In %
Article 2.9 Notification of a technical regulation by a national government department, normal period of notice	332	410	740	562	592	505	3,141	88.6
Article 2.10 Notification of a technical regulation by a national government department, reduced period of notice	14	19	30	11	24	33	131	3.7
Article 3.2 Notification of a technical regulation by a local department	2	1	0	0	0	0	3	0.1
Article 5.6 Conformity assessment procedure, notified by a national government department, normal period of notice	17	20	24	68	54	67	250	7.0
Article 5.7 Conformity assessment procedure, notified by a national government department, reduced period of notice	6	3	5	8	16	11	49	1.4
Article 7.2 Conformity assessment procedure, notified by a local department	0	0	0	3	0	0	3	0.1
Not specified	7	26	11	24	19	21	108	3.0
Total number of notifications	365	460	794	648	669	611	3,547	100.0

* Some notifications appear in more than one category.

Source: Compiled from the annual reports on application of the Agreement on Technical Barriers to Trade for the years 1995 to 1999 (G/TBT/3, G/TBT/4, G/TBT/6, G/TBT/7, G/TBT/8, G/TBT/10).

The number of product categories for notifications in accordance with the TBT Agreement can be broken down in greater detail for 2001 (cf. *Table 3*). The largest category concerns foodstuffs, followed by vehicles, communication electronics, other electrical items, and hazardous substances. Neither the more detailed breakdown of product categories performed since the beginning of 2001, nor a random inspection of individual notifications¹⁷, nor occasional comments on individual notifications or the annual reports on the application of the TBT Agreement, contain information on whether the notifications also contain planned provisions governing the health and safety of workers at work, the conditions of use of appliances in businesses or households, or the procedures employed during the production of products.

Table 3: Number of notifications in accordance with the TBT Agreement broken down by product category, 2001

Product categories	Number of notifications
Foodstuffs	133
Vehicles and accessories	67
Communications electronics	37
Other electrical items	30
Hazardous substances	27
Medical products	21
Construction products	19
Measuring instruments	19
Steel and steel products	14
Fuels	14
Medical devices	11
Domestic appliances	11
Toys	10
Packaging materials	10
Gas appliances and gas installation materials	9
Cosmetics	5
Tobacco products	3
Other products	96
Notifications, total	536

Source: G/TBT/GEN/N/1, G/TBT/GEN/N/2, G/TBT/GEN/N/3, G/TBT/GEN/N/4, G/TBT/GEN/N/5, G/TBT/GEN/N/6, G/TBT/GEN/N/7, G/TBT/GEN/N/8, G/TBT/GEN/N/9, G/TBT/GEN/N/10, G/TBT/GEN/N/11, G/TBT/GEN/N/12.

In order for the notifications received for the technical regulations issued on the territory of WTO members not to be over-estimated, the distribution of the notifications among the WTO members must be taken into consideration. *Table 4* shows the number of notifications in accordance with the TBT Agreement for the period from 1995 to 2000, classified by individual WTO members.

¹⁷ They are available over the Internet under document reference G/TBT/N/....

Table 4: Number of notifications in accordance with the TBT Agreement for the period from 1995 to 2000, according to WTO member

Member country	Number of notifications
Netherlands	530
Japan	233
United States of America	201
European Community	184
Mexico	182
Belgium	167
Malaysia	161
Denmark	155
Canada	135
Brazil	115
Czech Republic	114
Thailand	108
Australia	98
Sweden	93
Republic of Korea	92
Chile	71
Switzerland	71
France	64
Norway	58
Argentina	55
El Salvador	55
Israel	55
Philippines	55
Germany	8
36 other countries	Total: 487
Greece, Ireland, Italy, Luxembourg, Portugal	0
Total	3,547

Source: Sixth Annual Review of the Implementation and Operation of the Agreement, G/TBT/10, 5-7.

The Netherlands alone is responsible for over one-seventh of all notifications, accounting for more notifications than the 37 countries with the lowest number of notifications together. It exceeds the notifications of the EC by a factor of three. In contrast, Greece, Ireland, Italy, Luxembourg and Portugal did not issue a single notification in the period indicated, and only eight notifications were recorded for Germany. The notifications are not a suitable indicator of the number of technical regulations in force in the respective countries, nor of the extent to which individual countries consider it necessary to deviate from the relevant international standards or conformity assessment procedures for the legitimate reasons available.

Insert: The EU Directive¹⁸ on the provision of information in the field of technical standards and regulations exhibits crucial differences to the notification provisions of the TBT

18 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services, OJ 21.7.98 L 204, 37-48, amended by Directive 98/48/EC, OJ 5.8.98 L 217,

Agreement. Whereas the Secretariat of the WTO Committee on Technical Barriers to Trade possesses no authority to conduct investigations or impose sanctions, the European Commission has done so systematically for many years. It has launched many infringement proceedings for failure to notify; further investigation by the courts is based upon requests for preliminary rulings by national courts.¹⁹ The Commission adopted at an early stage the legal position, initially highly controversial, that failure to observe the duty of notification resulted in the technical regulations concerned not being applicable and thus not being enforceable upon third parties.²⁰ The European Court of Justice has confirmed this position by its judgement in the “CIA Security”²¹ case. From 1995 to 1998, the Commission responded to around half of all notifications with comments, a detailed position statement, or announcement of a proposed directive; responses were received from among the other member states in 55% of all cases.²² The announcement of a binding Community act (“standstill decision”) results in the member state being able to adopt its planned regulation no earlier than one year from the date of notification.²³

d) Summary

- The legal bases stated in Council Decision 94/800/EC of 22 December 1994 do not enable conclusions to be drawn concerning the scope of the content of the TBT Agreement and the obligations assumed as a result by the EC and its member states.
- The TBT Agreement, according to its wording and the practice of its application, extends to all products, whether they be produced industrially, by artisans, or agriculturally.
- The TBT Agreement affects all areas of policy of the EC Treaty relevant to products, with the exception of the purchasing specifications for production or consumption issued from government departments, which are expressly excluded by the TBT Agreement, and the sanitary and phytosanitary measures described in Annex A of the SPS Agreement. The implications of this for regulations governing the health and safety of workers at work, which is subject to Article 137 of the EC Treaty (formerly Article 118a of the EC Treaty) and not Article 95 of the EC Treaty (formerly Article 100a of the EC Treaty), must be clarified in relation to the terms “technical regulation” and “standard”.²⁴

18-26. It represents a further development of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations, OJ 26.4.1983 L 109, 8-13. On the Information Directive, cf. European Commission, *Maintaining the Single Market, Directive 83/189/EEC - A Commentary. A Guide to the Procedure for the Provision of Information in the Field of Technical Standards and Regulations*, Luxembourg 1998. For further information, see <http://europa.eu.int/comm/enterprise/tris/>.

19 Cf. the list of relevant judgements at

http://www.europa.eu.int/comm/enterprise/tris/case-law/index_en.htm. For judgements and Commission practice, cf. also European Commission, *Directive 98/34/EC: The 83/189 Notification Procedure*, Working Paper: Court of Justice Judgements and Commission Practice, Committee on Standards and Technical Regulations, Doc. 39/89-rev.2-EN.

20 Commission Communication of 1 October 1986, OJ 1.10.1986 C 245, 4.

21 European Court of Justice, Judgement of 30 April 1996 in case C-194/94 – CIA Security, Jur. 1996-I, 2201. Cf. more comprehensively Committee on Standards and Technical Regulations, *Directive 98/34/EC, The 83/189 Notification Procedure*, Working Paper: Court of Justice Judgements and Commission Practice, Doc. 39/98-rev.2 – EN.

22 Cf. specifically Report from the Commission to the Council, the European Parliament and the Economic and Social Committee, on the Operation of Directive 98/34/EC from 1995 to 1998, COM (2000) 429, final version of 7 July 2000, 26-31. – According to this report, the greatest number of notifications within the EU are also attributable since 1997 to the Netherlands, with 463 of 1,504 notifications, see pp. 37 and 69.

23 Cf. Article 9 Paragraphs 3 and 4 of Directive 98/34/EC.

24 For details, see 3.

- The technical regulations of relevance to occupational health and safety represent an unidentifiable and unquantifiable sub-set of the notifications performed in accordance with the TBT Agreement with the regulatory objective of protecting human health or safety. The documented data on the notifications do not enable conclusions to be drawn regarding the extent to which the notified technical regulations concern those relating to production conditions and processes and the conditions of use of the product (*process regulation*) in addition to those concerning the characteristics of the product (*product regulation*).
- The notifications are not a suitable indicator of the number of technical regulations in the respective countries, nor of the extent to which individual countries consider it necessary to deviate from the relevant international standards or conformity assessment procedures for the available legitimate reasons.

2. Scope of the support of technical regulations by standards

Question: *In what policy areas of the EC Treaty affected by the TBT Agreement are technical regulations supported by standards?*

a) Harmonized standards within the scope of the New Approach

Examination of the key areas governed by New Approach directives in the area of technical harmonization and standardization is a suitable starting point for identification of the policy areas of the EC Treaty affected by the TBT Agreement in which technical requirements are supported by standards²⁵. This core area has been addressed comprehensively on the relevant web site²⁶ maintained jointly by the European Commission, the EFTA Secretariat and the European standardization organizations CEN, CENELEC and ETSI; the latest edition of the Guide to the Implementation of Directives Based upon the New Approach and the Global Approach²⁷ also provides a suitable overview.

Table 5 shows, for each of the *New Approach* directives, the start of application, the level of detail in the essential requirements formulated in the respective annexes in terms of the number of pages in the EC Official Journal, and the number of harmonized standards reported in the EC Official Journal up to the end of 2001. For two directives, namely those governing explosives for civil uses and cableway installations designed to carry persons, no harmonized standards exist as yet the references of which have been published in the EC Official Journal. For the area of construction products, which is of particular economic significance, the relevant directive²⁸ came into force in June 1991, yet the reference of the first standard was not published in the EC Official Journal until January 2001²⁹, even though over 1,000 harmonized standards in total are required for this sector. The references of a further 41 harmonized standards for construction products have since followed. The Packaging and Packaging Waste Directive³⁰ resulted in fundamental, stalling disputes between CEN and the Environment Directorate-General, responsible for the standardization mandate in question, regarding proper fulfilment of the standardization mandate and observance of the essential requirements, before the Commission published, with constraints, the references for two of five harmonized standards.³¹ The greatest proportion of the harmonized standards, 43.2%, concerns the Low-voltage Directive³², which is in fact not subject to the New Approach, but which anticipated the latter's regulatory philosophy and chief structural elements.

A third (33.4%) of the harmonized standards are identical to international standards developed by ISO or IEC; a further 13.2% adopt international standards with modifications. For the core area of Community standardization policy, in which the political terms of

25 OJ 4.6.85 C 136, 1-9.

26 <http://www.NewApproach.org/>.

27 European Commission, Guide to the implementation of directives based upon the New Approach and the Global Approach, Luxembourg 2000.

28 Council Directive of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products, OJ 11.2.1989 L 40, 12-26.

29 OJ 23.1.2001 C 20, 5.

30 European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, OJ 31.12.1994 L 365, 10-23.

31 Commission Decision 2001/524/EC of 28 June 2001 relating to the publication of references for standards EN 13428:2000, EN 13429:2000, EN 13430:2000, EN 13431:2000 and EN 13432:2000 in the Official Journal of the European Communities in connection with Directive 94/62/EC on packaging and packaging waste, OJ 12.7.2001 L 190, 21-23.

32 Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of Member States relating to electrical equipment designed for use within certain voltage limits, OJ 26.3.73 L 77, 29-33.

reference for the European standards organizations expressed through the essential requirements in the annexes to the directives and through the Commission's standardization mandates are particularly detailed and frequent, this is a remarkable result. A more precise analysis places this initial result in perspective, and reveals considerable differences between the different sectors. None of the 165 documents stated in the area of telecommunications terminals equipment has an equivalent in the international body of standards. The reason for this is probably that ETSI retains a clear pioneering status in comparison to ITU; it has made particular provision for its structures and procedures to be opened up, including to interested manufacturers and users of telecommunications and information technology in third states. The harmonized standards in the sectors of appliances burning gaseous fuels, potentially explosive atmospheres, safety of toys, lifts, construction products, and non-automatic weighing instruments are also without equivalent in the international body of standards. All harmonized standards for recreational craft are identical to ISO standards, or are modifications of them. Low-voltage appliances exhibit a particularly high degree of internationalization: 77% of the harmonized standards are identical to IEC standards, or mere modifications of them. The areas of electromagnetic compatibility (51%) and medical devices (42%) feature an above-average proportion of equivalent standards. The area of machine safety, which is of particular importance to occupational health and safety, manages a proportion of 29%; conversely, personal protective equipment only the very low value of 5%. Of the complete or partial equivalents, 987 of 1,151, i.e. 85.5%, are accounted for by IEC electrotechnical standards alone. In other words: in the non-electrical area of harmonized standards, international penetration is still largely in its infancy. The area of standardization co-ordinated by ETSI in the area of telecommunications and information technology represents a special case.

Table 6 shows the standardization activity of CEN pursuant to New Approach directives, in terms of the number of standards mandated by the Commission and drafted by the end of 1995, 2000 and 2005. In 1995, CEN had drafted approximately one-fifth of the harmonized standards mandated by the Commission, in 2000 substantially over half; in 2005, CEN will, by its own forecast, have completed 96% of the standardization activity mandated by the Commission within the scope of the New Approach. The majority of harmonized standards apply to construction products, followed by the areas of pressure equipment and safety of machinery. The standards governing pressure equipment, machinery, and personal protective equipment are of particular relevance to occupational health and safety. The relevant directives oblige the member states to take suitable measures to enable both sides of industry to have an input at national level in the process of preparing and developing harmonized standards. The number of harmonized standards concerning construction products and pressure equipment, the references of which have been published in the Official Journal and which therefore give rise to the presumption of conformity, is notably lower than the number of standards already adopted.

Table 5: New Approach Directives, level of detail of the essential requirements and the number of harmonized standards reported in the EC Official Journal up to the end of 2001, and their reference to international standards

Directive	Product area	Applicable since	Scale of essential req'ments. ¹	Number of harmonized stds indicated in the EC OJ					
				Total	ISO Ident.	ISO Modif.	IEC Ident.	IEC Modif.	CISPR Ident.
73/23/EEC	“Low-voltage appliances”	19.8.74	0.5	1,066	0	0	544	277	0
87/404/EEC	Simple pressure vessels	1.7.90	3	12	1	0	0	0	0
88/378/EEC	Safety of toys	1.1.90	3	13	0	0	0	0	0
89/106/EEC	Construction products	27.6.91	1 ²	42	0	0	0	0	0
89/336/EEC	Electromagnetic compatibility	1.1.92	0.5	193	1	0	51	28	19
98/37/EC ³	Machinery	1.1.93	27	333	75	5	9	7	0
89/686/EEC	Personal protective equipment	1.7.92	9	221	6	0	1	3	0
90/384/EEC	Non-automatic weighing instruments	1.1.93	5	1	0	0	0	0	0
90/385/EEC	Active implantable medical devices	1.1.93	3	34	13	0	3	0	0
90/396/EEC	Appliances burning gaseous fuels	1.1.92	2.5	86	0	0	0	0	0
93/15/EEC	Explosives for civil uses	1.1.95	1.5	0	0	0	0	0	0
93/42/EEC	Medical devices	1.1.95	6	207	41	1	45	0	0
94/9/EC	“Potentially explosive atmospheres”	1.3.96	7.5	20	0	0	0	0	0
94/25/EC	Recreational craft	16.6.96	4.5	15	11	4	0	0	0
94/62/EC	Packaging and packaging waste	30.6.96	1	2	0	0	0	0	0
95/16/EC	Lifts	1.7.97	3.5	3	0	0	0	0	0
97/23/EC	Pressure equipment	29.11.99	10	47	4	0	0	0	0
99/5/EC ³	Telecommunications terminal eqmt.	6.11.92	0.5	165	0	0	0	0	0
98/79/EC	In vitro diagnostic medical devices	7.12.98	7	10	2	0	0	0	0
2000/9/EC	Cableway installations designed to carry persons	3.5.02	4.5	0	0	0	0	0	0
Total				2,470	154	10	653	315	19

1 In terms of the number of pages in the EC Official Journal; 2 Excluding basic documents 163 pages in length; 3 Codified preceding directives.

Table 6: Standardization activity of CEN pursuant to New Approach directives, in terms of the number of standards mandated by the Commission and drafted by the end of 1995, 2000 and 2005, and the number of harmonized standards reported in the EC Official Journal up to the end of 2001*

Directive	Product area References in the EC Official Journal	End of 2001	1995		2000		2005	
			Man-dates	Stds	Man-dates	Stds	Man-dates	Stds
87/404/EEC	Simple pressure vessels	12	42	29	47	43	47	47
88/378/EEC	Safety of toys	13	7	5	11	6	11	10
89/106/EEC	Construction products	42	471	92	1.035	504	1.035	969
98/37/EC	Machinery	333	604	69	719	319	719	709
89/686/EEC	Personal protective equipment	221	205	98	326	202	326	322
90/385/EEC	Active implantable medical devices	34	47	14	53	35	53	52
90/396/EEC	Appliances burning gaseous fuels	86	85	21	96	76	96	96
93/15/EEC	Explosives for civil uses	0	61	0	68	0	68	68
93/42/EEC	Medical devices	207	167	21	230	134	231	210
94/9/EC	“Potentially explosive atmospheres”	20	62	0	94	25	94	88
94/25/EC	Recreational craft	15	46	12	55	23	56	52
94/62/EC	Packaging and packaging waste	2	8	0	15	9	15	15
95/16/EC	Lifts	3	9	2	19	5	19	19
97/23/EC	Pressure equipment	47	661	136	763	469	763	743
98/79/EC	In vitro diagnostic medical devices	10	0	0	20	6	20	20
Total		1,035	2,475	499	3,551	1,856	3,553	3,420

* In certain cases, the number of references reported in the EC Official Journal up to the end of 2001 exceeds the number of standards adopted at the end of the year by CEN, as CENELEC was commissioned to draft harmonized standards in addition to CEN, and the number of references in the EC Official Journal is not limited to the standards drafted by CEN.

Compiled from the information available at <http://www.cenorm.be/newapproach/dirlist.asp>.

In its 1995 Communication on the broader use of standardisation in Community policy³³, the Commission named the following areas for which technical standards are to be considered for the supporting of Community policy: public procurement, information technology and telecommunications, biotechnology, advanced materials, foodstuffs, health and safety at the workplace, energy, the environment, transeuropean networks, and consumer protection. At the same time, the Commission conceded that recourse to technical standards was a new development for the majority of the areas stated, and has yet to be defined clearly with regard to the conditions and potential for use.

According to the various directives governing *public procurement*³⁴, the reference to European standards, where they exist, is mandatory in the terms of the invitation to tender issued by the contracting bodies. The directives in the area of public procurement do not however refer themselves to standards for the detailing of technical regulations. The prioritization of reference to European technical specifications would be without consequence if European standards did not exist for many products and services which are the subject of public invitations to tender.

In the area of *information technology* and *telecommunications*, substantial recourse is made to the technical specifications developed within the activities of the ETSI. Attention must be paid here to the characteristic derogations in the standards development process and to some extent with regard to co-operation with the Commission and the declaration of certain parts of telecommunications standards as binding, in contrast to the traditional area of the New Approach.³⁵ ETSI offers interested suppliers and users of telecommunications equipment and services and also the network operators, by way of direct membership, the opportunity of closer involvement in the standards development process. As a result, and by means of particular categories of technical specifications which are developed in advance of conventional standards, the time elapsing between new technical developments and the completion of standardization activity is reduced. As with other network technologies, standards are required in telecommunications and information technology in order to share the effort of furthering technical development.

Within the context of the New Approach to technical harmonization and standardization, environmental requirements have to date been of secondary importance to those of the safety of users and employees. The *Construction Products Directive*³⁶ contains *inter alia* essential requirements concerning the environment, protection against noise, energy economy and heat retention. As these essential requirements, which were formulated very briefly in comparison with the other New Approach directives, represented a wholly unsatisfactory basis for an agenda for the European standards organizations, they were defined, following tough negotiations, in greater detail in comprehensive basic documents governing subjects including hygiene, health and the environment, protection against noise, and energy economy and heat

33 COM (95) 412, final, 30 October 1995.

34 Cf. most recently the proposals presented by the Commission in May 2000 for simplification and modernisation of the statutory framework for public procurement: Proposal for a Directive of the European Parliament and of the Council on coordination of procedures for the award of public supply contracts, public service contracts and public works contracts, COM (2000) 275, final, 10 May 2000; Proposal for a Directive of the European Parliament and of the Council coordinating the procurement procedures of entities operating in the water, energy and transport sectors, COM (2000) 276, final, 10 May 2000.

35 Regarding some of these aspects, cf. Schepel, Harm, Falke, Josef, Legal aspects of standardisation of the Member States of the EC and EFTA, Vol. 1: Comparative report, Luxembourg 2000, 10-15, 98-100.

36 Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products, OJ 11.2.1989 L 40, 12-26.

retention.³⁷ The work process leading to publication of the references of harmonized standards in the EC Official Journal is progressing much more slowly for construction products than in the other product sectors to which the New Approach applies. In 2000, 504 of a total of 1,035 mandated harmonized standards had been adopted; by July 2001, however, the references of only fifteen had been published in the Official Journal.

To date, only very general requirements for protection against water pollution have been included in the way of provisions for environmental protection in the *Recreational Craft Directive*³⁸; detailed threshold values and measurement regulations for exhaust and noise emissions are to be added.³⁹ It is notable that the proposed amendment itself defines the precise level of protection in the form of threshold values and measurement procedures, in harmony with the other Community acts governing the protection of air quality⁴⁰ and noise abatement⁴¹.

Fundamental disagreements arose between CEN, the Directorate-General of the Commission responsible for environmental issues and the European Environment Bureau (EEB) on the one hand, and ANEC, the body representing consumer associations in standardization, on the other, regarding the standardization of requirements for the composition, re-usability and recyclability, including material recyclability, of *packaging*^{42, 43}. Belgium and Denmark ultimately asserted that the controversial standards did not fully comply with the essential requirements of the Packaging Directive. Following consultation of the Standing Committee on Standards and Technical Regulations, and review of the standards concerned, the Commission determined⁴⁴ that of the standards developed by CEN, only one complied fully with the requirements, and a further one only with constraints. The three remaining standards failed to comply with the essential requirements of the Directive, or failed to satisfy the

37 Communication of the Commission with regard to the interpretative documents of Council Directive 89/106/EEC, OJ 28.2.94 C 62, 1-163.

38 Directive 94/25/EC of the European Parliament and of the Council of 16 June 1994 on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, OJ 30.6.94 L 164, 15-38.

39 Proposal for a Directive of the European Parliament and of the Council modifying Directive 94/25/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, COM (2000) 639 final, 12 October 2000.

40 Directive 98/69/EC of the European Parliament and of the Council of 13 October 1998 relating to measures to be taken against air pollution from motor vehicles and amending Council Directive 70/220/EEC, OJ 28.12.98 L 350, 1-57; Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management, OJ 21.11.96 L 296, 55-63; Council Directive 1999/30/EC of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air, OJ 29.6.99 L 163, 41-60; Directive 2000/69/EC of the European Parliament and of the Council of 16 November 2000 relating to the limit values for benzene and carbon monoxide in ambient air, OJ 13.12.2000 L 313, 12-21.

41 Cf. most recently Directive 2000/14/EC of 8 May 2000 on the approximation of the laws of the Member States relating to the noise emission in the environment by equipment for use outdoors, OJ 3.7.200 L 162, 1-78; Proposal for a Directive relating to the Assessment and Management of Environmental Noise, COM (2000) 468 final, 26 July 2000.

42 Cf. Article 10 and Annex II of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, OJ 31.12.94 L 365, 10-23.

43 Cf. in this context on the one hand, the CEN Consultant's presentation on the CEN standards on packaging and the environment, and on the other European Environmental Bureau (EEB), CEN at work: How the requirements of the European Packaging Waste Directive (94/62) are bypassed by CEN standards. A legal analysis, Brussels 2000; ANEC, CEN standards in the field of packaging and the environment – an inadequate complement to the Packaging Directive. A review by ANEC, ANEC2000/ENV/033, Brussels 2000.

44 Commission Decision 2001/524/EC of 28 June 2001, OJ 12.7.2001 L 190, 21-23. – cf. supra, Footnote 31.

conditions stated in the standardization mandate; their references were not therefore published in the Official Journal. The Commission called upon CEN to improve immediately the standards to which objections were raised.

b) Requirements upon the interoperability of the railway system

The technical requirements for the interoperability of the trans-European high-speed rail system⁴⁵ and the conventional trans-European rail system⁴⁶ exhibit features of particular interest. The Community expressly emphasises its interest in an international standardization system which meets the requirements of Community policy and by which standards can be created which are actually applied by international trade partners. The European standards organizations are therefore requested to continue their co-operation with the international standards organizations.⁴⁷ The Technical Specifications for Interoperability (TSI) are drawn up under the Commission's mandate by a joint committee on which the infrastructure operators, railway companies and industry are represented. Representatives from third states may be permitted to attend as observers.⁴⁸ Employers' and employees' representatives must be consulted within the sectoral dialogue committee⁴⁹ with regard to issues of personnel qualification and occupational health and safety falling within the scope of the TSI.⁵⁰

The essential requirements contain provisions which make clear reference to the use of products and the operation of trains. Materials which, for example, by virtue of their mode of use present a hazard to the health of persons with access to them, must not be used on board trains and in infrastructure facilities.⁵¹ The operation of the power supply facilities must not jeopardize the safety of trains and persons, and any impact by them upon the environment must not exceed the specified threshold levels.⁵² The technical equipment and working procedures in the maintenance facilities must not present a health hazard to human beings.⁵³ The stipulated noise limits must be observed during operation of the railway systems.⁵⁴ The conditions relating to vocational qualification and to hygiene and safety at the workplace which are necessary for operation and maintenance of the sub-system concerned and for implementation of the TSI (Technical Specifications for Interoperability) must be indicated in the TSI.

45 Cf. Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system, OJ 17.9.96 L 235, 6-24; Commission Report to the Council and the European Parliament on the implementation and effects of Directive 96/48/EC on the interoperability of the trans-European high-speed rail system, COM (99) 414 final, 10 September 1999.

46 Cf. Directive 2001/16/EC of the European Parliament and of the Council of 19 March 2001 on the interoperability of the trans-European conventional rail system, OJ 20.4.2001 L 110, 1-27.

47 17th recital of Directive 96/48/EC and 24th recital of Directive 2001/16/EC.

48 Cf. specifically Article 6 and Annex VII of Directive 2001/16/EC and Article 6 of Directive 96/48/EC.

49 Cf. Commission Decision 98/500/EC of 20 May 1998 on the establishment of Sectoral Dialogue Committees promoting the dialogue between the social partners at European level, OJ 12.8.98 L 225, 27 f.

50 Article 6 Paragraph 9 of Directive 2001/16/EC.

51 Item 1.3.1 of the respective Annex III.

52 Item 2.2.1 and 2.2.2 of the respective Annexes.

53 Item 2.5.1 of the respective Annex III.

54 Item 2.6.1 of Annex III of Directive 96/48/EC and Item 1.4.4 of Annex III of Directive 2001/16/EC.

c) Generation of BAT codes of practice for industrial plant

A particular development can be observed with regard to the *licensing of industrial plants*.⁵⁵ According to the IPPC Directive⁵⁶, the licensing authorities must satisfy themselves that the plant operators take all suitable measures to prevent pollution of the environment, in particular by the use of the best available techniques (BAT)⁵⁷ (Article 3 (1) a). The Commission organizes an exchange of information between member states and the industries concerned regarding the best available techniques, associated surveillance measures, and developments in this area (Article 16 (2)). BAT codes of practice for all industrial sectors falling within the scope of the directive are drawn up in a long-term programme co-ordinated by the European IPPC Office⁵⁸ at the *Institute for Prospective Technological Studies* in Seville.

The ambitious plan is to draw up all necessary BAT codes of practice for 26 categories of plant and six generic aspects by the end of 2004. Technical working groups have been formed for each reference document to be drafted. In addition to representatives of the member states, numerous experts from industry particularly qualified for the areas concerned, the environment associations, represented by a small number of experts from the European Environmental Bureau, and representatives of the Commission are also working on the document. A close working relationship to the European or national standards organizations does not, as yet, appear to have been established.⁵⁹ Among the technical reference documents listed, over 2,000 in number, very few contain technical standards.

No formal voting rules exist for the technical working groups. Such rules would correspondingly also require clear rules governing group membership. As is usual in international standards committees, the principle applies that a document must be rejected explicitly and reasons for the rejection stated, and that agreement is to be reached by consensus. The Commission's view is that agreement or formal adoption of the BAT codes of practice is not necessary, as Article 16 (2) of the IPPC Directive requires only that the Commission organize an exchange of information and report upon it.⁶⁰ This view may well avoid potential system-related losses in the run-up to formal voting; it conceals, however, the high practical significance of the BAT codes of practice, as the latter, irrespective of their precise legal status, are the documents of decisive importance employed by the licensing authorities and by the manufacturers and operators of plant for identification of the best available techniques. It cannot be foreseen at this stage when the Commission will begin

55 For comprehensive details, see Falke, Josef, Konkretisierung von Anforderungen des integrierten Umweltschutzes an Anlagen und Produkte durch untergesetzliche Regelungen, insbesondere durch technische Normen, Yearbook 2000 of the Braunschweigischen Wissenschaftlichen Gesellschaft, 199-242.

56 Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control, OJ 10.10.96 L 257, 26-40.

57 "Best available techniques" are deemed to be the most effective and advanced stage in the development of activities and their methods of operation which indicate the practical suitability of particular techniques for providing in principle the basis for emission limit values designed to prevent and, where that is not practicable, generally to reduce emissions and the impact on the environment as a whole (Article 2 Item 11).

58 IPPC – integrated pollution prevention and control.

59 A representative of the European standards organization CEN is involved only in the working group responsible for emissions monitoring. The Strategic Advisory Body on Environment (SABE) of CEN has established a group for observation of the activities co-ordinated by the EIPPC Office in Seville, and has compiled the European standards relevant to the exchange of information on best available techniques. The detailed agendas of the individual CEN standards committees, in which parallel activity and potential partners for co-operation are also listed, contain no reference to work on BAT codes of practice.

60 Gislev, Magnus, European innovation and exchange of information about BAT, in: Umweltbundesamt (ed.), The Sevilla Process. A Driver for Environmental Performance in Industry, UBA-Texte 2000/16, 77-82 (81).

publishing the documents⁶¹, which have already been available for some time, nor which documents will be given priority. The Commission is prohibited under Community law from delegating decisions with a direct legal effect to private bodies or committees. The fact that publication of the results of the exchange of information is a prerogative of the Commission does not necessarily enable it to monitor the quality; it does however permit some degree of monitoring for abuse.

d) References to international, European, and selected national standards in Community law

Numerous Community acts outside the New Approach to technical harmonization and standardization contain references to technical standards. Locating these references is a time-consuming task and is dependent upon a number of conditions. The present project is the first attempt claiming to be complete and up to date for the full body of Community law, which currently encompasses over 16,000 legal instruments in the form of regulations, directives, decisions, orders and agreements, and for the current proposals for Community legal instruments, which comprise some 3,300 documents.⁶²

The availability of Community law⁶³ in electronic form now permits precise full-text searches in the complete body of Community law in force, and in the body of the proposals for legislation currently under discussion. The consolidated texts of numerous, frequently amended legal instruments are available, with a few exceptions, only in electronic form. A number of search operations were performed in which in the first instance the legal instruments and proposals for legislation were identified which contain, at any point in the text, international, European or selected national standards organizations or bodies issuing technical regulations, or the technical regulations issued by such organizations, which in many cases are identical to the name of the organizations themselves. The precise points in the text at which reference was made to the standards organizations sought and their regulations were identified in all legislative texts. By this means, the text passages actually containing references of the desired kind to standards could be identified. The mere mention of standards organizations and technical standards in the recitals was ignored. All references to standards were recorded for further analysis with sufficient precision to permit comparison with the relevant catalogues of standards. A comparison of this kind was performed and documented for the most significant bodies of standards in the context of the present study.

Following preparation, the comprehensive data permits further analyses, which may be useful in particular for co-ordination between the Commission's many Directorates-General. Many of the latter occasionally deal in their work with references to standards, but are not able to focus upon their content, as witnessed by a lack of coherence between them, and a need for co-ordination with the respective latest versions of the standards to which reference is made.

Table 7 shows, in a survey of the searches performed, the number of Community legal instruments and the associated proposals which make reference to the standards of certain international, European, and selected national standards organizations and other sources of technical regulations.

61 The lists of members of the individual technical committees and the relevant technical reference documents, the minutes of the opening sessions, the first and where applicable second draft, the final draft, and finally the concluding BAT codes of practice are available to the public on the Internet at <http://eipccb.jrc.es/Bactivities.htm>.

62 **Heinz Jung** and **Max Hammer** provided intensive and valuable support during the electronic research.

63 The index of applicable Community law can be found for example at <http://europa.eu.int/eur-lex/de/lif/index.html>.

Table 7: Number of Community legal instruments and proposals for legislation which make reference to the standards of international, European, and selected national standards organizations and other sources of technical regulations (as of April 2001)

Standards organizations	Legal instruments Total	Categories of Community legal instrumentsProposals						
		L	R	D	A	X	Y	
International organizations:								
ISO	129	82	15	24	3	5	0	7
IEC	22	20	0	1	1	0	0	5
ISO/IEC	2	0	2	0	0	0	1	0
ITU	7	1	1	1	0	1	3	0
CCITT	8	3	0	2	0	3	0	0
IMO	15	10	3	0	0	0	2	6
WHO	3	2	1	0	0	0	0	0
Codex Alimentarius- Commission (CAC)	3	2	0	1	0	0	0	1
OIE	13	0	0	12	0	1	0	2
OECD	10	8	0	1	1	0	0	0
ILO	1	1	0	0	0	0	0	0
ICAO	3	1	0	0	0	1	1	2
FAO	8	5	3	0	0	0	0	0
European organizations:								
CEN, CENELEC, ETSI	77	31	17	25	0	3	1	9
UN/ECE	24	18	2	0	2	2	0	3
Eurocontrol	3	2	1	0	0	0	0	0
ECAC	1	0	1	0	0	0	0	0
CEPT	2	2	0	0	0	0	0	0
ECMA	2	0	0	2	0	0	0	0
National standards organizations outside Europe:								
ANSI	1	1	0	0	0	0	0	0
API	2	1	1	0	0	0	0	0
ASTM	55	22	11	9	13	0	0	6
JISC	2	2	0	0	0	0	0	0
National standards organizations within Europe:								
AENOR	1	0	0	1	0	0	0	0
AFNOR	3	3	0	0	0	0	0	0
BSI	6	3	1	1	0	1	0	0
DIN	18	5	6	6	0	1	0	0
NNI	4	2	0	1	0	1	0	0
NSAI	1	0	0	1	0	0	0	0
SFS	3	0	0	3	0	0	0	0
UNI	1	0	0	0	0	1	0	0

Legal instruments	L	Directive	A	International agreement
	R	Regulation	X	Recommendation
	D	Decision, order	Y	Resolution

A legal instrument is included in the table as a relevant case irrespective of whether it contains only a single reference to technical standards, or numerous such references. Only legal instruments which actually refer to the regulatory content of a standard are included; this is not the case when the content of a standard is reproduced unchanged or in full in the annex of a directive or regulation.⁶⁴ The analysis is almost complete for the international and European standards organizations. No systematic attempt has however been made to include the standards organizations and trade associations which have drawn up standards at European and international level for a single product category only. Two regulations governing the quality requirements of dairy products, for example, contained reference to a highly specialized international organization of this kind which has presented definitive test methods for the analysis of milk and dairy products.

The majority of references to international standards organizations concern ISO⁶⁵, as this organization covers a much wider range of products with its activities than do other standards organizations. The International Electrotechnical Commission (IEC)⁶⁶ is responsible for the particular area of electrical engineering, the IMO⁶⁷ for the safety of ocean shipping, the International Telecommunication Union (ITU)⁶⁸ for the field of telecommunications technology, and also the CCITT for certain older legal instruments. In the area of veterinary legislation, a large number of Community legal instruments refer in their recitals to provisions of the World Organization for Animal Health (OIE)⁶⁹; only in a substantially smaller number of decisions is formal reference in the present context made to a standard from the body of technical regulations issued by this organization. The content of a high proportion of the directives and regulations in Community foodstuffs legislation has been co-ordinated with the provisions of the FAO and WHO Codex Alimentarius Commission (CAC)⁷⁰ and makes express reference to this fact in the recitals⁷¹; in this case, only legal instruments making reference to specific parts of the CAC regulations, i.e. which supplement the Community legal instruments externally, were considered.⁷² The World Health Organization (WHO)⁷³ is one of the highly regarded international organizations to whose provisions the Community makes recourse in order to present, in complex and controversial situations, scientifically validated solutions which can then be supported by the proponents of different interests. The air pollution limit values which were adopted in the directives for specific pollutants⁷⁴ in

64 A topical example is the Proposal for a European Parliament and Council Directive amending Directive 94/25/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to recreational craft, COM (2000) 639, final, 12 October 2000.

65 Cf. in this respect also to **Annex A, Item 4**.

66 Cf. in this respect also to **Annex A, Item 2**.

67 Cf. in this respect also to **Annex A, Item 3**.

68 Cf. in this respect also to **Annex A, Item 5**.

69 Cf. in this respect also to **Annex A, Item 7**.

70 Cf. in this respect also to **Annex A, Item 1**.

71 Cf. the 4th recital of Commission Directive 2000/63/EC of 5 October 2000 amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners, OJ 30.10.2000 L 277, 1-61; see also the 4th recital of Commission Directive 2000/51/EC of 26 July 2000 amending Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs, OJ 4.8.2000 L 198, 41-43.

72 E.g. Article 7 (2) of Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation, OJ 13.3.1999 L 66, 16-23.

73 Cf. in this respect also **Annex A, Item 10**.

support of the Air Pollution Framework Directive⁷⁵ are a topical example. Without the activities of the OECD⁷⁶, the Community's chemicals policy would have been virtually impossible in the form actually implemented in terms of the development of concepts, achievement of compromises, and co-ordination with the chemicals policy of the USA.⁷⁷ At present, the planning activities of the OECD for the combating of fraud in international finance transactions are important for the associated activities involving co-operation in the area of justice and internal affairs. The very areas in which the activity of international organizations has the effect of regulation and the reaching of compromises within the scope of Community policy are those in which such activity does not produce formal reference to standards to any substantial degree.

Table 7 contains only references to European standards which are not related to the New Approach. The search strategy employed would in any case not have revealed directives adopted within the New Approach, as these do not, strictly speaking, make reference to standards. The requirements which products must satisfy if they are to be marketable within the European Single Market are specified by the directives themselves in annexes containing the essential requirements. Observance of the harmonized standards the references of which are published by the Commission in the Official Journal of the EC gives rise to a rebuttable presumption that the requirements are met. Their observance is therefore regarded as the "fast-track solution" for demonstration of suitability for distribution which entails the least administrative expense.

References to the *United Nations Economic Commission for Europe (UN/ECE)*⁷⁸ are to be found in many other legal instruments in addition to those listed in the table on the basis of a formal reference to a standard. Development of detailed technical requirements for motor vehicles and motor vehicle components has been conducted under the auspices of the UN/ECE since 1958. The manner in which the EC is involved is described in detail elsewhere.⁷⁹ The numerous directives governing the requirements for motor vehicles and motor vehicle components which have been drawn up since 1970 are based to a large extent upon the preliminary technical work of the UN/ECE. This comprehensive body of directives, which is also of great importance to the economy and to transport and environment policy, is the most important instance of the adoption into the annexes of Community legal instruments of comprehensive and detailed technical rules drawn up externally. This does not routinely involve a formal reference to standards.

In order to facilitate international trade, the UN/ECE Working Party on Standardization of Perishable Produce and Quality Development has defined some 100 quality standards for

74 Council Directive 1999/30/EC of 22 April 1999 relating to limit values for sulphur dioxide, nitrogen dioxide and oxides of nitrogen, particulate matter and lead in ambient air, OJ 29.6.99 L 163, 41-60; Directive 2000/69/EC of the European Parliament and of the Council of 16 November 2000 relating to the limit values for benzene and carbon monoxide in ambient air, OJ 13.12.-2000 L 313, 12-21.

75 Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management, OJ 21.11.1996 L 296, 55-63.

76 Cf. in this respect also **Annex A, Item 6**.

77 Cf. Council Decision 89/569/EEC of 28 July 1989 on the acceptance by the European Economic Community of an OECD decision/recommendation on compliance with principles of good laboratory practice, OJ 28.10.1989 L 315, 1-32, as a specific regulation and one very relevant to practice external to the development of concepts and the preparation of compromises.

78 Cf. in this respect also **Annex A, Item 9**.

79 Cf. below under 5 c) for details.

perishable products such as foodstuffs, plants and cut flowers.⁸⁰ The standardization activity, the launch of which dates back to October 1949, was consolidated in 1962 by the OECD⁸¹ and developed into a system for the “common organisation of the market in fruit and vegetables”. The content of these recommendations has been taken into consideration in numerous Community marketing standards for agricultural products⁸², without involving any formal reference to standards. The basic regulation on the common organisation of the market in fruit and vegetables makes provision for specification of standards for fresh fruit and vegetables in the Regulatory Committee Procedure, and for attention therefore to be given to the UN/ECE standards recommended by the Working Party on Standardisation of Perishable Produce and Quality Development of the United Nations Economic Commission for Europe.⁸³ The Commission has now called for the quality standards for fruit and vegetables to be merged with the standards governing food safety, in order to create greater market transparency.⁸⁴ According to the SPS Agreement, the relevant provisions of the Codex Alimentarius Commission are to be adopted with priority with regard to the safety of foodstuffs.⁸⁵

The references to national standards were also recorded. An attempt was made here to produce a complete record for the national standards organizations in Europe. Among the standards organizations outside Europe, the American Society for Testing and Materials (ASTM) has an outstanding role. These references to the work of a standards organization of a third state, which are in fact astonishing in the context of Community law, are dealt with in greater detail below.⁸⁶

80 More detailed information can be found at http://www.unece.org/trade/agr/standard/fresh/fresh_e.htm. Cf. also the Revised Geneva Protocol on Standardization of Fresh Fruit and Vegetables and Dry and Dried Fruit.

81 More detailed information on the relevant OECD activities can be found at <http://www.oecd.org/agr/code/f&v/fruitveg.htm>.

82 In this respect, the 2nd recital of Commission Regulation (EC) No 716/2001 of 10 April 2001 amending Regulation (EC) No 2789/1999 laying down the marketing standard for table grapes, OJ 11.4.2001 L 100, 9 f is particularly clear and topical. Similar new regulations exist for tomatoes, avocados, garlic, cauliflower and artichokes, carrots, red peppers and peas.

83 Article 2 (2) of Council Regulation 2200/96 of 18 October 1996 on the common organisation of the market in fruit and vegetables, OJ 21.11.96 L 297, 1-28.

84 Cf. Commission Report to the Council on the state of implementation of Regulation (EC) No 2200/96 on the common organisation of the market in fruit and vegetables, COM (2001) 36, final, 24 January 2001, 12.

85 Cf. discussion under 5 a) for details.

86 Cf. discussion under 2 g) for details.

Table 8 lists, classified by the area of regulation, the number of Community legal instruments which refer to international, European, ASTM or DIN standards; like *Table 7*, it does not include the numbers of individual standards references, which are several times higher. The legal instruments were assigned clearly to a single, main area of regulation in each case; many may however be multifunctional in character. A directive with the purpose of noise abatement, for example, also contains aspects of environmental protection and occupational health and safety. Numerous directives which specify requirements upon motor vehicles or motor vehicle components have at the same time the objective of road safety or environmental protection.

Table 8: Number of Community legal instruments which make reference to international, European, ASTM or DIN standards, classified by their area of regulation

Area of regulation	ISO	IEC	IMO	ITU	CCITT	OIE	OECD	FAO	ECE	EN	ASTM	DIN
Motor vehicles	27	6							11	6	12	
Tractors	5	2					3		1	5	1	
Motorcycles	2	2							6			
Ecolabeling	16	1								13		4
Environmental protection	10							2		9	3	1
Energy savings										4		
Noise abatement	7	2								1		
Occupational health and safety	2	1										
Chemicals	9	1					5			3	4	3
Cosmetics	6											
Pesticides, fertilizers	3						1	2				
Electrical appliances		1								5		
Metrology	5	2										
Common agricultural policy	13							2	2	8	2	1
Veterinary practice	3					13						
Foodstuffs, tobacco	3							1		2		
Telecommunications and information technology	3			6	8				1	9		
Fireproofing	1											1
Safety in ocean shipping	1	3	15							3		
Safety in road traffic	2								1	1		
Transport of hazardous goods	3									1	1	1
Air safety				1								
Customs duties	2									3	12	3
Import/export										16	19	3
Miscellaneous	6	1					1		7	1	1	

The identified references to standards differ fundamentally from the regulatory mechanism by which the New Approach to technical harmonization and standardization makes use of standards. Whereas in the latter case, all product characteristics relevant to distribution of the products are regulated in numerous harmonized standards for fulfilment of the essential requirements for a category of products, the cases listed here generally involve amendments of specific points concerning product requirements of greater or lesser detail which are specified in the Community legal instruments themselves. Consequently, the standards overwhelmingly concern the definition of measurement and test methods. Supplementary standards are employed in the area of customs duty and import/export, in particular, for precise identification of products.

Standards for specification of the quality of services arise only indirectly through the series of standards governing quality management (ISO 9000 ff.), environmental management (EN ISO 14000 ff.), and the requirements upon certification bodies (EN 45000 ff.). These are also aimed indirectly at the quality, environmental impact and safety of products. These standards have also found clear acceptance on the market, even outside Community jurisdiction, and without serious alternatives. The areas in which they are applied can be found in Tables 9, 10, 14 and 15. The frequent supplementary inclusion of EN 14001 in the decisions concerning product-specific conditions for the issuing of a Community ecolabel is particularly notable.

At no stage in the evaluation was the scale of product safety or threshold values for environmental impact or noise pollution of technical products found to be undefined without the reference made to technical standards. Rather, technical standards are employed without exception for reliable verification of observance of the product requirements defined by the Community's legislative organs themselves. A more in-depth analysis is however appropriate with regard to the references to various IMO regulations in the area of ocean shipping safety.⁸⁷ Such an analysis may be beneficial with regard to the fact that aspects of product safety, environmental protection and occupational health and safety are more closely interrelated in this sector than in others.

Tables 15 to 26 in the **annex** contain more detailed analyses. They can be mentioned only briefly here.

Table 15 lists the references to ISO standards found in current Community law and compares them with the current body of ISO standards; *Table 16* performs the same comparison for the proposed Community legal instruments. In the same way, *Tables 17* and *18* deal with references to IEC standards in current legislation and in current legislative proposals. *Table 19* refers to the few references to joint ISO and IEC standards. The electronic versions of the ISO and IEC standards catalogues were employed for the comparison with the current body of standards.

The use of rigid references to standards, i.e. reference to a particular standard additionally specified by its date of issue, may give rise to problems with all of the references contained in these tables. This form of reference represents a particularly suitable solution in terms of conformity with the rule of law and democratic principles. It is, however, subject to rapid obsolescence, and proves to be more suitable for causing confusion. Is the intention really to refer to the old versions, which the standards committees presumably have had good reason to revise? Is this course to be followed with no consideration for the difficulties which arise through the fact that the obsolete versions are no longer available or contradict other parts of the current body of standards? What is to happen in the relatively frequent cases in which standards are withdrawn without replacement?⁸⁸ What is to happen in the even more frequent

⁸⁷ Cf. discussion under 2 e).

⁸⁸ Cf. Nos. 1, 2, 6, 15, 17, 18, 20, 43, 45, 49, 57 and 77 in *Table 15*.

cases, not limited to those with a rigid standards reference, in which a number of standards are developed from what was formerly a single standard in its own right?⁸⁹ Only one case involves the provision, albeit one which presents problems of its own, that where reference is made to international standards, any changes or withdrawals are to be observed.⁹⁰ The provision that the latest edition of a standard is to be applied, that the currently valid version is to apply⁹¹, or that the ISO standard denoted explicitly or a revised version of the same standard are applicable, gives rise to flexibility and scope for speculation.⁹² Occasionally, the reference is accompanied by phrases such as “or equivalent standards”⁹³ or “or comparable standards”⁹⁴.

Table 20 and *Table 21* list the references to European standards and compare them to the current body of European standards. The electronic version of the DIN catalogue was employed for this comparison. The problems mentioned concerning references to international standards also arise here. Thirteen standards cannot be found in the current standards catalogue.⁹⁵ Eighteen standards to which rigid reference is made have been revised since the edition to which reference was made.⁹⁶ A particular feature encountered here for the first time is that a directive itself contains amendments to the content of the standard referred to.⁹⁷ A further new mechanism is the continuous adaptation clause, by which regulations which may be adopted in future and which are stricter than those of the available draft standards are to apply.⁹⁸ In many cases in which reference is still made to a draft standard, the standard has since been adopted.⁹⁹ Does the text of the draft remain authoritative even following adoption of a standard? What is to happen in cases in which the draft standard is subjected to changes in content in the final stage of the standardization process, or a standardization project is abandoned completely? Are cases in which a legal instrument refers to a draft standard, although the standard had already been adopted at completion of the legislative activity, to be regarded as conscious political acts, or as technical errors?¹⁰⁰

For the sake of completeness, *Table 22* lists the cases in which Community legal instruments or proposals for legislation refer to anticipated European standards without being able to name a specific draft standard. At least in the case of directives from 1988 and 1994, it may be appropriate to ascertain whether the standards anticipated at that time now exist, and if so to make correct reference to them, or to specify alternative methods of measurement.

89 Cf. Nos. 3, 5, 16, 24, 26, 28, 37, 38, 45, 51, 53, 58, 62, 63, 66, 67, 68, 71, 84, 88, 91, 93, 98, 99, 107, 110, 118, 128 and 129 in *Table 15*; No. 4 in *Table 16*; Nos. 5, 17 and 18 in *Table 17*.

90 No. 126 in *Table 15*.

91 Cf. Nos. 105 and 125 in *Table 15*.

92 Cf. Nos. 75 and 83 in *Table 15*.

93 Cf. Nos. 82 and 100 in *Table 15*.

94 Cf. Nos. 28 and 85 in *Table 15*.

95 Cf. Nos. 2, 4, 5, 6, 8, 15, 19, 24, 36, 44, 66, 67 and 68 in *Table 20*.

96 Cf. Nos. 1, 3, 9, 10, 12, 18, 28, 35, 38, 49, 50, 58 and 60 in *Table 20*.

97 Cf. Nos. 3 and 5 in *Table 20*.

98 Cf. No. 24 in *Table 20*.

99 Cf. Nos. 17, 26, 33, 35, 38, 41, 42, 50 and 61 in *Table 20*.

100 Examples can be found in Nos. 12, 18, 45, 68, 77, 81, 85, 87, 93 and 125 in *Table 15* and in Nos. 17, 26, 41, 42, 49, 50 and 69 in *Table 20*.

Finally, attention is drawn to the fact that many European standards to which reference is made in Community legal instruments can be shown to be based upon an international standard.¹⁰¹

e) References to IMO provisions

Tables 23 and 24 show the scale to which reference is made to IMO provisions, and with regard to which rules in current Community law and legislative proposals.

Council Directive 95/21/EC of 19 June 1995 concerning the enforcement, in respect of shipping using Community ports and sailing in the waters under the jurisdiction of the member states, of international standards for ship safety, pollution prevention and shipboard living and working conditions (port state control)¹⁰², is of particular importance for the *safety of ocean shipping*. Its purpose is to reduce dramatically the number of sub-standard ships in the territorial waters of the member states by promoting the observance of international and relevant Community regulations for safety at sea, the protection of the marine environment, and the living and working conditions on board ships sailing under any flag, and by the specification of common surveillance criteria. It makes reference in this regard to six international agreements within the competence of the IMO and to the Merchant Shipping (Minimum Standards) Convention No. 147. The Marine Equipment Directive¹⁰³ also makes reference, owing to the technical requirements, to a number of international standards by means of certain international agreements. In accordance with this directive, the Community requests that the IMO develop standards, including detailed test standards, for the equipment stated in the annex of the directive. Only when the IMO or other international organizations have not adopted the corresponding standards within a reasonable period of time or have rejected adoption may standards which are based upon the activity of the European standards organizations be adopted in the Regulatory Committee Procedure.¹⁰⁴

The Community has consistently co-operated with the International Maritime Organization (IMO) in the area of ocean shipping safety, at least since 1993.¹⁰⁵ It supports the IMO's role in the safety of ocean shipping and the prevention of ocean pollution, in particular by the specification of standards for ships, crews, and ocean shipping infrastructure. The IMO standards should apply where practical to all vessels sailing in the waters of EC member states, irrespective of the flag under which they sail, in order for marine resources and coasts to be protected, and the competitiveness of the Community fleet not to be placed at risk. As the majority of ships employed in international maritime transport place themselves outside the specific jurisdiction of Community law by sailing under flags of convenience, the Community primarily promotes effective and uniform application of international rules in areas such as the following¹⁰⁶:

101 Even though this fact is reflected in the designation EN ISO, the standard is nevertheless a European standard. Certain community Acts or proposals for them contain the expression "International standard EN ISO xxyy". Cf. Commission Regulation (EC) No 2248/98 of 19 October 1998 amending Regulation (EEC) No 2568/91 on the characteristics of olive oil and olive-residue oil (...), OJ 20.10.1998 L 282, 55 f.

102 OJ 7.7.95 L 157, 1-19.

103 Council Directive 96/98/EC of 20 December 1996 on marine equipment, OJ 17.2.1997 L 46, 25-56.

104 Article 7 (5) of Directive 96/98/EC.

105 Cf. Communication from the Commission on a common policy on safe seas, COM (93) 66 final, 24 February 1993, and Council Resolution of 8 June 1993 on a common policy on safe seas, OJ 7.10.93 C 271, 1-3. – Conversely, for the current situation of acute hazards to safety at sea and community measures in this respect, see the Report from the Commission for the Biarritz European Council on the Community's strategy for safety at sea, COM (2000) 603, final, 27 September 2000.

106 Cf. Item II, 1 of the Council Resolution cited above of 8 June 1993.

- port state control; denial of access to community ports for ships identified as not complying with internationally agreed standards and refusing to undertake the necessary retrofitting;
- supplementing of the existing IMO resolutions with the objective of improving the safety of ocean vessels entering Community territorial waters, irrespective of the flag under which they are sailing;
- harmonizing of the application of IMO regulations and the licensing procedures for maritime equipment.

The IMO cannot be regarded as a standards organization in the conventional sense. It has drawn up, in addition to binding statutory agreements and protocols, a large number of other standards which are recognized as international standards with no formal legal force. These include the numerous codes of practice, recommendations and guidelines, for example in the areas of loading, ship safety and ship technology, marine pollution, navigation, search and rescue, radio at sea, and training.¹⁰⁷ The strength of the IMO lies in its expert drafting of rules, supported by the Maritime Safety Commission (MSC), in all areas of the technical safety of shipping, and by the Marine Environment Protection Committee (MEPC) for the prevention and combating of ocean pollution by shipping. Its greatest weakness is the implementation of the standards. The Community understands its own policy in the area of shipping safety as an attempt to implement, in a uniform and co-ordinated manner, the international standards agreed within the framework of the IMO. Consistent with this view are the Commission's efforts to introduce the latest standards as quickly as possible and consistently in the regulatory procedure, and the linking of many references to IMO regulations with the comment that the latest version of the IMO provision should apply. The reference to specified IMO resolutions would otherwise invariably result in rigid standards references, i.e. in a need for the Community legal instruments to be continually updated. The close linking of Community law with the IMO regulations is on the one hand appropriate in the face of the global dimension of ocean shipping; on the other hand, however, it restricts the political freedom of the EU to specify stricter provisions in a pioneering role without establishing a willingness by other parties on an international level to follow suit. For the proposed directive concerning double-hull tankers¹⁰⁸, for example, the Commission considers it necessary to ensure that the same requirements be specified by the IMO without delay.¹⁰⁹

f) References in the area of air traffic

Air traffic has a global dimension comparable to that of ocean shipping. In 1991, the Council issued a regulation on the harmonization of technical requirements and administrative procedures in the field of civil aviation safety with reference to the design, manufacture, operation and maintenance of aircraft and with reference to persons and organizations involved in these tasks.¹¹⁰ This regulation declares, in the interest of air traffic safety and proper functioning of the Single Market, certain Joint Aviation Requirements (JAR) of the Joint Aviation Authorities (JAA), an associate body of the European Civil Aviation

107 For an overview of the organization and activities of the IMO, cf. Seidel, Peter, IMO – Internationale Seeschiffahrts-Organisation, in: Rüdiger Wolfrum (ed.), *Handbuch Vereinte Nationen*, 2nd edition, Munich 1991, 355-362. For up-to-date information, refer to the comprehensive web pages at <http://www.imo.org/>.

108 Cf. the amended proposal for a Regulation of the European Parliament and of the Council on the accelerated phasing-in of double hull or equivalent design requirements for single hull tankers, COM (2000) 848 final, 12 December 2000.

109 Cf. COM (2000) 603 final, 27 September 2000, 4.

110 Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation, OJ 31.12.91 L 373, 4-8.

Conference, to be binding, and grants the Commission authority to implement the amendments made by the JAA to the common technical requirements and administrative procedures adopted by the Council. This procedure thus departs from the traditional area of references to standards, which differ from binding technical regulations by virtue of the voluntary nature of their application. The same applies to the issuing of binding technical specifications for purchasing policy in air traffic management.¹¹¹

g) References to ASTM standards

As references to standards of a standards organization located in a non-EU country are a peculiarity requiring explanation, in particular in the frequency with which they are encountered here, *Tables 25* and *26* list the references to ASTM standards, also noting their content, and indicating whether the standard in question is stated as being the sole standard governing the measurement and test procedure in question.

The *American Society for Testing and Materials (ASTM)* was founded in 1898 as a non-profit-making standards organization. Its areas of activity concern, first and foremost, material and product standardization of metals, paints, plastics, textiles, petroleum products, construction products, medical devices and consumer goods, and the standardization of systems and services in the area of information technology and power generation. ASTM has 32,000 members world-wide; some 10,000 standards have been produced to date.¹¹²

All references to ASTM standards noted here deal exclusively with measurement and testing procedures. The majority of references concern particular measurements of petroleum products, and frequently fuels. As directives have been updated, international standards have been stated for many measurement procedures for which, initially, only ASTM procedures were referred to. Some directives state explicitly that equivalent ISO procedures are to be adopted as soon as they are published for all product properties stated.¹¹³ This has now been implemented for the tests of many fuels. If the development of the more recently adopted legal instruments which make reference to ASTM standards is examined, a very small number of test procedures are seen to remain, for which these standards are repeatedly stated.

h) Summary

- A third (33.4%) of the harmonized standards are identical to international standards drafted by ISO or IEC; a further 13.2% adopt international standards with modifications. For the core area of Community standardization policy, in which the political specifications for the European standards organizations concerning the essential requirements contained in the annexes to the directives and concerning the Commission's standardization mandates are particularly detailed and frequent, this is a remarkable result. A more precise analysis reveals considerable differences between the different sectors. Only one-eighth of the harmonized standards which correspond fully or in modified form to international standards fall outside the area of electrical engineering.
- Numerous Community legal instruments outside the New Approach to technical harmonization and standardization contain references to technical standards. Recording of these references is a time-consuming task and is conditional upon many factors. The present project is the first attempt to produce such a record, which is intended to be

111 Governed fundamentally by Council Directive 93/65/EEC of 19 July 1993 on the definition and use of compatible technical specifications for the procurement of air-traffic management equipment and systems, OJ 29.7.93 L 187, 187, 52-56.

112 Further information can be found at <http://www.astm.org>.

113 See Nos. 6, 9, 10, 11 and 48 in *Table 25*.

complete and up-to-date, for the full body of Community law and for the current proposals for Community legislation.

- The references to standards which are identified differ fundamentally from the regulatory mechanism of the New Approach to technical harmonization and standardization. Whereas in the latter case, all product characteristics relevant to distribution of the products are regulated in numerous harmonized standards for fulfilment of the essential requirements for a category of products, the requirements identified here are generally supplements to specific points concerning product requirements of greater or lesser detail which are defined in the Community legal instruments themselves. Consequently, the standards overwhelmingly concern the definition of measurement and test methods. In the area of customs duty and import/export, in particular, certain standards are added for precise identification of products.
- References to technical standards are found for almost all product categories. Particularly frequent reference is made to ISO and European standards. Many international standards are based upon the latter.
- At no stage in the analysis did the results suggest that the scale of product safety or threshold values for environmental impact or noise pollution of technical products are not defined except by the technical standards to which reference was made. Rather, technical standards are without exception employed to define or reliably assess observance of the product requirements defined by the Community's legislative organs themselves.
- Close analysis of the references to standards has revealed a considerable need for co-ordination within the European Commission. The rigid reference to standards, common for a long time in Community law, gives rise in particular to numerous problems.

3. Validity of the TBT Agreement for measures concerning the health and safety of workers at work

Question: *Does the TBT Agreement also apply to measures concerning the health and safety of workers at work, which in the EU fall within the scope of EC Directives pursuant to Article 137 of the EC Treaty?*

a) Text of the TBT Agreement

Whether the TBT Agreement applies to measures governing the health and safety of workers at work, which in the EU fall within the scope of the directives pursuant to Article 137 of the EC Treaty (formerly Article 118a), is dependent upon the interpretation of the terms “technical regulation” and “standard” as they appear in items 1 and 2 of Annex 1 to the TBT Agreement. The definition of these terms and certain others for the purposes of the TBT Agreement departs consciously from the corresponding definitions in ISO/IEC Guide 2 “General Terms and Their Definitions Concerning Standardization and Related Activities” (6th Edition, 1991). For the purposes of the TBT Agreement, the following definitions contained in it apply:

“1. Technical regulation

A document which lays down *product characteristics or their related processes and production methods*, including the applicable administrative provisions, with which compliance is mandatory. It may also include or consist entirely of provisions concerning terminology, symbols, packaging, marking or labelling requirements as they apply to a *product, process or production method*.

2. Standard

Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for *products or related processes and production methods*, with which compliance is not mandatory. It may also include or consist entirely of provisions concerning terminology, symbols, or packaging, marking or labelling requirements as they apply to a *product, process or production method*.¹¹⁴

The differences between these independent definitions and those provided in the ISO/IEC-Guide 2 are reinforced by description in an explanatory note as follows:

“The terms as defined in ISO/IEC Guide 2 cover products, processes and services. This Agreement deals only with technical regulations, standards and conformity assessment procedures related to products or processes and production methods.

Standards as defined by ISO/IEC Guide 2 may be mandatory or voluntary. For the purpose of this Agreement standards are defined as voluntary and technical regulations as mandatory documents.

Standards prepared by the international standardization community are based on consensus. This Agreement covers also documents that are not based on consensus.”

The description of the differences between the TBT Agreement and the ISO/IEC Guide 2 is very appropriate. With regard to whether the TBT Agreement also applies to measures concerning the health and safety of workers at work, these points are not at issue; the first sentence of the definition of “technical regulation” and “standard” respectively is decisive¹¹⁵:

1. Technical regulation

¹¹⁴ Italics are the author’s.

¹¹⁵ Cf. editor’s note in the compendium of texts on the WTO (Beck-Texte, dtv), Munich 2000.

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

2. Standard

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method

The previous, 1979¹¹⁶ edition of the TBT Agreement contained no reference to “related processes and production methods”¹¹⁷ in either definition.¹¹⁸ Prior to the new edition of the TBT Agreement¹¹⁹, controversy arose regarding the permissibility of requiring certain processes and production methods to be observed for imported goods for reasons of environmental protection or occupational health and safety.

b) Procedures and production methods in WTO arbitration

In 1991 and 1994, two GATT arbitration cases were conducted regarding the permissibility of a trade embargo against tuna fish imports.¹²⁰ The embargo resulted from the US Marine

116 1979 Agreement on Technical Barriers to Trade, OJ 17.3.80 L 71, 29-43. – cf. Groetzinger, Jon, *The New GATT Code and the International Harmonization of Product Standards*, Cornell International Law Journal 8 (1975), 168-188 (still regarding the draft of a GATT Standards Code); Middleton, R.W., *The GATT Standards Code*, Journal of World Trade Law 14 (1980), 201-219; Sweeney, Robert E., *Technical Analysis of the Technical Barriers to Trade Agreement, Law and Policy in International Business* 12 (1980), 179-217; Sturen, Olle, *Gedanken zu den Anforderungen des GATT-Normenkodex*, DIN-Mitteilung 59 (1980), 591-595; Bourgeois, J.H.J., *The Tokyo Round Agreements on Technical Barriers and on Government Procurement in International and EEC Perspective*, Common Market Law Review 19 (1982), 5-33; Nusbaumer, Jacques, *The GATT Standards Code in Operation*, Journal of World Trade Law 18 (1984), 542-552.

117 The PPMs have frequently been the subject of controversial discussion in the literature. Cf. in particular Petersmann, Ernst-Ulrich, *International Trade Law and International Environmental Law. Prevention and Settlement of International Environmental Disputes in GATT*, JWT 27-1 (1993), 43-81 (68-72); Quick, Reinhard, *The Agreement on the Technical Barriers to Trade in the Context of the Trade and Environment Discussion*, in: Jacques H.J. Bourgeois, Frédérique Berrod, Eric Grippini Fournier (eds.), *The Uruguay Round Results. A European Lawyer’s Perspective*, Brussels 1995, 311-329; Schlagenhof, Markus, *Trade Measures Based on Environmental Processes and Production Methods*, JWT 29-6 (1995), 123-155; OECD, *Processes and Production Methods (PPMs): Conceptual Framework and Considerations on Use of PPM-Based Trade Measures*, OCDE/GD(97)137, Paris 1997; Howse, Robert, Regan, Donald, *The Product/Process Distinction – An Illusionary Basis for Disciplining ‘Unilateralism’ in Trade Policy*, European Journal of International Law 11 (2000), 249-289; John H. Jackson, *Comments on Shrimps/Turtle and Product/Process Distinction*, European Journal of International Law 11 (2000), 303-307.

118 On extension of the TBT Agreement to production methods in the run-up to the new TBT Agreement, cf. Foy, George, *Toward Extension of the GATT Standards Code to Production Processes*, JWT 26-6 (1992), 121-131.

119 On the background to the new issue of the TBT Agreement concerning the introduction of procedures and production methods, cf. the very detailed document published by the Secretariat of the WTO Committee on Technical Barriers to Trade, *Negotiating History of the Coverage of the Agreement on Technical Barriers to Trade with regard to Labelling Requirements, Voluntary Standards, and Processes and Production Methods Unrelated to Product Characteristics*. Note by the Secretariat, G/TBT/W/11, 27-43.

120 A brief summary can be found in Hohmann, Harald, *Der Konflikt zwischen freiem Handel und Umweltschutz*, Recht der Internationalen Wirtschaft 2000, 88-99 (92-94).

Mammals Protection Act, which regulated tuna fishing by US fishing vessels such that only methods of fishing which reduced the unintentional killing of dolphins were permitted. The act empowered the authorities responsible to ban other countries from importing commercially harvested fish into the USA if fishing methods suitable for the protection of dolphins were not employed. This primary embargo was followed by a secondary embargo which was to affect intermediary states should they not be able to prove that, within six months prior to importing tuna into the USA, they had purchased no tuna fish from a state not conducting measures for dolphin protection. Both panel reports¹²¹ rejected the permissibility of unilateral, international environmental measures on the grounds that the multilateral GATT system would be undermined if a state were to be permitted to impose its unilateral environmental protection measures on other countries. Measures for environmental protection must be absolutely essential in order to justify an exception to free trade. In the absence of satisfactory attempts to negotiate international measures for the protection of dolphins, the need for extraterritorial application of a national measure was questioned. Owing to the panel reports' orientation towards very basic principles, they presented no opportunity for comment upon the extent, which is important in the present context, to which the influence of different fishing methods or production measures upon the characteristics of the product itself was crucial to the decision reached.

The Shrimps-Turtle dispute¹²² ruled upon in 1998 by the Appellate Body of the WTO concerned a similar case. By amendments to the Endangered Species Act, the USA had obliged American operators of shrimp fishing boats to employ equipment intended to prevent the unintentional killing of sea turtles. Countries whose shrimp fishing technology presented a particular danger to the protected sea turtles were banned from importing shrimps into the USA unless the countries concerned demonstrated implementation of a comparable protection programme. The measures were classified as unjustifiable discrimination between countries where the same conditions prevail; under such circumstances, the measures could not be justified by the provisions of Article XX (b) GATT relating to environmental concerns. The principle of sustainable development contained within the preamble to the WTO Treaty permits only solutions involving multilateral agreements, and not unilateral, national measures. This report by the WTO Appellate Body also failed to comment upon whether the reflection of disparate fishing or production methods in the characteristics of the end product was crucial to the decision. The cases ruled upon in the area of environmental protection therefore make no contribution to answering the original question.

c) Procedures and production methods pursuant to the TBT Agreement

The interpretation of the extended definitions of the terms “technical regulation” and “standard” must be geared first and foremost to the purpose of the TBT Agreement, namely that of promoting the unhindered trade in goods, and not that of harmonizing the production methods, much less the conditions of use, of technical equipment or plant. Despite the extension of its objectives, as indicated most impressively, albeit relatively without

121 Tuna fish case I (Mexico/USA), Panel Report of 16 June 1991, *International Legal Materials* 30 (1991), 1594 ff.; Tuna fish case II (EU and Netherlands/USA), Panel Report of June 1994, *International Legal Materials* 33 (1994) 839 ff. – On the Tuna fish case cf. Petersmann, Ernst-Ulrich, *International Trade Law and International Environmental Law. Prevention and Settlement of International Environmental Disputes in GATT*, *JWT* 27-1 (1993), 43-81 (60-62).

122 Appellate Body Report, *US Import Prohibition of Certain Shrimp and Shrimp Products (WT/DS58/AB/R)*, 12 October 1998. Cf. in this regard Ginzky, Harald, *Umweltschutz und der internationale Handel mit Waren*, *Zeitschrift für Umweltrecht* 1997, 124-132; Mavroidis, Petros M., *Trade and Environment after the Shrimps-Turtles Litigation*, *JWT* 34-1 (2000), 73-88.

consequence, in the preamble to the WTO agreement, it has not yet proved possible to adopt independent regulations in areas of policy such as environmental protection, occupational health and safety, or the regulation of minimum working conditions which extend beyond the exemptions and exceptions in the existing agreements in favour of particular protective policies of the WTO members, such as in particular those in Article XXIV GATT, but also in the TBT and SPS Agreements. Proposals to this end were admittedly developed in the run-up to the Seattle Conference of Ministers¹²³. They must first and foremost address the accusation levelled by developing countries that they contain new forms of protectionism.

Even to reach the adoption of an elementary set of minimum working conditions is a difficult undertaking¹²⁴. Whilst renewing the obligation to observe the internationally recognized basic rights concerning occupational health and safety, the concluding declaration of the Singapore ministerial conference in December 1996¹²⁵ asserted at the same time that the International Labour Organization (ILO) was the competent body to define and develop such standards. In the best tradition of free trade, confidence is asserted that economic growth and development, supported by growing trade and further liberalization of trade, would contribute to the promotion of such standards. The use of employee rights for protectionist purposes is rejected. The comparative advantages of countries, in particular low-wage developing countries, must not under any circumstances be called into question. It is above all the developing countries who appeal to this declaration to reject any extension of the WTO's competencies in the area of occupational and social regulation and who refuse to enter into any discussion of the observance of minimum working conditions within the framework of selected countries' regular reviews of trade policy.

In consideration of this political environment, it must be established whether the "related" processes and production methods refer only to those which are reflected in the characteristics of the products, i.e. which in a sense leave their mark upon them, or whether standards and technical regulations in the context of the TBT Agreement might also encompass standards governing work processes or environmental protection measures in the manufacture of a product which are not reflected in the product itself. In the negotiations on further development of the 1979 standardization code, the USA – in accordance with the legislative position which it adopted in the tuna cases – called for unrestricted inclusion of processes and production methods. The EC rejected this proposal. The inclusion of the word "related" indicates the compromise which was found. In accordance with this formulation, only processes and production methods with a direct bearing upon the product characteristics, i.e. which are reflected in the product as it is distributed, are covered by the definition in Annex 1

123 On the position of the EU, cf. the Communication from the Commission to the Council and the European Parliament on the EU approach to the WTO Millennium Round, COM (99) 331 final, 8 July 1999 (very reservedly, however, with regard to the basic standards governing working practices, loc. cit., 24-27). For a rational stock-take on the subject of world trade and environmental protection, see Hilf, Meinhard, *Freiheit des Welthandels contra Umweltschutz?*, *Neue Zeitschrift für Verwaltungsrecht* 2000, 481-490; cf. also Jackson, John H., *World Trade Rules and Environmental Policies: Congruence or Conflict?*, in: idem, *The Jurisprudence of GATT and the WTO. Insights on Treaty Law and Economic Relations*, Cambridge 2000, 414-448. On the development of the WTO subsequent to conclusion of the Uruguay round and future perspectives, see Senti, Richard, *WTO: System und Funktionsweise der Welthandelsordnung*, Zürich 2000, 685-699.

124 On the relationship between world trade and basic working conditions, see in particular OECD, *International Trade and Core Labour Standards*, Paris 2000; OECD, *Trade, Employment and Labour Standards. A Study of Core Worker's Rights and International Trade*, Paris 1996.

125 Reproduced in *Internationale Politik* 4/1997, 97 ff. and in *WTO-Focus* 15/1997, 7 ff.

(1) and (2).¹²⁶ In other words, the TBT Agreement applies only to procedures and production methods with a direct bearing upon the product quality.

The concept of separation of the process and production measures (PPMs) into those which are reflected in the product (*product-related*) and those which are not (*non-product-related*) has been developed particularly convincingly in an OECD¹²⁷ study, and its consequences formulated. Measures in the first category are described by the term *consumption externality*; they are covered by the TBT Agreement; imported goods must meet the same requirements as those from domestic production¹²⁸. Measures in the second category are described by the term *production externality*; they are not subject to the TBT Agreement. Unilateral restrictions upon trade are not permitted with respect to these products, as this would represent an export of the domestic production conditions. Conversely, multilateral agreements, for example for protection of the environment, which are binding upon all parties to them, are possible.

Müller-Graff reaches the same conclusion and restricts extension of the term “standard” or “technical regulation” to those which are “*produktprägend*”, i.e. those leaving their mark upon the product.¹²⁹ He thereby excludes standards governing the work process which do not leave a lasting mark upon the product, for example provisions governing minimum wages or working hours. He justifies his position by the wording of the TBT Agreement. The term “*related*” permits the conclusion that a standard cannot be a document which defines rules, guidelines or characteristics for procedures or production methods independent of rules, guidelines or features governing a product.

Insertion of the word “related” at the advanced stage of negotiations of the revised TBT Agreement is attributable to a proposal by Mexico, and was presented with the explicit objective of excluding processes and production methods which have no bearing upon the product from the scope of the agreement.¹³⁰ The revision of the TBT Agreement was intended to limit the possibility of trade restrictions being justified with reference to the mandatory use of certain processes and production methods for reasons of occupational health and safety, environmental protection, or other considerations. The solution reached meets this objective satisfactorily.

126 Also Völker, Edmond L.M., The Agreement on Technical Barriers to Trade, in: Jacques H.J. Bourgeois, Frédérique Berrod, Eric Grippini Fournier (eds.), The Uruguay Round Results. A European Lawyer’s Perspective, Brussels 1995, 281-310 (286); Ginzky, Harald, Saubere Produkte, schmutzige Produktion. Eine Untersuchung zu Importbeschränkungen wegen umweltschädigender Produktionsformen, Düsseldorf 1997, 192. With reference to the requirements of environmental protection, Quick, in The Agreement on Technical Barriers (...) defends the distinction between production-related and process-related provisions; cf. also Rege, Vinod, GATT Law and Environment-Related Issues Affecting the Trade of Developing Countries, JWT 28-3 (1994), 95-169 (110).

127 OECD, Processes and Production Methods (PPMs). Conceptual Framework and Considerations on Use of PPM-Based Trade Measures, OCDE/GD(97)137, Paris 1997, esp. 9-21.

128 The principle in the European Single Market of the freedom of movement of products which have legally been distributed in one member state does not apply in world trade.

129 Müller-Graff, Peter-Christian, Die Maßstäbe des Übereinkommens über technische Handelshemmnisse (ÜTH) als Bauelemente eines Weltmarktrechts, in: Müller-Graff (ed.), Die Europäische Gemeinschaft in der Welthandelsorganisation. Globalisierung und Weltmarktrecht als Herausforderung für Europa, Baden-Baden 2000, 111-130 (117 f.); cf. also idem, Normung und Welthandelsrecht – Zum Übereinkommen über technische Handelshemmnisse, in: Klaus Vieweg (ed.), Techniksteuerung und Recht. Referate und Diskussionen eines Symposiums an der Universität Erlangen-Nürnberg, Köln, i.a. 2000, 265-285 (271 f.); Vieweg, Normung und Welthandelsrecht – Verpflichtungen aus dem Übereinkommen über technische Handelshemmnisse, DIN-Mitteilung 77 (1998), 411-414 (412).

130 G/TBT/W/11, 29 August 1995, 39.

It is also well compatible with the central provision of Article III:4 GATT.¹³¹ In accordance with the requirement for equal treatment of foreign and domestic products in this provision, products imported from the territory of one party to the agreement into the territory of another party to the agreement may be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The practice of the WTO dispute settlement bodies is based, like the GATT arbitration procedure, upon the term “*like products*”, by which the scope of the prohibitory mechanism of Article III GATT is defined. The conditions under which a product of national origin and an imported product may be regarded as like products is of decisive importance. Article III GATT is intended to prevent imported products from being placed at a disadvantage in comparison with products of national origin. The intention is to prevent not only discrimination on the basis of explicit reference to the product origin (formal discrimination), which owing to its obvious nature is of lower relevance in practice, but also recourse being made to other criteria where these have the effect of a *de facto* discrimination against imported products (material discrimination). Article III GATT does not prohibit differential treatment of disparate products and product groups where such treatment is based neither directly nor indirectly upon the products’ origin. Differential treatment must however be defensible against the charge that its purpose is one of covert protectionism. Differential treatment of imported and national products may be justified when differentiation is suited to and necessary for pursuit of the relevant objective. Regulations which demonstrably address differences in the product should generally be justifiable; regulations which address differences in production methods which do not lead to differences in the product should not.¹³² Residual pollutants which remain in the product and which may endanger users or consumers or take effect during recycling represent a criterion of differentiation which is permissible in principle, with additional consideration of the principle of proportionality; the impact upon employees or the environment of antiquated production methods, where the latter have no manifest influence upon the final product, do not. The former case should also generally be easier to prove. Article III GATT has as its objective equal treatment of imported products with products of national origin, and does not provide a country with justification for exporting its own production methods.¹³³

Vinod Rege reached the same conclusion immediately following adoption of the revised TBT Agreement. As his argumentation is pointed and succinct, we include it here as a form of interim summary:

131 Cf. on the following considerations also Epiney, Astrid, *Welthandel und Umwelt. Ein Beitrag zur Dogmatik der Art. III, IX, XX GATT*, Deutsches Verwaltungsblatt 2000, 77-86 (79-81).

132 By contrast: Howse, Robert, Regan, Donald, *The Product/Process Distinction – An Illusionary Basis for Disciplining ‘Unilateralism’ in Trade Policy*, European Journal of International Law 11 (2000), 249-289 (258-268). The authors argue that compatibility of differential treatment with Article III GATT is dependent solely upon the objective suitability of a measure for attainment of a legitimate regulatory objective, and not upon the distinction between product-related or production-related measures. Their view is not shared by John H. Jackson, *Comments on Shrimps/Turtle and Product/Process Distinction*, European Journal of International Law 11 (2000), 303-307.

133 With regard to Germany, reference is made in this context to the judgement by the BGH of 9 May 1980 (ref.: 1 ZR 76/78), reproduced in *Gewerblicher Rechtsschutz und Urheberrecht* 1980, 858-861 and in *Neue Juristische Wochenschrift* 1980, 2018-2020. In this judgement, the BGH regarded the sale of imported asbestos goods which have been manufactured in another country in accordance with the provisions of that country but without consideration of the safety provisions applicable in Germany for the protection of employees against asbestosis not to constitute unfair competition in the context of § 1 UWG (Unfair Competition Act). Cf. the remarks to the contrary by Walter Oppenhoff, *Gewerblicher Rechtsschutz und Urheberrecht* 1980, 861 f. on the one hand and by Rolf Knieper and Harmut Fromm, *Neue Juristische Wochenschrift* 1980, 2020 on the other.

“It is only logical that each country should have a sovereign right to require that imported products should meet the product standards which it applies to products produced by domestic industries with a view to protecting the health and safety of its people. In applying such standards to imported products, countries have, however, to ensure that they are not applied in a way as to create unnecessary obstacles to the trade of other countries.

The countries, however, have no right under the GATT law to require that the imported products must have been produced according to the PPM standards which restrict the import of a product on the grounds that it has not been produced in a plant which meets its national standards regarding pollution of water or air, particularly in cases where the PPM used has no effect on the characteristics or the quality of the imported product. Any such requirement would amount to an exporting country's being required to follow the process or production standards of the importing country, which it may have good reasons not to follow, taking into account the environmental and ecological conditions in its own country.”¹³⁴

A distinction between processes or production methods according to whether they are demonstrably reflected in the product corresponds largely to the distinction prevailing in Community law between product-related occupational health and safety, which is governed by Article 95 of the EC Treaty, and the health and safety of workers of work, which may be regulated in directives pursuant to Article 137 of the EC Treaty, directives which in turn provide member states with scope for the implementation of higher standards of protection provided such standards do not impair the freedom of movement of distributable products and plant (Article 137 (5) EC Treaty).

It gives rise to comparable problems. It may prove difficult to draw a distinction in particular cases. This can be seen clearly not only from the relevant position statements concerning standardization within the scope of the directives pursuant to Article 118 of the EC Treaty (now Article 137 of the EC Treaty) governing occupational health and safety¹³⁵, but also by the work over many years of the Commission for Occupational Health and Safety and Standardization (KAN) in the area of research, promotion of awareness, and the exchange of information in this area.

The activities of the “Technical Barriers to Trade” Committee, which can be accessed over the Internet on the WTO server¹³⁶, were evaluated in order to clarify whether the TBT Agreement also applies to measures concerning the health and safety of workers at work, which in the EU fall within the regulatory scope of EC directives pursuant to Article 137. Insofar as can be established from the minutes¹³⁷ and members' decisions and recommendations¹³⁸, which are also accessible over the Internet, the committee has not concerned itself directly with occupational health and safety issues.

134 Rege, loc. cit., 110.

135 Gemeinsamer Standpunkt des Bundesministers für Arbeit und Sozialordnung, der obersten Arbeitsschutzbehörden der Länder, der Träger der gesetzlichen Unfallversicherungen, der Sozialpartner sowie des DIN Deutsches Institut für Normung e. V. zur Normung im Bereich der auf Artikel 118a des EWG-Vertrages gestützten Richtlinien, Bundesarbeitsblatt 1/1993, 37-39 (see here esp. the annex containing guidance for the assessment of standardization projects); European Commission, GD V, Memorandum: The role of standardization in the implementation of the directives adopted on the basis of article 118 A of the EEC Treaty; CEN & CENELEC Standardization Policy in the Area covered by Article 118a of the EU Treaty, CLC(PERM)023. – The positions become vaguer and briefer in the order indicated.

136 <http://www.wto.org/>.

137 Cf. G/TBT/M/.

138 Cf. G/TBT/W/.

d) WTO arbitration procedure concerning the French asbestos ban

Finally, the WTO arbitration procedures were to be examined in which interpretation of the TBT Agreement was a central or marginal issue.¹³⁹ Of primary relevance here is the Panel Report submitted on 18 September 2000 in the dispute between Canada and the EU concerning measures affecting asbestos and asbestos products¹⁴⁰ and in the report of the Appellate Body¹⁴¹, awaited with great anticipation¹⁴² and submitted on 12 March 2001, in the same matter. This dispute shows for the first time how much scope the WTO rules leave the members for a policy of occupational health and safety based upon high standards of protection.

Both the Panel Report and the report of the Appellate Body confirm the compatibility of the ban introduced by France – in anticipation of provisions which have since become applicable throughout the EU¹⁴³ – of asbestos and asbestos products, which permits only minor exemptions, with the requirements of WTO legislation. The reports agreed that the measures taken were necessary for the protection of human life and health in the context of Article XX (b) GATT. In view of the clear scientific evidence of the threat to human life presented by asbestos and the absence of a proven threshold value, the Appellate Body rejected the request for more precise quantification of the risk.¹⁴⁴ The Appellate Body particularly emphasized the right of a WTO member to specify the required level of protection of human health.¹⁴⁵ In the Appellate Body's view, Article XX (b) GATT accords utmost priority to the protection of human health; a state taking action may make use of the measures it considers most effective.

139 Of the 194 WTO arbitration procedures initiated between January 1995 and May 2000, 26 refer to the TBT Agreement or the SPS Agreement; http://www.wto.org/english/news_e/press00_e/pr180_e.htm. Cf. also Overview of the State-of-Play of WTO Disputes, 21 November 2000 and the summary in Wilson, *The Post-Seattle Agenda of the World Trade Organization in Standards and Technical Barriers to Trade. Issues for the Developing Countries*, Washington 1999, 16-32.

140 WT/DS135/R. – With the annexes, the Panel Report comfortably exceeds 500 pages. On the TBT Agreement, cf. *ibid.* pp. 99-147, 203-212, 222-224, 228-231, 401-413. On the Panel Report, cf. Wiers, Jochem, *Responsible Decision-makers, Do It Yourself: The Panel Report in the Asbestos Case: Legal Issues of Economic Integration* 28 (2001), 117-126.

141 WT/DS135/AB/R – On the TBT Agreement, cf. *ibid.*, para. 59-83.

142 Cf. esp. <http://www.etuc.org/tutb/uk/asbestos.html>. This web page, published by the European Trade Union Technical Bureau for Health and Safety, provides, in addition to the principal relevant documents, a comprehensive view of the background to the asbestos ban and world-wide measures for this purpose, together with responses to the reports of the Panel and the Appellate Body. A legal discussion of the Appellate Body's report has been held at <http://www.jeanmonnetprogram.org/wwwboard/index5.html> – On the dispute concerning the asbestos ban, see also Vogel, Laurent, *The WTO asbestos dispute: workplace health dictated by trade rules?* (available at <http://www.etuc.org/tutb/uk/asbestos>); Vogel, Laurent, *WTO asbestos ban hearing: update*, TUTB Newsletter No. 14, June 2000, 4 f.; Sapir, Marc, *Asbestos @ wto*, TUTB-Newsletter No. 13, March 2000, 1 f.; Zia-Zarifi, Sam, *The vital issues in the WTO asbestos dispute*, TUTB-Newsletter No. 13, March 2000, 3-5. See also Jügensen, Carsten, *Das gemeinschaftliche Asbestverbot auf dem Prüfstand des Welthandelsrechts*, Typoskript, Bremen 2001.

143 Commission Directive 1999/77/EC of 26 July 1999 adapting to technical progress for the sixth time Annex I to Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (asbestos), OJ 6.8.1999 L 207, 18-20. – cf. Grodzki, Karola, *Asbestos – refocusing protective measures on those who are now most at risk*, TUTB Newsletter No. 14, June 2000, 7 f.; Grodzki, Karola, *Asbestos ban: towards a European Consensus (IV): Final page tuned in an epic tale?*, TUTB Newsletter Nos. 11-12, June 1999, 4 f.

144 WT/DS135/AB/R, para. 167.

145 WT/DS/135/AB/R, para. 168: “As to Canada's third argument, relating to the level of protection, we note that it is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation.”

Controlled use of asbestos is a less severe measure which is not likely to be effective. Both the Panel Report and the Appellate Body however granted Canada the right under Article XXIII.1 (b) GATT to enter into negotiations with the EU owing to the possible economic loss resulting from the measures compliant with GATT.

Canada had justified its objection *inter alia* with the argument that asbestos and asbestos substitutes were “like” products in the context of Article III.4 GATT. This provision prohibits discrimination against foreign products in favour of like products from the national territory in respect of their sale, marketing or distribution. Although asbestos, unlike the majority of asbestos substitutes, is known to be carcinogenic, the Panel recognized it as a like product in the context of Article III.4 GATT, substantiating its position with the usual criteria, namely the physical and quality characteristics of a product, the end use, consumer behaviour, and the customs classification. The panel rejected health risks as a crucial criterion on the grounds that the exception provided for in Article XX (b) GATT would otherwise be superfluous. In addition to the fact that asbestos differs in its physical characteristics from many substitutes, it must be asserted here first and foremost that GATT’s primary function is to prevent protectionist measures, but not to assure general access to markets. All regulations which potentially impact upon market activity would otherwise have to be reviewed for their compliance with GATT. Conversely, the Appellate Body considers it necessary to take into account the health risks presented by asbestos fibres during assessment of whether products are “like products” in the context of Article III.4 GATT. Products presenting a health hazard may not be compared with substitutes presenting a lower hazard, even were their functionality to be the same. The Appellate Body reached this conclusion despite the fact that the criterion determining whether products are like products is to be interpreted broadly, in order to rule out protectionist measures. In the view of the Appellate Body, the undisputedly proven carcinogenic action of asbestos products also influences consumer behaviour. For this reason, and also owing to the complex and costly protective measures entailed by the use of asbestos, asbestos products and asbestos substitute products are not economically interchangeable. Unlike the Panel Report, the Appellate Body placed the burden of proof upon Canada for the assertion that asbestos products and certain asbestos substitute products are like products.

As the products are like products, it was no longer necessary to consider whether the measures taken are also applied in the same way to imported or national products. This may be a decisive criterion for conceivable future cases of measures against like products.

In contrast to the Panel Report, the Appellate Body classified the ban on asbestos and asbestos-containing products as a technical regulation in the context of Annex 1 (1) of the TBT Agreement owing to the rigid reference drawn between the content of the prohibitory regulation and the derogations. The French decision subject to review could not be divided into two independent components, i.e. a ban not constituting a technical regulation in the context of the TBT Agreement and a derogation, which Canada had not submitted for review. It did not represent a blanket ban, but rather permitted a limited use of asbestos under certain conditions by way of detailed derogations. A ban without derogation, in fact, could also have been classified as a technical regulation, as it regulates the product characteristic of having to be asbestos-free.

As no investigations had been conducted into this aspect in the Panel Procedure, the Appellate Body declined for procedural reasons to comment upon whether the asbestos ban which was classified as a technical regulation in the context of the TBT Agreement in derogation of the Panel Report met the latter’s requirements. The USA took a clear and convincing position:¹⁴⁶ in its view, the asbestos ban was compatible with the requirement for equal treatment with

146 WT/DS135/AB/R, para. 47.

national products inherent to Article 2.1 of the TBT Agreement for the same reasons as it was with Article III.4 GATT: Canada should be required, in contrast to the case of Article XX GATT, to demonstrate that the asbestos ban represented an unnecessary obstacle to trade in the context of Article 2.2 of the TBT Agreement. France had not needed, first and foremost, to refer to and apply the international standards stated by Canada in accordance with Article 2.4 of the TBT Agreement, as such standards were neither relevant, nor suitable for promoting the protection of health to a degree deemed necessary by France. The ban was ultimately compatible with the priority of *performance standards* over *design standards* required by Article 2.8 of the TBT Agreement, as no measure other than a ban was reasonable.

Whether the WTO dispute settlement bodies will follow this argumentation in future disputes, should such disputes arise, remains to be seen. Even if the trade interests of Canada are taken into consideration, it is alarming that a WTO member and an important and economically highly developed industrial nation does not hesitate, despite the overwhelming scientific evidence of the exceedingly high health risks presented by asbestos and despite the substitute substances and products which have been available for some time for the majority of areas of application, to attack an evidently well-founded asbestos ban on the grounds of alleged incompatibility with WTO legislation.

e) International incorporation of European standards governing occupational health and safety

aa) Normative constraints

The development of new standardization projects has largely been transferred from national to European and international level.¹⁴⁷ Article 2.4 of the TBT Agreement stipulates that where technical regulations are required and relevant international standards exist or their completion is imminent, WTO members must use them or relevant parts of them as a basis for their technical regulations, except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued. For the standards organizations, Item F of the Code of Good Practice for the Preparation, Adoption and Application of Standards contains a similar obligation, namely that international standards or relevant parts of them should be used as a basis for the standards organizations' own standards, except where such international standards or relevant parts would be ineffective or inappropriate, for instance because of an insufficient level of protection or fundamental climatic or geographical factors or fundamental technological problems.

Even where international product standards exist, the TBT Agreement initiates no mechanism for the adoption of such standards in corresponding technical regulations and regional or national standards. Rather, Articles 2.2 and 2.4 of the TBT Agreement and Item F of the Code of Good Practice for the Preparation, Adoption and Application of Standards contain the following reservations and alleviatory measures:

¹⁴⁷ In greater detail, Falke, Josef, *Rechtliche Aspekte der technischen Normung in den EG-Mitgliedstaaten und der EFTA*, Vol. 3: Deutschland, Luxemburg 2000, 227-235; Schepel, Harm, Falke, Josef, *Legal Aspects of Standardisation in the Member States of the EC and the EFTA*, Vol. 1: Comparative Report, Luxembourg 2000, 43-53; Falke, Josef, *Techniksteuerung durch Normung im europäischen Rechtsvergleich*, in: Klaus Vieweg (ed.), *Techniksteuerung und Recht. Referate und Diskussionen eines Symposiums an der Universität Erlangen-Nürnberg*, Köln i.a. 2000, 177-223 (201-209).

- Relevant international standards are only to serve as the *basis* for technical regulations or regional or national standards; they therefore represent a basis for further deliberations, the content of which must nonetheless be given thorough consideration.
- They must be *effective and appropriate means for fulfilment of the legitimate objectives pursued*. These objectives and the level of protection deemed appropriate for their attainment may be drawn up independently by the bodies or organizations responsible for drafting technical regulations or standards, on condition that they are not employed arbitrarily or in a discriminatory fashion.
- The examples listed of technical regulations or standards being *an inappropriate or ineffective means for fulfilment of the legitimate objectives pursued* (fundamental climatic or geographical factors, fundamental technological problems in Article 2.4 of the TBT Agreement; insufficient level of protection, fundamental climatic or geographical factors, fundamental technological problems under Item F of the Code of Good Practice) are not exhaustive.
- The list (likewise not exhaustive) of *legitimate objectives* which may be pursued in the drafting of technical regulations (Article 2.2, Sentence 3 of the TBT Agreement) is indicative of the wide scope of political responsibility which is not affected by the TBT Agreement. The following objectives are expressly stated: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. Where the pursuit of one of these objectives is also among a standards organization's tasks, it may claim to be pursuing a legitimate objective by demonstration of the unsatisfactory level of protection offered by an international standard in a comparable manner to the bodies drafting technical regulations.
- The legitimate objective of protection of human health and safety with regard to technical regulations and the satisfactory safety level in the case of standards may be brought to bear in the interests of a high standard of occupational health and safety.

The Vienna Agreement on technical co-operation between CEN and ISO¹⁴⁸ and the Dresden Agreement between IEC and CENELEC on common planning of new work and parallel voting¹⁴⁹ have created a basis for close co-ordination between European and international standardization, and have enabled the European standards organizations to fulfil their obligations arising from Item F of the Code of Good Practice. The concentration of activities in the electrical engineering sector is more pronounced. CEN has undertaken to take the necessary steps together with ISO where possible at the launch of new standardization projects and the revision of existing standards. Standardization projects can be conducted in parallel during all phases, under the aegis of either ISO or CEN. Co-operation expressly includes the drafting of standards in response to European Commission mandates, and makes provision for review of the concluding draft by the responsible Consultant prior to final voting in this case.¹⁵⁰ CENELEC examines all new standardization projects as a matter of priority for whether they can be performed under the aegis of the IEC.¹⁵¹ Voting on international

148 Agreement on technical co-operation between CEN and ISO of 1991 (Vienna Agreement). For further details, see Guidelines for T/SC Chairmen and Secretariats for implementation of the Agreement on technical co-operation between ISO and CEN, 2nd revision, September 1998. Cf. also Smith, M.A., Vienna Agreements on Technical Cooperation between ISO and CEN, ISO/IEC Directives seminar, June 1995.

149 IEC-CENELEC Agreement on common planning of new work and parallel voting of 1996 (Dresden Agreement).

150 Section 4.3.3 of the Guidelines for implementation of the Vienna Agreement.

151 Section 2.1 of the Dresden Agreement.

standards is always conducted in parallel under the auspices of CENELEC¹⁵²; international standardization projects are therefore automatically also European standardization projects.

bb) Example empirical findings

Selected information on involvement of the CEN member organizations on the ISO Technical Committees in selected areas, on the working documents upon which the current standardization activities of selected CEN committees are based, and on the close working relationship between CEN and ISO Technical Committees responsible for fundamental issues of machine safety, is provided here with reference to the current state of integration of European standardization into international standardization.

Table 9 shows which CEN member organizations are currently participating actively and which with observer status in the ISO Technical Committees in the area of occupational health and safety and selected products which are regulated in the EU in accordance with the New Approach to technical harmonization and standardization. *Table 10* provides a corresponding overview for the field of machine safety.

152 Section 3.1.1 of the Dresden Agreement.

Table 9: Participation by CEN member organizations on ISO Technical Committees in the area of occupational health and safety and selected products which are regulated in the EU in accordance with the New Approach to technical harmonization and standardization (as of April 2001)

Standards organization	Country	ISO Technical Committees						
		159	94	108	11	59	178	
Responsible for secretariat		DIN	SAI	ANSI	ANSI	NSF	AFNOR	DS
Number of participating standards organizations – P		24	28	22	26	30	23	29
Number of standards organizations with observer status – O		25	32	24	32	38	29	28
AENOR	Spain	P	P	O	P	P	P	P
AFNOR	France	P	P	P	P	P	P	P
BSI	United Kingdom	P	P	P	P	P	P	P
DIN	Germany	P	P	P	P	P	P	P
DS	Denmark	P	P	P	P	O	O	P
ELOT	Greece	O	O		O	O		O
IBN	Belgium	P	P	O	P	P	P	O
IPQ	Portugal		O	O	O	O	O	O
NEN	Netherlands	P	P	O	O	O	P	P
NSAI	Ireland	O	O	O	O	O	O	P
ON	Austria	P	P	P	P	P	P	O
SFS	Finland	P	P	O	O	P	P	O
SIS	Sweden	P	P	P	P	P	P	P
UNI	Italy	P	P	P	P	P	P	P
NSF	Norway	P	O	P	O	P	P	P
SNV	Switzerland	O	P	P	P	O	P	O
STRI	Iceland					O	O	
CSNI	Czech Republic	P	P	P	O	O	P	P
Number of actively participating CEN members in relation to total number of active participants		10:30	13:23	11:29	13:24	13:28	10:22	10:26

ISO Technical Committees:

- TC 159 Ergonomics,
- TC 94 Personal safety– protective clothing and equipment,
- TC 108 Mechanical vibration and shock,
- TC 11 Boilers and pressure vessels,
- TC 59 Building construction,
- TC 178 Lifts, escalators, passenger conveyors,
- TC 181 Safety of toys

Table 10: Participation by CEN member organizations on ISO Technical Committees in the area of machine safety (as of April 2001)

Standards organization		Country				ISO Technical		
Committees		199	39	72	118	127	195	214
Responsible for secretariat			DIN	UNI	SNV	SIS	ANSI	PKN
		ANSI						
Number of standards organizations actively involved – P		21	20	13	13	18	10	14
Number of standards organizations with observer status – O		20	22	8	23	20	22	17
AENOR	Spain	O	P	P	O	P	O	O
AFNOR	France	P	P	P	P	P	P	P
BSI	United Kingdom	P	O	P	P	P	P	P
DIN	Germany	P	P	P	P	P	P	P
DS	Denmark	P	O		P	O		O
ELOT	Greece		O		O	O		
IBN	Belgium	O	O		P	P	O	O
IPQ	Portugal		P					
NEN	Netherlands	P	O		P	P	O	P
NSAI	Ireland				O	O		O
ON	Austria	P	O		O	O	O	O
SFS	Finland	P	O	O	O	O	O	P
SIS	Sweden	P	P		P	P	O	P
UNI	Italy	P	P	P	P	P	P	P
NSF	Norway	P	O				O	O
SNV	Switzerland	P	P	P	P			
STRI	Iceland	O						
CSNI	Czech Republic	P	P	O	O	O	O	O
Number of actively participating CEN members in relation to total number of participating members		12:21	8:20	6:13	9:13	8:18	4:10	7:14
ISO Technical Committees:		TC 199 Safety of machinery, TC 39 Machine tools, TC 72 Safety requirements for textile machinery, TC 118 Compressors, pneumatic tools and pneumatic machines, TC 127 Earth-moving machinery, TC 195 Building construction machinery and equipment, TC 214 Elevating work platforms						

The member organizations of the CEN are consistently well represented among the active members in the technical committees of the ISO in the areas of occupational health and safety, machine safety, and certain areas covered by the New Approach. This facilitates optimum co-ordination between the European and international standardization projects and represents a sound basis for the inclusion of a European standpoint in international standardization activity.

Table 11 attempts to provide an impression of the documentation upon which the standardization activity of CEN is based in the area of machine safety, occupational health and safety, environmental protection, construction products and construction works, transport, medicine and analysis procedures. Distinction is drawn between the following categories: proposals for a European Standard or Pre-standard (prEN, prEPS); revision of a European Standard (EN); activities of a CEN standards committee for which a document forming the basis of the activity cannot yet be named (CEN-TC); proposal for a European Standard based upon an ISO standard (prEN ISO); standardization projects based upon various types of ISO documents (ISO doc); revision of an ISO standard (ISO); and finally, revision of a European Standard based upon an ISO standard (EN ISO). Only projects which have progressed sufficiently for a specific working document to be named have been included. Unfortunately, the agendas of the committees do not indicate in which projects provision is made for parallel voting in the context of the Vienna Agreement. The high total proportion accounted for by standardization projects based only upon a European draft standard is striking.

This paper will not draw a detailed comparison between the individual sectors, which would be possible from the table; certain distinct tendencies will however be noted. In the area of ocean shipping and marine technology and for the test procedures for milk and dairy products, international documents are employed exclusively with the exception of one revision of a European Standard. International documents also predominate in the area of telematics for road traffic and transport, odontology, sterilization, optometry, and water analysis. In the economically significant area of standardization of construction products, the proportion of standardization projects with an international character is marginal; the same applies to certain areas of environmental protection. With the exception of acoustics, the proportion of European working documents is very high in the area of machine safety and occupational health and safety, indicating that the European body of standards in occupational health and safety is generally poorly mirrored at international level.

The close co-ordination between the two committees responsible for general aspects of machine safety, ISO/TC 199 and CEN TC 114, can be seen clearly from *Table 12*. In response to the scarcity of personnel resources, and to the availability of a European concept, ISO has adopted completely the relevant European body of standards governing the principles of machine safety. New standardization projects and the revision of existing European standards are undertaken within the forms of co-operation provided for within the Vienna Agreement.

Table 11: Standardization activity of CEN in the area of machine safety, occupational health and safety, environmental protection, construction products and construction works, transport, medicine and analysis procedures –number of European and international documents upon which activities are based (as of 30 April 2001)

Area of standardization	CEN-TC prEN, EN	Documents upon which the standardization activity is based						
		[CEN-prEN prEPS	ISO TC]*	ISO EN	ISO Doc.**	ISO EN	ISO Doc.**	ISO EN
Machine safety:								
Safety of machinery, general	114	7	0	1	4	1	2	0
Safety of specific machines	142, 143, 145, 151, 153, 196, 198, 200, 201, 214	168	2	2	13	2	0	0
Tractors, agricultural machinery	144	20	1	0	1	1	1	1
Occupational health and safety:								
Personal protective equipment	79, 85, 158-162	98	21	2	37	5	1	1
Ergonomics	122	10	0	2	13	15	2	0
Assessment of impact at the workplace	137	5	0	0	0	0	0	0
Mechanical vibration and shock	231	3	2	1	4	0	0	0
Acoustics	211	0	1	0	17	10	2	1
Environmental protection:								
Water supply, waste water engineering, water analysis	164, 165, 230	94	8	1	15	10	2	0
Flue systems, air quality	166, 264	26	0	2	2	0	0	0
Characteristics of solid waste and sludges	292, 308	15	0	3	0	0	0	0
Construction products and construction works:								
Concrete and concrete products	104, 177, 229	89	0	11	0	0	0	0
Construction products, various	33, 71, 88, 99, 128, 129, 134, 163, 189, 241, 246, 303	245	8	42	8	5	8	0
Timber construction, masonry	124, 125	50	0	4	0	0	0	0
Acoustics, ventilation and heating of buildings	126, 156, 228, 295	37	0	6	8	5	0	1
Construction measures for fireproofing	127	31	0	0	4	0	0	0
Temporary building structures	53	15	0	0	0	0	0	0

Area of standardization	CEN-TC prEN, EN	Documents upon which the standardization activity is based						
		[CEN-prEN prEPS	ISO TC]*	ISO EN	ISO Doc.**	ISO EN	ISO Doc.**	ISO EN
Eurocodes for the design of buildings and civil engineering structures	250	59	0	0	1	1	0	0
Transport:								
Vessels for inland navigation	15	7	0	7	1	0	0	0
Railway engineering	256	87	0	5	6	0	0	0
Air traffic – ground equipment	274	22	0	1	0	0	0	0
Ocean-going vessels and marine engineering	300	0	0	0	14	5	4	0
Containers	119, 280	8	0	0	1	0	0	0
Telematics for road traffic and transport	278	11	0	2	21	9	2	0
Medicine:								
Odontology	55	6	0	0	17	18	1	0
Sterilization (in the broadest sense)	102, 204, 216, 258	18	2	0	8	17	0	0
In-vitro diagnostics	140	8	1	0	5	1	0	0
Non-active medical devices, implants	205, 285	19	2	0	8	1	1	2
Biocompatibility of medical products	206	0	0	0	7	1	0	0
Medical information technology	251	27	0	17	0	0	0	0
Optometry	170	3	0	0	19	11	4	1
Analysis procedures:								
Water analysis	230	9	0	0	15	10	2	0
Foodstuffs analysis, horizontal procedures	275	25	0	5	4	6	0	2
Analysis procedures for milk and dairy products	302	0	0	0	16	2	1	0

Only standardization activities which have progressed sufficiently for a specific working document to be named are included in the survey.

* As an exception, projects have also been included for which a specific working group within a Technical Committee has begun work without a specific document existing upon which the work is based.

** ISO drafts in various categories.

Compiled from the information available at http://www.cenorm.be/standardization/tech_bodies/cen_bp/workpro/.

Table 12: Agenda of ISO/TC 199 – Safety of machinery (as of 24 November 2000) and its correspondence to CEN/TC 114

No.	ISO projects	Draft available	Specific subject of regulation in the area of machine safety	Equivalent in CEN
1	ISO/TR 12100-1:1992		Basic concepts, general principles for design, Part 1: Basic terminology, methodology	EN 292-1:1991
2	ISO/TR 12100-2:1992		Basic concepts, general principles for design, Part 2: Technical principles and specifications	EN 292-2:1991
3	ISO 13849-1:1999		Safety-related parts of control systems, Part 1: General principles for design	EN 954-1:1996
4	ISO/TR 13849-100:2000		Safety-related parts of control systems, Part 100: Guide on the use and application of ISO 13849-1	CR 954-100:1999
5	ISO 13850:1996		Emergency stop – Principles for design	EN 418:1992
6	ISO 13852:1996		Safety distances to prevent danger zones being reached by the upper limbs	EN 294:1992
7	ISO 13853:1996		Safety distances to prevent danger zones being reached by the lower limbs	EN 811:1996
8	ISO 13854:1996		Minimum gaps to avoid crushing of parts of the human body	EN 349:1993
9	ISO 14118:2000		Prevention of unexpected start-up	EN 1037:1995
10	ISO 14119:1999		Interlocking devices associated with guards – Principles for design and selection	EN 1088:1995
11	ISO 14123-1:1998		Principles for risk assessment	EN 1050:1996
12	ISO 14123-1:1998		Reduction of risks to health from hazardous substances emitted by machinery, Part 1: Principles and specifications for machinery manufacturers	EN 626-1:1994
13	ISO 14123-2:1998		Reduction of risks to health from hazardous substances emitted by machinery, Part 2: Methodology leading the verification procedures	EN 626-2:1996
14	ISO/DIS 12100-1	2000-04	Basic concepts, general principles for design, Part 1: Basic terminology, methodology	ISO/IEC/CEN/CENELEC parallel processing – VA, CEN lead

No.	ISO projects	Draft available	Specific subject of regulation in the area of machine safety	Equivalent in CEN
15	ISO/DIS 12100-2	2000-04	Basic concepts, general principles for design, Part 2: Technical principles and specifications	ISO/IEC/CEN/CENELEC parallel processing –VA, CEN lead
16	AWI 13489-1	2002-10	Safety-related parts of control systems, Part 1: General principles for design (Revision of ISO 13849-1)	ISO/CEN parallel processing –VA, CEN lead
17	ISO/DIS 13851	1997-03	Two hand control devices – Functional aspects and design principles	EN 574:1996
18	ISO/DIS13855	1999-08	Positioning of protective equipment with respect to the approach speeds of parts of the human body	EN 999:1998
19	ISO/DIS 13856-1	1996-10	Pressure-sensitive protective devices, Part 1: General principles for design and testing of pressure-sensitive mats and pressure-sensitive floors	EN 1760-1:1997
20	ISO/DIS 14120	1999-08	Guards – General requirements for the design and construction of fixed and movable guards	EN 953:1997
21	ISO/FDIS 14122-1	1996-07	Permanent means of access to machines and industrial plants – Part 1: Choice of a fixed means of access between two levels	ISO/CEN parallel processing –VA, CEN lead
22	ISO/FDIS 14222-2	1996-07	Permanent means of access to machines and industrial plants – Part 2: Working platforms and walkways	ISO/CEN parallel processing –VA, CEN lead
23	ISO/FDIS 14222-3	1996-07	Permanent means of access to machines and industrial plants – Part 3: Stairways, stepladders and guardrails	ISO/CEN parallel processing –VA, CEN lead
24	ISO/FDIS 14222-4	1996-07	Permanent means of access to machines and industrial plants – Part 4: Fixed ladders	ISO/CEN parallel processing –VA, CEN lead
25	ISO/DIS 14159	1999-02	Hygiene requirements for the design of machinery standards	ISO/CEN parallel processing –VA, ISO lead
26	WD/TR 18569		Guideline to the understanding and use of safety of machinery standards	–

VA Vienna Agreement

f) Consequences for the perspective on standardization in the area of the health and safety of workers at work at international level

This integration of national and European standardization activity into the international context has not yet been reflected upon sufficiently thoroughly with regard to its consequences for the status of standardization regarding the health and safety of workers at work as governed by Article 137 of the EC Treaty. Neither in the German Consensus Statement concerning standardization within the scope of directives pursuant to Article 118a of the EC Treaty, nor in the corresponding Memorandum of the European Commission or in the joint CEN and CENELEC statement concerning standardization within the scope of Article 118a of the EC Treaty, is consideration given to international standardization. If the current status of standardization within the area of the health and safety of workers at work is to be maintained, this viewpoint must also be presented at international level. The basis for it must however extend substantially beyond the particular provisions concerning the relationship between product-related and production or usage-related occupational health and safety provided for in the EC Treaty. For this purpose it may be advantageous to apply the OECD concept concerning the PPMs¹⁵³, which draws its examples primarily from environmental protection, to occupational health and safety, in order thereby to obtain clear criteria representing the basis for a consensus for processes and other production methods which determine product characteristics, and therefore which potentially require standardization, for which standards are not to be drafted.

In Europe, the perspective on the role of standardization in the area of the health and safety of workers at work has as its key objective that of maintaining the high standards which have been attained and are applied in the individual countries and by bodies representing employers and employees. This basic position and objective cannot be extrapolated without review to the international level. Many countries throughout the world rely heavily upon the transfer of expertise and technology within the area of occupational health and safety. If technical standards are to be ruled out as a conceivable form of transfer in order to avoid an undesired levelling of occupational health and safety, other possibilities for achieving the same end must be exploited. Technical Reports of the international standards organizations must be considered with high priority for this function. As mere recommendations, they leave scope for decisions concerning the desired level of occupational health and safety to be attained. They may be detailed in content and adapted relatively easily to new developments. They may be adapted much more freely than product-related standards to different constraints, and be compatible with alternative scenarios.

In implementation of common ISO/IEC provisions, KAN has presented the convincing proposal¹⁵⁴ not to include any requirements concerning use, maintenance and installation in the form of codes of practice for the safety of users or operators in the safety standards relevant to the marketability of a product. Where these requirements are not formulated as a requirement upon the instruction handbook or labelling and are directed at the manufacturer of the product, they should be dealt with in a separate section of the standard or in a dedicated standard. They would thus be available to countries which do not possess a well-developed body of regulations of their own for the safety of employees and users; in Europe, they need not be adopted. With the same general objective, the European Commission has proposed that

153 OECD, Processes and Production Methods (PPMs). Conceptual Framework and Considerations on Use of PPM-Based Trade Measures, OCDE/GD(97)137, Paris 1997, esp. 9-21.

154 Mattiuzzo, Corado, Ackers, Daniel, Lambert, Joachim, Weltweite Handelsfreiheit setzt technische Harmonisierung voraus, nicht aber Vereinheitlichung von Sozialstandards, DIN-Mitteilung 80 (2001), 204-207 (207).

standards be drafted in a modular fashion in order to simplify the transfer of international standards and to permit a maximum of coherence; product-related aspects should be dealt with separately from their associated processes, production methods and environmental requirements, according to the circumstances.¹⁵⁵

The concept of occupational health and safety being integral to the product becomes more attractive in the light of the crass variations globally in the health and safety standards of workers at work.¹⁵⁶ This concept has been implemented in a marked fashion in the Machinery Directive¹⁵⁷, according to which the design of the machine itself must ensure that provided the machine is used properly, operation, fitting and maintenance can be performed without danger to human life or health.¹⁵⁸ The manufacturer must apply the following principles in the order indicated when selecting the most suitable solutions:¹⁵⁹

- elimination or minimizing of hazards (integration of the safety concept into development and construction of the machine);
- application of the necessary protection measures against hazards which cannot be eliminated;
- informing of users of residual risks arising from failure of the protective measures taken to be fully effective; reference to any special training and personal protective equipment which may be necessary.

In addition, the machine must be designed such that improper use is prevented, where such use presents a risk.¹⁶⁰

Scope for more far-reaching requirements upon the health and safety of workers at work, which must not be obstructed by the instrument of standards, exists only beyond the occupational health and safety which is to be assured by the design of a product.

Standardization is the traditional means by which design offices and manufacturers are supported in the attainment of a high standard of occupational health and safety inherent to the product. This is also reflected clearly in the provisions of New Approach directives which expressly refer to the authority of the member states to place stricter requirements upon use. Article 2 (2) of the Machinery Directive states for example:¹⁶¹

155 Report from the Commission to the Council and Parliament on actions taken following the resolutions on European standardisation adopted by the Council and Parliament in 1999, COM (2001) 527 final, 26 September 2001, Ref. 49.

156 The concept of product-integrated environmental protection is much more recent, but is much better marketed. Cf. European Commission, Green Paper on Integrated Product Policy, COM (2001) 68 final, 8 February 2001. See in this regard Falke, Josef, *Das Grünbuch zur integrierten Produktpolitik – erste Etappe auf dem Weg zu einer Richtlinie über ökologische Produktverantwortung?*, Zeitschrift für Umweltrecht 2001, 314-321.

157 Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery, OJ L 207, 1-46.

158 Ibid., Annex I, Item 1.1.2 lit. a).

159 Ibid., Annex I, Item 1.1.2 lit. b).

160 Ibid., Annex I Item 1.12.2 lit. c) Sentence 2.

161 Cf. also Article 2 (2) of Council Directive 78/404/EEC of 25 June 1987 on the approximation of the laws of the Member States relating to simple pressure vessels, OJ 8.8.1987 L 220, 48-64; Article 1 (4) of Council Directive 89/16/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to construction products, OJ 10.2.1989 L 40, 12-26; Article 2 (2) of Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment, OJ 30.12.1989 L 399, 18-38; Article 2 (2) of Directive 94/9/EC of the European Parliament and the Council of 23 March 1994 on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres, OJ 19.4.94 L 100, 1-29; Article 2 (4) of European Parliament and Council Directive 95/16/EC of 29 June 1995 on the approximation of the laws of the Member States relating to lifts, OJ 7.9.1995 L 213, 1-32; Article 2 (2) of Directive

“The provisions of this Directive shall not affect Member States' entitlement to lay down, with due regard to the provisions of the Treaty, such requirements as they may deem necessary to ensure that persons and, in particular, workers are protected during use of the pressure equipment or assemblies in question provided that this does not mean modifications to such equipment or assemblies in a way not specified in this Directive.”

g) Engineered occupational health and safety within the scope of the ILO?

Countries which decline to recognize basic WTO labour standards nevertheless recognize the International Labour Organization (ILO) as the body responsible for defining and developing such standards.

Forty-four conventions and twenty-four recommendations of the ILO concerning safety and protection of health at the workplace were in place as of July 2001.¹⁶² They can be divided into the following five categories:

- Convention 155 and Recommendation 164 concerning occupational health and safety contain the essential fundamental principles, namely responsibility of the employer for safety and health protection at the workplace; information and involvement of the employees; the role of OH&S authorities in regulation, supervision and implementation; hierarchy of preventive measures (engineered measures, organizational precautionary measures, personal protective equipment); hierarchical relationship between prevention, rehabilitation and compensation; basic employee rights: right to participation, right to information, right to cessation of work in the event of imminent danger.
- A number of provisions contain protective measures concerning particular occupations (seamen, fishermen, dock workers, agricultural workers, miners, construction workers).
- Other conventions and recommendations are aimed at protection against particular risks such as ionizing radiation, asbestos, hazardous substances; at protection against atmospheric pollution, noise and vibration at the workplace; and at protection during the handling of heavy loads.
- Further regulations relate to particular protective measures such as medical examinations, company health services, and preventive measures against occupationally induced cancer.
- Finally, certain provisions are aimed at the protection of groups requiring particular protection, i.e. women, children, and migratory workers.

Only a small number of provisions therefore concern engineered OH&S measures in the strict sense of the term. Many of these provisions are also obsolete. The convention and recommendations concerning guarding of machinery, for example, date back to 1963, the provisions governing the handling of heavy loads to 1967. Furthermore, the majority of ILO conventions of relevance to occupational health and safety have been ratified only by a minority of ILO member states: the two conventions mentioned, for example, by only 49 and 25 countries respectively, and the convention concerning protection in relation to construction work in fact by only 14 countries.

With its “Safework: Global Programme on Safety and Health at Work and the Environment”¹⁶³ programme, the ILO pursues the following four main objectives:

- preventive policies and programmes are to be developed to protect workers in hazardous occupations and sectors;

97/23/EC of the European Parliament and of the Council of 29 May 1997 on the approximation of the laws of the Member States concerning pressure equipment, OJ 9.7.1997 L 181, 1-55.

¹⁶² Cf. specifically the overview at

<http://www.ilo.org/public/english/protection/safework/cis/oshworld/ilostd/inesx.htm>.

¹⁶³ More detailed information can be found at

<http://www.ilo.org/public/english/protection/safework/mandate.htm>.

- effective protection is to be extended to vulnerable groups of workers falling outside the scope of traditional protective measures;
- governments and employers' and workers' organizations are to be better equipped to address problems of workers' well-being, occupational health care and the quality of working life;
- the social and economic impact of improving workers' protection is to be documented and recognized by policy- and decision-makers.

The ILO is without equal in fulfilling important functions in the area of social occupational health and safety and in representing a joint forum for OH&S authorities, trades unions and employers' representatives, for both developing and industrial countries. Its work is geared especially to particularly vulnerable occupational groups, and to particularly serious impacts. Precisely because of the procedures governing the drafting of its regulations, however, it is too slow and cumbersome for the rapid adaptation necessary in the area of engineered occupational health and safety. In November 2000, however, the ILO presented for the first time a concept for systematic revision of its body of standards¹⁶⁴, and drafted examples, specifically for the area of engineered occupational health and safety.¹⁶⁵ Twenty-nine conventions and recommendations of relevance to occupational health and safety were certified as fulfilling present requirements; provision has been made for revision of five conventions and six recommendations.¹⁶⁶

Doubts are justified as to whether the ILO has access to suitable experts for detailed issues of engineered occupational health and safety. The relevant technical body of standards of the international standards organizations is considerably more detailed, much more up to date, and much more relevant with regard to the technical requirements upon products. The body of standards also meets the strictest requirements upon mutual coherence of the individual provisions, and is also subject to continual updating. No alternative to technical standards exists for occupational health and safety integral within products.

Engineered occupational health and safety within the framework of the ILO does not therefore represent a serious alternative to international standardization in the area of occupational health and safety. It would indeed be foolish to play down the significance of occupational health and safety in international standardization with the argument that the ILO is, after all, launching activities in the area of occupational health and safety. In view of the low rate of ratification of the relevant ILO conventions, the argument that the application of technical standards is voluntary can also be ignored.

The basic 1981 ILO convention 155 on workplace health and safety is comparable in its content and sociopolitical status with the EC OH&S framework directive¹⁶⁷. It contains minimum requirements and accords the signatory states considerable scope in the area of the health and safety of workers at work. In the light of national conditions and practice, and in consultation with employers' and workers' representatives, each member is to formulate, implement and periodically review a coherent national policy on occupational safety, occupational health and the working environment (Article 4 (1), Article 8). The aim of the policy is to prevent accidents and injury to health by eliminating, so far as is reasonably

164 Possible improvements in ILO standards-related activities, GB.279/4.

165 ILO standards-related activities in the area of occupational safety and health, GB.279/5/2. Cf. also Information note on the progress of work and decisions taken concerning the revision of standards, GB.279/LILS/WP/PRS/5.

166 Including the 1963 Agreement 119 and Recommendation 118 on machine safety.

167 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, OJ 30.12.1989 L 393, 1-7.

practicable, their causes throughout the working environment (Article 4 (2)). The following spheres of action are named (Article 5):

- design, testing, choice, substitution, installation, arrangement, use and maintenance of the material elements of work (workplaces, working environment, tools, machinery and equipment, chemical, physical and biological substances and agents, work processes);
- relationships between the material elements of work and the persons who carry out or supervise the work, and adaptation of machinery, equipment, working time, organisation of work and work processes to the physical and mental capacities of the workers;
- training, further training, qualifications and motivations of persons involved concerning measures for safety and health protection;
- communication and co-operation at working group, enterprise and all other appropriate levels up to and including the national level;
- the protection of workers and their representatives from disciplinary measures as a result of actions taken by them in conformity with the policy objectives for safety and the protection of health at the workplace.

Those who design, manufacture or import equipment or substances for occupational use are obliged (under Article 12):

- to satisfy themselves that the machinery, equipment or substance does not entail dangers to the safety and health of those using it correctly;
- to make available information concerning the correct installation and use of machinery and equipment and the correct use of substances, and information on hazards of machinery and equipment and dangerous properties of chemical substances and physical and biological agents or products, as well as instructions on how hazards are to be avoided;
- to undertake studies and research or otherwise keep abreast of the scientific and technical knowledge necessary to comply with the above requirements.

At company level, employers have particular obligations (Article 16). They must

- ensure that the workplaces, machinery, equipment and processes under their control are safe and without risk to health;
- ensure that the chemical, physical and biological substances and agents under their control are without risk to health when the appropriate measures of protection are taken;
- provide, where necessary, adequate protective clothing and protective equipment to prevent risk of accidents or of adverse effects on health.

The latest and most comprehensive measure taken by the ILO in the area of occupational health and safety is the formulation and formal adoption of the Guidelines on Occupational Safety and Health Management Systems in April 2001.

h) Summary

- In its definition of the terms “technical regulation” and “standard”, the TBT Agreement encompasses only processes and production methods which have a direct bearing upon the product characteristics, i.e. which are reflected in the product as it is distributed.
- A distinction between processes or production methods on the basis of whether they are demonstrably reflected in the product corresponds largely to the usual distinction within Community law between product-related occupational health and safety and production- or company-related occupational health and safety governed by directives pursuant to Article 95 of the EC Treaty, which may be regulated by directives pursuant to Article 137 of the EC Treaty, which provides member states with scope for the implementation of higher protective standards provided such standards do not impair the circulation of distributable products and plant. It gives rise to comparable problems.

- The WTO arbitration case concerning the French asbestos ban shows for the first time what scope the WTO rules leave the members for a policy of occupational health and safety geared to high standards of protection. The consequences for less scandalous cases have yet to be established.
- Even where international product standards exist, the TBT Agreement initiates no mechanism for adoption of such standards in corresponding technical regulations and regional or national standards. Rather, Articles 2.2 and 2.4 of the TBT Agreement and Item F of the Code of Good Practice for the Preparation, Adoption and Application of Standards contain numerous reservations and alleviatory measures. International standards, for example, serve only as a basis for national technical regulations; they must be effective and appropriate means for the fulfilment of the legitimate objectives pursued. The objectives which may legitimately be pursued in the drafting of national technical regulations include, under the heading of protection of the safety and health of human beings, occupational health and safety. The legitimate objectives listed are not exhaustive.
- The concept of integration of national and European standardization activity into the international context has not yet been given adequate consideration with regard to its consequences for the status of standardization regarding the health and safety of workers at work as governed by Article 137 of the EC Treaty.
- If the current status of standardization within the area of the health and safety of workers at work is to be maintained, this perspective must also be represented at international level. Legitimization must however extend substantially beyond the particular arrangements governing the relationship between product-related and production or application-related occupational health and safety in the EC Treaty.
- The perspective of the role of standardization in the area of the health and safety of workers at work has as its essential objective in the European context that of maintaining the high standards drawn up and applied in the individual countries and by the social partners. This basic position and objective cannot be transferred to the international context without undergoing review.
- Rather than pursuing at international level the concept of foregoing standardization of aspects of the health and safety of workers at work, forms of standardization activity must be provided which enable the developed industrial nations with established OH&S systems to retain their scope, whilst at the same time recognizing the interests of the developing countries in a transfer of expertise and technology in this area. Whether an ISO guideline for the treatment of OH&S aspects in product standardization is a suitable instrument for this purpose must be examined.
- For practical international standardization activity, an internal memorandum of understanding could be beneficial for a division between safety standards of relevance to products on the one hand and standardization documents governing requirements for the use, maintenance and installation in the form of codes of practice for the safety of users or operators on the other. Such a memorandum could further the reaching of a consensus at international level on the significance of the health and safety of workers at work in standardization, and the avoidance of discrepancies between the terms of reference of the respective working groups involved.
- In view of the crass variations globally in the level of the health and safety of workers at work, the concept of occupational health and safety integral to the product, which is embodied particularly succinctly in the Machinery Directive, becomes more attractive. Scope for further requirements upon the health and safety of workers at work, which may not be obstructed by standards, exists only beyond the occupational health and safety

which is to be assured by the design of a product. Standardization is the traditional means by which design offices and manufacturers are supported in the attainment of a high level of occupational health and safety inherent to the product.

- The ILO is without equal in fulfilling important functions in the area of social occupational health and safety, and represents a common forum for OH&S authorities, trades unions and employers' representatives, for both developing and industrial countries. Its work is geared to occupational groups especially in need of particular protection, and to particularly serious impacts. Precisely because of the procedures applicable to the drafting of its regulations, however, it is too slow and cumbersome for rapid adaptation in the area of engineered occupational health and safety.
- The relevant technical body of standards of the international standards organizations is considerably more detailed, much more up to date, and much more relevant with regard to the technical requirements upon products. The body of standards also meets the strictest requirements upon mutual coherence of the individual provisions, and is also subject to continual updating. No alternative exists for occupational health and safety integral within products.
- Engineered occupational health and safety within the framework of the ILO does not represent a serious alternative to international standardization in the area of occupational health and safety. It would indeed be foolish to play down the significance of occupational health and safety in international standardization with the argument that the ILO is, after all, launching activities in the area of occupational health and safety.

4. Applicability of the TBT Agreement to production methods

Question: *Can it be inferred from the provision that the TBT Agreement refers not only to products but also to production methods that the work process for manufacture of a product must also be taken into consideration? Do requirements upon the manufacturer's in-plant organization (e.g. management standards relating to quality, environmental protection and occupational health and safety) thus fall within the scope of the TBT Agreement?*

a) Production methods and the TBT Agreement

Whether management standards relating to quality, environmental protection and occupational health and safety fall within the scope of the TBT Agreement depends upon how strictly the relationship to the product in the definition of “technical standard” is interpreted. As far as can be ascertained from the documents available, Canada is the only country on the Committee on Technical Barriers to Trade to have attempted to have management standards governing quality assurance and in-plant environmental protection expressly included in the TBT Agreement.¹⁶⁸ The TBT Agreement applies to products, whether they be produced industrially, by artisans, or agriculturally. Processes and production methods are covered by the definition of “standard” and “technical regulation” only where they have a specific relationship to the product and are reflected lastingly in it. The management standards governing environmental protection and occupational health and safety have by their very nature no specific relationship to a product. Product quality is only one of many criteria to be considered in environmental management. The series of standards governing quality assurance provide a general organizational and management system which is generally suited to the control and assurance of quality. All management standards share the common feature that they provide information on management and certain plant processes, but owing, apart from other considerations, to the (desired) universality of their scope in manufacturing, service and administration environments, do not permit conclusions of relevance to products.¹⁶⁹ Management standards relating to quality, environmental protection and occupational health and safety do not therefore fall within the scope of the TBT Agreement. The ISO 9000 and ISO 14000 series of standards governing quality assurance and environmental management respectively have become established world-wide for sound economic reasons, irrespective of whether they are standards as defined by the TBT Agreement and are therefore to be based on national or regional standardization projects.¹⁷⁰ In view of the wide variation in the standard of occupational health and safety on a world scale and the considerable variations in production conditions, sound reasons can be found for rejecting the need for globally valid standards for OH&S management¹⁷¹, in particular since all previous attempts to anchor elementary OH&S standards within the world trade system by recourse to a core of fundamental ILO conventions have failed.

168 G/TBT/W/41.

169 In order to avoid misunderstandings, the symbol attesting to a successful outcome of environmental enterprise assessment may not be employed by organizations in product marketing.

170 ISO standards for management systems applied in over 430,000 organizations world-wide at the end of October 2001. Cf. <http://www.iso.ch/en/iso9000-14000/ims.html>.

171 Comprehensive information can be found in KAN Report 11, Standardization in the field of occupational health and safety management systems, 2nd edition, Sankt Augustin 1997; refer however also to Loch, Hans-Joachim, Arbeitsschutzmanagement – Notwendigkeit, Ziele, Elemente, DIN-Mitteilung 79 (2000), 397-402 and Vogel, Laurent, New turns in the debates on occupational health management systems, TUTB-Newsletter No. 11-12, June 1999, 41-43.

An international ISO workshop conducted in 1996 on the drafting of a standard for an OH&S management system concluded with the recommendation that the ISO should suspend its activities in this area, as owing to its tripartite structure, the ILO may be in a better position to draw up an international guidance document for the establishment and implementation of effective management systems in the area of the health and safety of workers at work. In 1998, the IOHA (International Occupational Hygiene Association) reviewed existing and proposed relevant standards, codes of practice and guidance documents concerning OH&S management systems at the request of ILO 24; the review produced very detailed recommendations for the drafting of guidelines for OH&S management systems by the ILO.¹⁷² Following two years of intensive consultation, a tripartite expert committee adopted the ILO Guidelines on Occupational Safety and Health Management Systems in April 2001; the ILO Government Body approved their publication in June 2001.¹⁷³ These guidelines are not legally binding and do not have the objective of revoking existing provisions. They provide, firstly, the necessary framework provisions for an OH&S management system at national level, i.e. a certain regulatory context.¹⁷⁴ Secondly, they provide an organizational and procedural model, oriented strongly towards the existing management systems for quality assurance and in-plant environmental protection, for the development of an OH&S policy geared towards continual improvement of the health and safety of workers at work¹⁷⁵ which, as a minimum requirement, observes the binding applicable rules¹⁷⁶ and makes provision for employee participation at all levels¹⁷⁷. The usual sequence of priorities for prevention and protective measures applies: avoidance of risks, control of risks at their origin by engineered or organizational protective measures, minimization of risks by the establishment of safe work processes with the inclusion of administrative monitoring, the use of personal protective equipment where residual risks remain despite collectively effective measures.¹⁷⁸ The guidelines make no reference to technical standards at any point. Audits need not be performed by outside persons, provided technical competence and impartiality are assured.¹⁷⁹ Following comprehensive substantiation, the previous chapter concluded that the TBT Agreement and its definition of the terms “technical regulation” and “standard” encompass only processes and production methods which have a direct bearing upon the product characteristics, i.e. which are reflected in the product as it is distributed. Requirements upon the manufacturer’s in-plant organization (e.g. management standards relating to quality, environmental protection and occupational health and safety) do not fall within the scope of the TBT Agreement.

172 IOHA, Occupational Health and Safety Management Systems. Review and Analysis of International, National, and Regional Systems and Proposals for a New International Document, Geneva 1998, available at <http://www.ilo.org/public/english/protection/safework/cis/management/ioha/index.htm>.

173 Guidelines on Occupational Safety and Health Management Systems (MEOSH/2001/2(Rev.)). Cf. also Report of the Meeting of Experts on Guidelines on Occupational Safety and Health Management Systems (Geneva, 19-27 April 2001), GB.281/4. Further information at <http://www.ilo.org/public/english/protection/safework/management/guide.htm>.

174 MEOSH/2001/2(Rev.), Chapter 2.

175 MEOSH/2001/2(Rev.), Chapter 3.

176 A minimum objective is “complying with relevant OSH national laws and regulations, voluntary programmes, collective agreements on OSH and other requirements to which the organization subscribes”, MEOSH/2001/2(Rev.), No. 3.1.2 lit. b); see also *ibid.*, No. 3.7.2 lit. a), No. 3.9.1 lit. b), No. 3.11.6 lit. e).

177 “Ensuring that workers and their representatives are consulted and encouraged to actively participate in all elements of the OSH management system“, MEOSH/2001/2(Rev.), No. 3.1.2 lit. c); see also *ibid.*, No. 3.2.

178 MEOSH/2001/2(Rev.), No. 3.10.1.

179 MEOSH/2001/2(Rev.), No. 3.13.5.

b) Summary

- Requirements upon the manufacturer's in-plant organization (e.g. management standards relating to quality, environmental protection and occupational health and safety) do not fall within the scope of the TBT Agreement.

5. Other international agreements affecting the relationship between EU legislation and international standards

Question: *Do international agreements other than the TBT Agreement exist which affect the relationship between EU legislation and international standards?*

The question as to which other international agreements reached by the Community affect the relationship between EU legislation and international standards cannot be answered exhaustively within the present report. The SPS Agreement, the Agreement on Public Procurement and, as a contrast to the reference to technical international standards, the specification of technical regulations for motor vehicles and motor vehicle components under the aegis of the UN/ECE, are dealt with in greater detail.

The reader's attention is first drawn to the complex of regulations governing the transport of hazardous goods. (A detailed description will not be provided here.)¹⁸⁰ International agreements, EC directives, national legislation and a wealth of technical standards are extremely closely interwoven in this area. All member states of the European Union with the exception of Ireland are party to the European Agreement concerning the international carriage of dangerous goods by road (ADR)¹⁸¹, the geographical scope of which extends beyond the Community's borders, and which stipulates uniform rules for the safe international transport of dangerous goods by road. The Directive on the transport of dangerous goods by road¹⁸² extends these rules to transport within national borders so as to harmonize the conditions for road transport of dangerous goods throughout the Community. All member states are parties to the Convention concerning International Carriage by Rail (COTIF)¹⁸³, the scope of which extends beyond the territory of the Community. Appendix B of this convention contains the Uniform Rules concerning the Contract for International Carriage of Goods by Rail (CIM).¹⁸⁴ Annex I contains the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). These regulations do not however apply to the transport of dangerous goods by rail within national borders. The objective of the Directive on the transport of dangerous goods by rail¹⁸⁵ is to harmonize the application of safety regulations throughout the Community. Both directives take precedence over other Community legislation governing environmental protection and the safety of employees. CEN has been mandated with certain standardization activity pursuant to both directives, as yet without result.

180 This represents only a subset of the transport sector. For the transport sector as a whole, the Transport Division of UN/ECE lists 55 international UN/ECE transport agreements and conventions alone. For details, see <http://www.unece.org/trans/conventn/legalinst.html>.

181 European Agreement concerning the International Carriage of Dangerous Goods by Road – ADR. The relevant legislation and further information can be found at http://www.unece.org/trans/danger/publi/adr/adr_e.html.

182 Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road, OJ 12.12.94 L 319, 7-13; last amended by European Parliament and Council Directive 2000/61/EC of 10 October 2000, OJ 1.11.2000 L 279, 40-43.

183 Convention concerning International Carriage by Rail (COTIF) of 9 May 1980, Federal Gazette 1985 II, p. 144.

184 Federal Gazette 1985 II, p. 224.

185 Council Directive 96/49/EC on the approximation of the laws of the Member States with regard to the transport of dangerous goods by rail, OJ 17.9.96 L 235, 25-30; last amended by European Parliament and Council Directive 2000/62/EC of 10 October 2000, OJ 1.11.2000 L 279, 44 f.

a) SPS Agreement

In addition to the TBT Agreement, the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement)¹⁸⁶ in particular governs the relationship between EU legislation and international standards. The following constitute international standards, guides or recommendations in this context:¹⁸⁷

- standards, guides or recommendations of the Codex Alimentarius¹⁸⁸ relating to food additives, residues of veterinary pharmaceuticals and pesticides, impurities, analysis and sampling methods, and codes of practice and practical guidelines;
- for animal health and zoonoses, the standards, guides or recommendations drawn up under the aegis of the World Organization for Animal Health¹⁸⁹;
- for plant health, the international standards, guides or recommendations drawn up under the aegis of the Secretariat of the International Plant Protection Convention in conjunction with the regional organizations operating within the framework of the International Plant Protection Convention.

This list is not exhaustive. For issues not addressed by the above organizations, suitable standards, guides or recommendations of other relevant international organizations may be considered whose membership is deemed by the committee responsible for administration of the SPS Agreement to be open to all WTO members.¹⁹⁰

In order to attain the greatest possible harmonization of sanitary and phytosanitary policy measures, Article 3 (1) of the SPS Agreement obliges WTO members to base their health and plant protection policy measures upon international standards, guides or recommendations, where such exist, except where the SPS Agreement contains provisions to the contrary. Sanitary or phytosanitary policy measures which comply with international standards, guides or recommendations are deemed by Article 3 (2) of the SPS Agreement to be necessary for the protection of human, animal or plant life or health, and presumed to be consistent with the relevant provisions of the SPS Agreement and of GATT 1994. They thus meet the requirements of the general derogation of Article XX (b) GATT, provided the remaining provisions of the latter are observed.

In accordance with Article 3 (4) of the WTO Agreement on Sanitary and Phytosanitary Measures, members are obliged to play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies, in particular the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organizations operating within the framework of the International Plant Protection Convention, to promote within the framework of these organizations the development and periodic review of standards, guidelines and recommendations relating to all aspects of sanitary and phytosanitary measures. The obligation to promote international standards is thus formulated much more explicitly than in the parallel provision of Article 2.6 of the TBT Agreement.

186 OJ 23.12.94 L 336, 40-49.

187 Cf. Item 3 lit. a), b) and c) of Annex to the SPS Agreement.

188 Regarding the Codex Alimentarius Commission, cf. FAO/WHO, *Understanding the Codex Alimentarius*, Geneva 1999; Merkle, Rüdiger, *Der Codex Alimentarius der FAO und der WHO. Die Entwicklung von Codex Standards und deren Auswirkungen auf das Europäische Gemeinschaftsrecht und die nationalen Lebensmittelrechte*, Bayreuth 1994; Sander, Gerald G., *Gesundheitsschutz in der WTO – eine neue Bedeutung des Codex Alimentarius im Lebensmittelrecht*, *Zeitschrift für europarechtliche Studien*, 2000, 335-375. – Refer also to the information in **Annex A, Item 1**.

189 Cf. in this context also **Annex A, Item 7**.

190 Cf. Item 3 lit. d) of Annex A of the SPS Agreement.

According to Article 3 (3) Item 1 of the TBT Agreement, Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations. In this case, either the members must submit scientific justification, or the higher level must be a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of Article 5. For the purpose of Article 3 Paragraph 3 of the SPS Agreement, scientific justification exists when a WTO member establishes, on the basis of a review and assessment of available scientific data in accordance with the relevant provisions of the SPS Agreement, that the relevant international standards, guidelines or recommendations are not sufficient for attainment of the level of protection which is considered appropriate. This autonomous risk assessment and definition of the reasonable level of protection accorded by sanitary or phytosanitary policy is linked to a number of conditions and references to international benchmarks. The measures taken must be based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the responsible international organizations (Article 5 Paragraph 1). In the assessment of risks, members must take into account available scientific evidence; relevant processes, production methods and inspection methods, and a number of other factors (Article 5 Paragraph 2). In assessing the risks and determining measures to be applied, a number of economic factors must be taken into account (Article 5 Paragraph 3). In determining measures to be applied, negative trade effects must be minimized (Article 5 Paragraph 4). Arbitrary or unjustifiable distinctions in the levels of protection must be avoided if they result in discrimination or a covert restriction of international trade (Article 5 Paragraph 1 Sentence 1). Protective measures may not be more trade-restrictive than required to achieve the level of protection considered appropriate (Article 5 Paragraph 6). Should the relevant scientific evidence be insufficient, members may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information. Those doing so must seek to obtain the additional information necessary for a more objective assessment of risk, and must review the measure within a reasonable period of time (Article 5 Paragraph 7).

The dispute between the EC on the one hand and the USA and Canada on the other over “hormone meat”, which continues despite the report by the WTO Appellate Body¹⁹¹, and the Commission communication on the applicability of the precautionary principle¹⁹², indicate the sensitive and very fundamental questions which arise during risk assessment and determination of the appropriate level of sanitary or phytosanitary protection.¹⁹³ As indicated, the members may introduce sanitary or phytosanitary measures which result in a higher level

191 Report of the Appellate Body of January 1998 (WT/DS 26/AB/R, WT/DS 48/AB/R). – Cf. e.g. Godt, Christine, Der Bericht des Appellate Body der WTO zum EG-Einfuhrverbot von Hormonfleisch. Risikoregulierung im Weltmarkt, *Europäisches Wirtschafts- und Steuerrecht* 9 (1998), 202-209; Eggers, Barbara, Die Entscheidung des WTO Appellate Body im Hormonfall. Doch ein Recht auf Vorsorge?, *EuZW* 9 (1998), 147-151; Wetzig, Wolfram, Bedeutung des SPS-Übereinkommens der WTO für das europäische Lebensmittelrecht und umgekehrte Diskriminierung am Beispiel des Hormonverbots, *ZLR* 2000, 11-29.

192 COM (2000) 1, final, 2 February 2000.

193 For general information on the influence of world trade law upon national foodstuffs law, cf. Eckert, Dieter, Die neue Welthandelsordnung und ihre Bedeutung für den internationalen Verkehr mit Lebensmitteln, *ZLR* 1995, 363-395; Ritter, Markus, Das WTO-Übereinkommen und seine Auswirkungen auf das deutsche und europäische Lebensmittelrecht. Hormonrückstände in Lebensmitteln als künftiger Standard?, *EuZW* 1997, 133-138; Rabe, Hans-Jürgen, Auswirkungen der Welthandelsordnung auf das deutsche und das europäische Lebensmittelrecht, *ZLR* 1998, 129-143; Correa, Carlos, Implementing National Public Health Policies in the Framework of WTO Agreements, *JWT* 34-5, 89-121; Wetzig, Wolfram, Einfluss der EG und der WTO auf das Lebensmittelrecht. Bindung an internationale und ausländische Standards, Frankfurt et al 2000.

of health or plant protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, provided such measures can be justified scientifically, or where the members consider such measures necessary in an uncertain risk situation following consideration of a number of aspects, and maintain such measures pending clarification of the uncertainty concerning appropriate protection of legal rights. The requirements relating to the justification of temporary stricter protective measures is subject to strict requirements. Conflicts between the requirements of world trade law and an appropriate level of protection of important legal rights will therefore become all the more probable and serious, the less the procedures of the relevant international bodies are able to guarantee that appropriate measures of protection are defined and reinforced in good time when new risks arise.¹⁹⁴

b) Government Procurement Agreement

Within the framework of the WTO, the EU is party to the Government Procurement Agreement, which is plurilateral, i.e. it is not binding upon all WTO members.¹⁹⁵ The exact scope, level of compliance, and economic importance of this agreement will not be considered here; only the relationship between EU legislation and international technical standards will be addressed. According to Article VI Paragraph 2 of the agreement, the technical specification prescribed by procurement entities must, where appropriate (sic!), be formulated in terms of performance rather than design¹⁹⁶ and descriptive characteristics, and be based upon international standards, where such exist; otherwise, upon national technical regulations, recognized national standards, or building codes.¹⁹⁷ Owing to the inclusion of the phrase “where appropriate”, the obligation for reference to be made by priority to international standards for the definition of technical specifications must be regarded as very weak. The condition “where such exist” is more than justified; international standards have as yet hardly been created for construction products and services, which represent the main areas affected by public procurement procedures. According to Article VI § 1 of this agreement, technical specifications laying down the characteristics of the products or services to be procured, such as quality, performance, safety and dimensions, symbols, terminology, packaging, marking and labelling, or the processes and methods for their production or for the provision of services, and requirements relating to conformity assessment procedures prescribed by procuring entities, may not be prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade.

c) Specification of technical regulations for motor vehicles and motor vehicle components within the framework of the UN/ECE

As a counterpoint to the reference to international technical standards, a brief diversion will be made here to the specification of technical requirements for motor vehicles. The numerous and exceptionally detailed Community directives containing these specifications are familiar. Since 1958, this very detailed body of regulations has been linked extremely closely with the

194 Regarding the constitutional requirements upon international standardization in foodstuffs legislation, see Hilf, Meinhard, Reuss, Matthias, *Verfassungsfragen lebensmittelrechtlicher Normierung in europäischem und internationalem Recht*, ZLR 1997, 289-302.

195 Published 15 April 1994, reproduced in: OJ 23.12.94 L 336, 273-289 (English text); OJ 3.9.96 C 256, 2 ff. (German text).

196 Cf. the corresponding passages in Article 2.8 of the TBT Agreement and Item I of the Code of Good Practice.

197 In contrast to the provisions of the TBT Agreement, services are expressly included here within the terms “technical regulation” and “standard”.

relevant technical provisions of the United Nations Economic Commission for Europe (UN/ECE). It was drawn up within the framework of the 1958 UN/ECE Agreement concerning the adoption of uniform technical prescriptions for motor vehicles and parts and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions.¹⁹⁸ The specific provisions, around a hundred in number, which cover all vehicle equipment and parts, were adopted on the basis of optional harmonization by a final total of 24 parties. This means that each signatory was able to issue derogating national regulations which were required however to permit the vehicles in compliance with the ECE provisions from another signatory country.

Since its revision in 1995, the agreement has been open to non-European states and regional organizations for economic integration to whom competencies in the areas covered by the scope of the agreement had been transferred by their respective member states, including the authorization to take decisions binding upon their members. In March 1998, the EU acceded to the modified agreement¹⁹⁹ in order to strengthen it as a world-wide instrument for the technical harmonization of motor vehicles and to assure coherence between the legislative activities in Geneva and those at Community level. At that point, the agreement had 30 signatories, namely the EC countries with the exception of Ireland; Switzerland, Hungary, the Czech Republic, the Federal Republic of Yugoslavia, Croatia, Norway, Romania, Poland, the Russian Federation, Slovakia, Belarus, Estonia, Turkey and Slovenia. Japan became a signatory in November 1998. South Africa and Australia gave consideration to accession. Certain other countries, notably the USA, did not fulfil their original intention of acceding to the agreement. The reasons for this can be traced primarily to differences in the certification systems (self-certification - type approval), the reciprocal recognition of licensing procedures provided for in the 1958 agreement, and the reservations of the USA, which indicated that it could accept a provision specified within the framework of the agreement only if it corresponded to a provision already issued in the USA or proposed and enacted in accordance with the US legislative procedure.

In order for all major automotive manufacturing or purchasing countries to be able to participate in the international harmonization process, a new agreement was negotiated by Working Party 29 of the UN/ECE, which is also responsible for the 1958 agreement. This agreement enabled parties to participate in international standardization activity without a commitment to reciprocal recognition of certification and licensing. It operates in parallel to the amended 1958 agreement, and international harmonization is extended beyond the latter's geographical boundaries, albeit with less far-reaching legislative consequences. It is generally referred to as the "parallel agreement".²⁰⁰

198 Cf. the agreement reached in the UN/ECE on 20 March 1958 concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles, Equipment and Parts which can be Fitted and/or be Used on Wheeled Vehicles and the Conditions for Reciprocal Recognition of Approvals Granted on the basis of these Prescriptions.

199 Council Decision of 27 November 1997 with a view to accession by the European Community to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ("Revised 1958 Agreement"), OJ 17.12.97 L 346, 78-94. Cf. also in this regard <http://europa.eu.int/comm/dg03/press/971128e.htm>.

200 Council Decision of 31 January 2000 concerning the conclusion of the Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles ("Parallel Agreement"), OJ 10.2.2000 L 35, 12-27.

The link between the regulatory activity within the framework of the UN/ECE and Community legislation is assured as follows²⁰¹: representatives of the Commission and the member states participate in the preparatory work of the UN/ECE committees of experts with the objective of drafting new ECE regulations or modifying existing regulations. Experts from the member states may comment at this stage upon technical issues and take part in discussion of technical issues without restriction, but only on the basis of their technical expertise, and without binding consequences for their respective national authorities or the Community. Following the preparatory phase, the Commission represents the Community in the Administrative Committee, which serves as the key decision-making body. The final position of the Community regarding adoption of a new ECE regulation is established by the European Parliament and the Council by way of the co-decision procedure on the basis of a proposal presented by the Commission in the case of a new ECE regulation, and by the Commission in the regulatory procedure with the involvement of the relevant committee consisting of representatives of the member states in the case of adaptation of an existing ECE regulation.

The agreement creates a mechanism in which the parties to the agreement who are present and participating in voting agree unanimously on the establishment of global technical regulations in a global register. The objective is the drafting of regulations in which a high level of safety, environmental protection, energy efficiency and protection against theft is attained worldwide.²⁰² Harmonization is attained either by

- the harmonization of existing national or regional technical regulations, which are first listed in the “compendium of candidate technical regulations”,
- harmonization on the basis of the regulations adopted within the framework of the 1958 agreement, or
- the drafting of completely new global technical regulations in areas in which technical regulations do not yet exist.

Inclusion of a global technical regulation in the global register commits the party acceding to the inclusion to undertake binding ratification at the earliest opportunity.²⁰³ The group of parties to the parallel agreement ensures that only one series of technical regulations, common to the main countries in which vehicles are manufactured and used, is established. Costly adaptations to vehicles in different markets thus become unnecessary.

Table 13 shows the relationship between the numerous EC directives governing type approval for motor vehicles and motor vehicle trailers on the one hand and the corresponding UN/ECE regulations on the other; *Table 14* fulfils the same function for two-wheeled and three-wheeled vehicles.

d) Summary

- In addition to the TBT Agreement, two further agreements exist for the Community which affect the relationship between EC legislation and international standards, namely the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Government Procurement Agreement.
- Only brief mention is made here of the complex relationship between international agreements, EC directives, national legislation and a wealth of technical standards in the area of dangerous goods transport.

201 Cf. *ibid.*, Annex III: Practical arrangements with regard to the involvement of the community and the member states in the revised agreement.

202 Cf. Items 1.1.6 and 4.1.2.1 of the Parallel Agreement.

203 Item 7.1 of the Parallel Agreement.

- The relationship between Community legislation governing motor vehicles and parts and the drafting of technical regulations under the aegis of the UN/ECE is particularly close. The “Parallel Agreement” recently created the basis for global technical co-operation under the aegis of the UN/ECE for a sector which has for many years been governed by a detailed body of technical regulations under national responsibility.

Table 13: Directives governing type approval for motor vehicles and motor vehicle trailers and their equivalents under the UN/ECE regulations (in chronological order, as of 25 April 2001)

No.	UN/ECE regulation	Scope of regulation	Council/European Parliament directives *	Commission directives
00	–	Type-approval of motor vehicles and their trailers	70/156/EWG 87/315/EWG, 78/547/EWG, 80/1267/EWG, 87/358/EWG, 87/403/EWG, 92/53/EWG, 96/27/EG, 96/79/EG, 97/27/EG, 98/91/EG, 2000/40/EG	93/81/EWG, 95/54/EG, 98/14/EG
01	51, 59	Permissible sound level and the exhaust system of motor vehicles	70/157/EWG 77/212/EWG, 84/424/EWG, 92/97/EWG	73/350/EWG, 81/334/EWG, 84/372/EWG, 89/491/EWG, 96/20/EG, 99/101/EG
02	83	Measures to be taken against air pollution by gases from positive-ignition engines of motor vehicles	70/220/EWG 74/290/EWG, 83/351/EWG, 88/76/EWG, 88/436/EWG, 89/458/EWG, 91/441/EWG, 93/59/EWG, 94/12/EG, 96/69/EG, 98/69/EG, 2001/1/EG	77/102/EWG, 78/665/EG, 89/491/EWG, 96/44/EG, 98/77/EG, 99/102/EG
03	58	[Liquid fuel tanks and] rear protective devices for motor vehicles and their trailers	70/221/EWG 2000/8/EG	81/333/EWG, 79/490/EWG, 97/19/EG
04	–	Space for mounting and the fixing of rear registration plates on motor vehicles and their trailers	70/222/EWG	
05	79	Steering equipment for motor vehicles and their trailers	70/311/EWG	92/62/EWG, 99/7/EG
06	11	Doors of motor vehicles and their trailers	70/387/EWG	98/90/EG
07	28	Audible warning devices for motor vehicles	70/388/EWG	
08	46	Rear-view mirrors of motor-vehicles	71/127/EWG	79/795/EWG, 85/205/EWG, 86/562/EWG, 88/321/EWG

No.	UN/ECE regulation	Scope of regulation	Council/European Parliament directives *	Commission directives
09	13, 90	Braking devices of certain categories of motor vehicles and of their trailers	71/320/EWG	74/132/EWG, 75/524/EWG, 79/489/EWG, 85/647/EWG, 88/194/EWG, 91/422/EWG, 98/12/EG
10	10	Radio interference produced by spark-ignition engines	72/245/EWG	89/491/EWG, 95/54/EG
11	24	Measures to be taken against the emission of pollutants from diesel engines for use in vehicles	72/306/EWG	89/491/EWG, 97/20/EG
12	21	Interior fitting of motor vehicles (interior parts of the passenger compartment other than the interior rear-view mirrors, layout of controls, the roof or sliding roof, the backrest and rear parts of the seats)	74/60/EWG 2000/4/EG	78/632/EWG
13	18	Devices to prevent the unauthorized use of motor vehicles	74/61/EWG	95/56/EG
14	12	Interior fittings of motor vehicles (the behaviour of the steering mechanism in the event of an impact)	74/297/EWG	91/662/EWG
15	17	Interior fittings of motor vehicles (strength of seats and their anchorages)	74/408/EWG 81/577/EWG	96/37/EG
16	26	External projections of motor vehicles	74/483/EWG	79/488/EWG
17	39	[Reverse and] speedometer equipment of motor vehicles	75/443/EWG	97/39/EG
18	–	Statutory plates and inscriptions for motor vehicles and their trailers, and their location and method of attachment	76/114/EWG	78/507/EWG
19	14	Anchorage for motor-vehicle safety belts	76/115/EWG 81/575/EWG	82/318/EWG, 90/629/EWG, 96/38/EG
20	48	Installation of lighting and light-signalling devices on motor vehicles and their trailers	76/756/EWG 83/276/EWG	80/233/EWG, 82/244/EWG, 84/8/EWG, 89/278/EWG, 91/633/EWG, 97/28/EG
21	3	Reflex reflectors for motor vehicles and their trailers	76/757/EWG	97/29/EG, 97/29/EG
22	7, 87, 91	End-outline marker lamps, front position (side) lamps, rear position (side) lamps and stop lamps for motor vehicles and their trailers	76/758/EWG	89/516/EWG, 97/30/EG

No.	UN/ECE regulation	Scope of regulation	Council/European Parliament directives *	Commission directives
23	6	Direction indicator lamps for motor vehicles and their trailers	76/759/EWG	89/277/EWG, 99/15/EG
24	4	Rear registration plate lamps for motor vehicles and their trailers	76/760/EWG	97/31/EG
25	1, 5, 8, 20, 31, 37, 98, 99	Motor-vehicle head lamps which function as main-beam and/or dipped-beam headlamps and to incandescent electric filament lamps for such head lamps	76/761/EWG	89/517/EWG, 99/17/EG
26	19	Front fog lamps for motor vehicles and filament lamps for such lamps	76/762/EWG	99/18/EG
27	–	Motor-vehicle towing-devices	77/389/EWG	96/64/EG
28	38	Rear fog lamps for motor vehicles and their trailers	77/538/EWG	89/518/EWG, 99/14/EG
29	23	Reversing lamps for motor vehicles and their trailers	77/539/EWG	97/32/EG
30	30	Parking lamps for motor vehicles	77/540/EWG	99/16/EG
31	16	Safety belts and restraint systems for motor vehicles	77/541/EWG	82/319/EWG, 90/628/EWG, 96/36/EG, 2000/3/EG
32	–	Field of vision of motor vehicle drivers	77/649/EWG	81/643/EWG, 88/366/EWG, 90/639/EWG
33	–	Interior fittings of motor vehicles (identification of controls, tell-tales and indicators)	78/316/EWG	93/91/EWG, 94/53/EG
34	–	Defrosting and demisting systems of glazed surfaces of motor vehicles	78/317/EWG	
35	–	Wiper and washer systems of motor vehicles	78/318/EWG	94/68/EG
36	–	Heating systems for the passenger compartment of motor vehicles	78/548/EWG	
37	–	Wheel guards of motor vehicles	78/549/EWG	94/78/EG
38	17	Head restraints of seats of motor vehicles	78/932/EWG	
39	–	Fuel consumption of motor vehicles	80/1268/EWG	89/491/EWG, 93/116/EG, 99/100/EG

No.	UN/ECE regulation	Scope of regulation	Council/European Parliament directives *	Commission directives
40	85	Engine power of motor vehicles	80/1269/EWG	89/491/EWG, 88/195/EWG, 97/21/EG, 99/99/EG
41	49	Measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles	88/77/EWG 99/96/EG	2001/27/EG
42	73	Lateral protection (side guards) of certain motor vehicles and their trailers	89/297/EWG	
43	–	Spray-suppression systems of certain categories of motor vehicles and their trailers	91/226/EWG	
44	–	Masses and dimensions of motor vehicles of category M 1	92/21/EWG	95/48/EG
45	43	Safety glazing and glazing materials on motor vehicles and their trailers	92/22/EWG	
46	30, 54, 64	Tyres for motor vehicles and their trailers and to their fittings	92/23/EWG	
47	–	Speed limitation devices or similar speed limitation on-board systems of certain categories of motor vehicles	92/24/EWG	
48	61	External projections forward of the cab's rear panel of motor vehicles of category N	92/114/EWG	
49	55	Mechanical coupling devices of motor vehicles and their trailers and their attachment to those vehicles	94/20/EG	
50	–	Burning behaviour of materials used in the interior construction of certain categories of motor vehicle	95/28/EG	
51	–	Protection of occupants of motor vehicles in the event of a side impact	96/27/EG	
52	–	Protection of occupants of motor vehicles in the event of a frontal impact	96/79/EG	99/98/EG

No.	UN/ECE regulation	Scope of regulation	Council/European Parliament directives *	Commission directives
53	–	Masses and dimensions of certain categories of motor vehicles and their trailers	97/27/EG	
54	–	Motor vehicles and their trailers intended for the transport of dangerous goods by road	98/91/EG	
55	93	Front underrun protection of motor vehicles	2000/40/EG	

* The directives are indicated in bold, the amendments in normal type.

Compiled from the Directory of Community Legislation in Force and the consolidated text of Commission Directive 98/14/EC of 6 February 1998 adapting to technical progress Council Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers.

Table 14: Directives governing type-approval for two-wheeled and three-wheeled motor vehicles and their equivalents under the UN/ECE regulations (in chronological order, as of 25 April 2001)

No.	UN/ECE regulation	Scope of regulation	Council/European Parliament directives *	Commission directives
00	–	Type-approval of two or three-wheel motor vehicles	92/61/EWG	2000/7/EG
01	78	Braking of two- or three-wheel motor vehicles	93/14/EWG	
02	60	Identification of controls, tell-tales and indicators for two- or three-wheel motor vehicles	93/29/EWG	2000/74/EG
03	28	Audible warning devices for two- or three wheel motor vehicles	93/30/EWG	
04	–	Stands for two-wheel motor vehicles	93/31/EWG	2000/72/EG
05	–	Passenger hand-holds on two-wheel motor vehicles	93/32/EWG	99/24/EG
06	62	Protective devices intended to prevent unauthorized use of two- and three-wheel motor vehicles	93/33/EWG	99/23/EG
07	–	Statutory markings for two- or three-wheel motor vehicles	93/34/EWG	99/25/EG
08	53	Installation of lighting and light signalling devices on two or three-wheel motor vehicles	93/92/EWG	2000/73/EG
09	–	Masses and dimensions of two or three-wheel motor vehicles	93/93/EWG	
10	–	Space for mounting the rear registration plate of two or three-wheel motor vehicles	93/94/EWG	99/26/EG
11	–	Maximum design speed, maximum torque, and maximum net power of two or three-wheel motor vehicles	95/1/EWG	
12	–	Certain components and characteristics of two or three-wheel motor vehicles	97/24/EG	
13	39	Speedometers for two or three-wheel motor vehicles	2000/7/EG	

* The directives are indicated in bold, the amendments in normal type.

6. Drafting of international basic safety requirements

Question: *To what extent has the concept of drafting international basic safety requirements according to the European “New Approach” model been taken up by European and international organizations (TABD, OECD, UN/ECE, etc.)?*

The concept of exploiting the EU model for technical harmonization and standardization as a basis for the development of international basic safety requirements has been suggested on several occasions, and with particular commitment by *Guido Gürtler*, who as a member of Siemens management holds a key position in the Transatlantic Business Dialogue (TABD) and the Industry Cooperation on Standards and Conformity Assessment (ICSCA).²⁰⁴ The criticism levelled at the beginning of deliberations at the plethora of agreements for recognition of testing and certification in selected product areas (*Mutual Recognition Agreements, MRA*) is convincing; conversely, the efficiency of international standardization and the influence of international standards upon national and regional bodies of standards are examined less closely.

a) OECD proposals

In March 2000, the OECD held a workshop under the heading “*Technical Barriers to Trade: International Standards and Conformity Assessment*” which, in the run-up to adoption of the second triennial Report on the implementation of the TBT Agreement, drew together over 130 experts, including representatives of public authorities, standards organizations, certification bodies, companies, and consumer bodies.²⁰⁵ International standards were recognized as a suitable basis for binding technical regulations only where the procedures employed for the creation of standards exhibit the following features: transparency, openness, responsibility, market relevance, and impartiality. An analysis of the possible regulatory effects of technical standards by the bodies responsible for national regulation could contribute to appropriate exploitation of the standards as a basis for binding technical regulations, and assist in the avoidance of unnecessary barriers to trade. The involvement of all interested parties (*stakeholders*) is important, in order to reinforce confidence in technical regulations based upon international standards. Different practical solutions may however be considered for such involvement, according to the features of the particular sectors concerned.

The New Approach to technical harmonization and standardization employed within the EU is geared towards drawing a distinction between fundamental decisions which fall within the

204 Most recently under the heading “Konzeptionelle Vorstellungen des TABD und der ICSCA” at the workshop organized by KAN on 10 November 2000 in Sankt Augustin under the heading “Internationale Harmonisierung. Auswirkung auf Sicherheit und Gesundheitsschutz”, previously at the “Technical Barriers to Trade: International Standards and Conformity Assessment” Special Meeting organized by the OECD in Paris on 16 and 17 March 2000, prior to that under the heading “The New Approach – Can it Work on the International Scene?” at the “Standardization for the 21st Century” conference organized by the European Commission, the EFTA Secretariat and DIN in Berlin on 15 to 17 March 1999. Cf. also Harless, Friedrich, *Praktische Umsetzung der Techniksteuerung aus der Sicht eines globalen Unternehmens – Fakten, Notwendigkeiten, Wünsche*, in: Klaus Vieweg, *Techniksteuerung und Recht. Referate und Diskussionen eines Symposiums an der Universität Erlangen-Nürnberg, Köln i.a. 2000*, 247-264.

205 A summary of the results of the discussion can be found in: OECD, Working Party of the Trade Committee, Special Meeting on Technical Barriers to Trade. Summary Report by the Secretariat, TD/TC/WP/RD(2000)1/FINAL, Paris 2000. This text can be found at <http://www.oecd.org/ech/16-17%20march%202000/16-1720March-eng.htm>, together with the conference documentation and papers by Anthony Kleitz, Evangelos Vardakas, June Ling, Guido Gürtler, and Christer Arvius.

realm of political responsibility, and detailed provisions consigned to technical self-regulation. This distinction is drawn within directives by the definition of essential requirements binding upon manufacturers, importers, standards organizations, certification bodies and market surveillance authorities which – supported by Commission standardization mandates – serve as a basis for the drafting of technical standards. No agreement could be reached upon whether such an approach might find world-wide acceptance. A consensus was found on the principle of exploiting technical standards as a basis for the formulation of binding technical regulations.

The recommendations that co-operation between standards organizations in partnership might contribute to the avoidance of disparate requirements, and that concentration on certain sectors would lead to more effective co-ordination between national, regional and international interests, do not extend beyond the TBT Agreement, and do not satisfactorily reflect the close co-ordination of standardization activity practised through the organization of technical committees by way of mirror committees and of the standardization programmes at international, regional and national level. Whilst it may be true that convergence of regulatory objectives, for example in the areas of health, safety and environmental protection, simplifies harmonization in technical regulation and assists in the avoidance of unnecessary barriers to trade, convergence is relevant in this context only when such a convergent development actually arises. This meeting of experts organized by the OECD was decidedly unanimous regarding the need to support developing countries effectively in their participation in standardization activity.

b) UN/ECE proposals

The UN/ECE recommendations on standardization policy contain a sub-section on the international harmonization of standards and technical regulations.²⁰⁶ Among the contents of the sub-section are the following proposals:

- Activity conducted on the harmonization of standards and technical regulations should be linked as closely as possible to international co-operation in the areas of business, science, technology and environmental protection.
- The harmonization of standards and technical regulations should preferably begin with the creation of a list formulating the requirement, the standards and technical regulations to be harmonized, and the existing and planned economic, scientific and technological agreements between the countries.
- Standards and technical regulations should be selected for the purpose of harmonization which
 - assure optimum technological and economic interchangeability and compatibility,
 - promote mutual understanding and influence other standards and technical regulations,
 - play a significant role in the mutual recognition of conformity assessment procedures,
 - influence the protection of the environment and human health, and occupational health and safety; improve fire protection,
 - contain requirements upon maintenance, packaging, marking, transport and storage,
 - promote sparing use of raw materials and energy,
 - create or threaten to create technical barriers to international trade.
- Other international standards and existing national and regional standards should be considered according to their suitability during the drafting of international standards.

²⁰⁶ ECE Recommendations on Standardization Policies, Chapter C, ECE/STAND/17/Rev.3. These were adopted in 1970 and revised in 1988 and 1995.

- During the drafting of national standards and technical regulations, international standards should first be employed as basis and then regional standards, wherever possible. National standards and the technical regulations of other countries should be given consideration wherever possible.
- The revision of regional and national standards should be timed where possible to coincide with the corresponding revision of international standards.
- Where national technical regulations or standards are undergoing preparation and relevant international standards exist or are to be adopted in the immediate future, the latter or relevant parts of them should be used as a basis for national technical regulations and standards, unless they are ineffective or unsuitable for attainment of the legitimate objectives, for example owing to basic climatic or geographical differences or basic technological problems.
- In the interests of promoting harmonization between national standards and technical regulations, representatives of the UN/ECE member states should participate as far as possible in the work of the responsible international standards organizations should they have adopted or be preparing technical regulations and standards at national level for the products concerned.

These recommendations correspond broadly in essential points to the relevant provisions of the TBT Agreement; they do not however match the latter in precision, partly owing to their failure to draw a clear distinction between binding technical regulations, and standards, which serve merely as recommendations only. The references to the establishment of need and to prioritization are based upon the criteria laid down by the UN/ECE during formulation of its standardization list²⁰⁷.

In September 1999, the *Working Party on Technical Harmonization and Standardization Policies* of the UN/ECE²⁰⁸ commissioned a team of specialists in the area of *Standardization And Regulatory Techniques* (“*START*” team) to formulate methods by which national technical regulations might be based on a larger scale upon international standards. The results of their work²⁰⁹, presented under the bold title “*International Model for Implementing Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations Via the Use of International Standards*”, are intended to contain principles for good regulatory practice; essentially, however, there merely repeat the applicable obligations of the TBT Agreement, whilst failing to meet the latter’s legislative precision. The model contains the following specific provisions:

- Where a number of countries aim to standardize technical regulations, their activities are concentrated on the defined *Common Regulatory Objectives (CROs)*, which relate to public health, safety, environmental protection, and other legitimate political objectives. Compliance with such objectives should be demonstrable by the observance of international standards. This should preferably be achieved by a declaration by the

207 Cf. ECE Standardization List, ECE/STAND/20/Rev.4.

208 Detailed information on UN/ECE standardization policy can be found at <http://www.unece.org/trade/stdpol>.

209 The draft of the report can be found in UN/ECE, TRADE/WP.6/2000.8, 14 August 2000, comments upon it in UN/ECE, TRADE/WP.6/2000/9, 27 October 2000. The report was presented to the UN/ECE Committee for Trade, Industry and Enterprise Development at its session on 13 to 15 July 2001. Cf. in this regard the press statement “Liberalizing Trade Through International Standardization” of 20 June 2001. – Cf. also Arvius, Christer, Project for a Global Model for Implementing Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations Via the Use of International Standards, OECD Special Meeting on Technical Barriers to Trade “International Standards and Conformity Assessment”, 16-17 March 2000, Paris; Project for “An International Model for Implementing Good Regulatory Practice for the Preparation, Adoption and Application of Technical Regulations via the Use of International Standards”. Communication from the United Nations Economic Commission for Europe, G/TBT/W/129/Rev.1, 11 May 2000.

manufacturer or importer, or in more sensitive situations, by a certificate issued by a recognized conformity assessment body. The applicable forms of conformity assessment are to be regulated in the CROs. The model therefore follows an international approach rather than a global one, with the facility for countries to vary their involvement according to their interest. The CROs correspond to the essential requirements of the New Approach to technical harmonization and standardization.

- Demonstration of compliance with the Common Regulatory Objectives provides market access in the countries involved without further controls. Should a country which has consented to the CROs impose further requirements, it must be prepared to face trade sanctions.
- General principles, rather than material criteria, are stated for identification of the need for harmonization. Such principles include the process of notification in accordance with the TBT Agreement. The UN/ECE may assume the role of moderator by way of a “*Call for Participation*”, in order to bring together the countries interested in harmonization activity for certain product groups.
- The CROs are to create a transparent work process, open to participation by other parties. The UN/ECE declares its willingness to register the CROs and their transposition in national technical regulations.
- By way of standardization mandates, modelled on the standardization mandates issued by the European Commission to the European standards organizations, the UN/ECE is to request that the relevant international standards organizations draft international standards to support the registered CROs (“*International Standardization Request*” – *ISR*). Should the countries involved deem the international standards thus created to be suitable for demonstration of fulfilment of the CROs, the standards are to be designated as “*Internationally Recognized Standards*” (*IRS*’s) and registered by the UN/ECE.
- The TBT Agreement imposes, albeit with far-reaching provisions for exemption, a general obligation upon member states to base technical regulations upon international standards. The procedures followed by the international standards organizations guarantee that international standards enjoy, by definition, wide international recognition, at least by the parties to standardization activity.
- A group of technical experts is to ensure that the Common Regulatory Objectives (CROs) and the International Standardization Requests (ISRs), which may be submitted to different international standards organizations, exhibit the necessary coherence. This requirement for assurance of the coherence is the result of differences on two counts: the group of countries agreeing on CROs varies from one product group to another; and the model does not assume global, universal responsibility of an international standards organization for a given sector, but rather an undefined number of international standards organizations.
- The conformity assessment bodies are to be accredited, and registered at the UN/ECE.
- Marketed products meeting the common requirements are to be marked as such. The requisite documentation includes the registration number of the relevant CROs deposited with the UN/ECE.
- The countries involved remain responsible for market surveillance upon their own territory. Where products harbour hazards, despite alleged fulfilment the CROs, they may trigger a safeguard clause for the protection of certain legal rights.

The proposal adopts almost all substantial elements of the New Approach. Important co-ordination tasks are assigned to the UN/ECE. Unfortunately, the relationship to the obligations applicable under the TBT Agreement remains unclear, despite a saving clause in the introduction²¹⁰. The specifically new slant of this approach is that it does not contain a

210 UN/ECE, TRADE/WP.6/1998/8, Item 5.

model purporting to be global, but is based upon initiatives by countries wishing to co-operate within certain product sectors. Whereas the TBT Agreement is based upon the assumption that suitable international standards may well be available to serve as a basis for national technical regulations, this approach assumes, as does the New Approach of the European Community, that agreement upon jointly formulated Common Regulatory Objectives (CROs) will result in a need for further international standards to be drafted.

c) TABD proposals

The Transatlantic Business Dialogue (TABD) has been bringing representatives of government and industry from the USA and the EU together since 1995.²¹¹ These representatives collaborate in “issue groups” and hold annual conferences, the objectives of which include the following:

- improvement of mutual understanding of market access mechanisms,
- identification of provisions which present barriers to free trade,
- recommendation of solutions for the harmonization of legislation,
- simplification of transatlantic and global trade.

In Working Group I, “*Standards and Regulatory Policy*” a large number of product-specific groups of experts are accompanied by four horizontal issue groups dealing with generic issues such as conformity assessment and product marking, co-operation in technical regulation, Mutual Recognition Agreements (MRAs), and measurement regulations. This activity has given rise to the proposal that certain basic elements of the New Approach to technical harmonization and standardization be transferred to the international arena. These include the principle of reference to international standards, agreement on selected product areas of particular significance to international trade, the establishment of co-ordinated, world-wide market surveillance, and the specification of essential requirements for protection. *Guido Gürtler* presented this concept in particular detail at the conference hosted in Berlin in March 1999 by the European Commission, the EFTA Secretariat and DIN, “*Standardization for the 21st Century*”.²¹² The broad approval of industry associations and standards bodies can generally be reduced to the principle “*Approved Once, Accepted Everywhere*”. This sub-element refers to the phase, crucial for access to global markets, in which a product’s fulfilment of the specified requirements is confirmed. In recent years, the TABD has made less effort to gain acceptance of its idea of transferring the New Approach to technical harmonization and standardization to the international level, and to the formulation and clarification of the conditions necessary for this transfer, and has instead attempted to influence the definition of technical requirements in various product sectors, such as those of aviation, motor cars, chemicals, cosmetics, medical devices, pharmaceuticals, and tyres.

The regulatory model preferred by the TABD is described in the 1999 annual report as follows:²¹³

“The EU, U.S., as well as other advanced countries, share the same goals with regard to the protection of health, safety and the environment. Although common in substance, regulatory objectives are rarely formulated in the same way. These differences in formulation of objectives create barriers to trade. The more detailed regulations are, the more difficult it is to overcome the trade

211 More detailed information at: <http://www.tabd.com/>. Cf. also Stern, Paula, *The Transatlantic Business Dialogue: A New Model for Trade Expansion and Regulatory Harmonization*, Washington 1999 (available at <http://www.tabd.org>); Stern, Paula, *The Transatlantic Business Dialogue: A New Paradigm for Standards and Regulatory Reform Sector-by-Sector*, Washington 1999 (available at <http://www.tabd.org>).

212 Gürtler, Guido, *The New Approach – can it work on the international scene?*, in: *Standardization for the 21st Century. Tackling the new challenge*, Berlin, 15-17 March 1999.

213 TABD, 1999 Mid Year Report, May 10, 1999, 4.

barriers. (...). The TABD encourages the EU and U.S. Governments to seek a regulatory model based on common objectives. These common objectives should cover what is essential for the protection of the public interest but they should not go into technical details. Technical matters should be solved by an interface with market driven international standards.“

The Berlin standards conference held in March 1999 made two highly specific recommendations regarding harmonization of the essential requirements, namely:

- to promote the use of international standards by the concluding, on a sectoral level, of more agreements such as those reached between ISO and CEN in the Vienna Agreement and between IEC and CENELEC in the Dresden Agreement;
- to propose a harmonized body of technical regulations for products by comparing the essential requirements formulated by the countries most intensely involved in world trade in selected sectors, and by drawing conclusions from the results for the priorities to be given in subsequent harmonization of technical regulation.²¹⁴

Whilst emphasizing the sector-by-sector aspect in its new activities, the TABD concentrates primarily upon the later phase of technical regulation and favours extension of Suppliers' Declarations of Conformity as the appropriate form of certification, in conjunction with enhanced market surveillance. Beyond this, it takes up new concepts within the regulation debate such as “*transparency in governance*”, and attempts to restrict the scope of the precautionary principle for government action on the grounds that each case of state regulation should be justified as an appropriate means to a legitimate end, and that good management practice on the part of manufacturers already encompasses precautionary measures.²¹⁵

Under strong US influence, the above statement by the TABD emphasizes the reference of technical regulations to international standards which has been brought about by market forces. National regulators should therefore select the appropriate basis for reference from the available international standards offered by competing standards organizations. Conversely, the New Approach to technical harmonization and standardization is based upon the premise that the national regulators responsible for the protection of elementary legal rights formulate the key constraints for standardization activity through the essential requirements, i.e. they lay down binding objectives of protection.

d) Limits to the concept for formulation of international essential requirements

The concept of formulating international basic safety requirements modelled on the European “New Approach” exhibits two essential flaws:

- a) The formulation of essential requirements at international level involves adoption of only one key element from the New Approach to technical harmonization and standardization²¹⁶. The efficacy and legitimacy of the New Approach, however, is attributable to the careful co-ordination of a number of elements, which can be presented here only in a brief summary:
 - The relevant directives each contain a catalogue of essential requirements binding upon all stakeholders in the economic process. The legislative bodies of the Community have retained the right to regulate basic issues of the level of protection, and also basic questions concerning the form to be taken by demonstration of compliance with the binding requirements.

214 Cf. Roed, Jan, Feedback Report Global Trade, in: Standardization for the 21st Century. Tackling the new challenge, Berlin, 15-17 March 1999.

215 TABD, 2001 Mid Year Report, May 15, 2001, 14 f.

216 Council Resolution of 7 May 1985 on a new approach to technical harmonization and standards, OJ 4.6.85 C 136, 1-9.

- The task of specifying the essential requirements is transferred to the European standardization organizations in accordance with corresponding European Commission mandates for the drafting of appropriate harmonized standards. The standardization mandates should indicate as precisely as possible what is expected of the standards organizations, and in what statutory framework the standards are to be presented.²¹⁷
- The harmonized standards give rise to a presumption of conformity only once the Commission has published, in the Official Journal of the European Communities, the references of the harmonized standards to be transposed in national standards. Rather than reviewing the standards upon completion, the Commission is involved directly in the ongoing standardization process, and makes use of facilities for informal negotiation and advance warning. The *New Approach Consultants*²¹⁸ have a key role in this activity.
- Compliance with the harmonized standards, or rather with the corresponding national standards which transpose the harmonized standards, remains voluntary. Manufacturers and importers are at liberty to demonstrate by other means that their products meet the essential requirements. Manufacturers and importers who demonstrate in accordance with the conformity assessment procedures²¹⁹ provided for in the individual directives that their products comply with the harmonized standards or otherwise satisfy the essential requirements may distribute their products without hindrance throughout the Community.
- The inspection bodies of the member states may restrict or temporarily prohibit the distribution of a product notwithstanding freedom of distribution confirmed in principle by the CE mark for reasons of safety or for protection of health or the environment; they must however make use of the safeguard clause²²⁰ provided for in all relevant directives.
- Should a Member State or the European Commission be of the opinion that a harmonized standard the reference of which is published in the Official Journal does not fully satisfy the essential requirements, a standard complaints procedure²²¹ is launched which may lead to the standard being deleted from the index of references. This does not prejudice the validity of a harmonized standard, which represents an autonomous regulation issued by an association; it results however in compliance with the national standards adopted for the

217 The discussions concerning fulfilment of the mandate for development of harmonized standards governing packaging materials – cf. the references above in footnotes 42-44 – have revealed the limits upon delegation to standardization committees. Such limits are clearly exceeded when the objectives of health, safety and environmental protection formulated in the essential requirements are not accepted faithfully in the relevant standardization committees as essential requirements which are the political responsibility of the Community legislator, or when directives make decisions the prerogative of the standardization committees.

218 Cf. specifically, with regard to this aspect and the following, CEN document JCR/HP/jc 1994-04-20, “Development of European Standards in the context of New Approach Directives Mandates (“Harmonised Standards”)”.

219 Cf. Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, OJ 30.8.93 L 220, 23-39.

220 Information on the safeguard clause procedure available in: European Commission, Guide to the implementation of directives based on the New Approach and the Global Approach, Luxembourg 2000, Section 8.3. – In 2000, the Commission received a total of 440 notifications in accordance with the safeguard clause procedure within the scope of New Approach directives; the Low-voltage directive alone accounted for 342 of these, and the EMC directive 72. Cf. Consultation Document Prepared by the Directorate General for Enterprise on the Review of the New Approach, 13 December 2001, 27; the document is available at http://europa.eu.int/comm/enterprise/consultations/new_approach_rev/index.htm.

221 Information in loc. cit., Section 4.4. – Since 1999, 10 harmonized standards have been the subject of a “formal objection” of this kind; cf. Report from the Commission to the Council and the European Parliament on actions taken following the resolutions on European Standardisation adopted by the Council and the European Parliament in 1999, COM (2001) 527, final, 26 September 2001, Ref. 26.

purpose of its transposition no longer sufficing for the rebuttable presumption of conformity with the essential requirements.

b) The main objection is that the formulation of essential requirements remains, with good reason, the prerogative of the legislative bodies holding political responsibility. What party might assume this task at international level, and by means of what instruments, is generally unclear. From a TABD participant, the proposal on the subject has been formulated as follows:²²²

For the future, we envisage a system which is supported and implemented by the WTO. The basis of this system will be world-wide harmonization of legislation, and reference to international standards. The participants in such a system must ultimately be all regions and countries of the world, such as the EU, NAFTA, APEC, Mercosur, and each country involved in its own right in world trade. This would represent considerable simplification, and would principally assure legislative security.

Should the political framework of international standardization therefore actually be steered from within the WTO? To date, no corresponding proposals have been submitted for preparation of a new World Trade Conference or under the auspices of the WTO Committee on Technical Barriers to Trade. The international model of the UN/ECE entrusts the control of such a framework for specific product sectors to the groups of countries indicating a wish to co-operate. Whether this permits consistent and continual control of the framework would appear doubtful.

e) **Summary**

- The OECD, the UN/ECE and the *Transatlantic Business Dialogue (TABD)* have presented proposals for the linking of binding technical regulations of individual states with international standards. The UN/ECE and the TABD have also developed models for this purpose in which essential requirements can be established as terms of reference for international standardization committees at international level in parallels to the New Approach to technical harmonization and standardization.
- The international model of the UN/ECE for good regulatory practice involving the use of international standards adopts almost all relevant elements of the New Approach. Important co-ordination tasks are assigned to the UN/ECE. The specific new slant of this approach is that it does not contain a model purporting to be global, but is based upon initiatives by countries wishing to co-operate in certain product sectors. Whereas the TBT Agreement is based upon the assumption that suitable international standards may well be available to serve as a basis for national technical regulations, this approach assumes, as does the New Approach of the European Community, that agreement upon jointly formulated Common Regulatory Objectives (CROs) will result in a need for further international standards to be drafted.
- The TABD is one of the forerunners of the concept of establishing essential requirements on a sector-by-sector basis at a global level as a binding orientation framework for international standardization activity. The broad approval of industry associations and standards bodies can generally be reduced to the principle "*Approved Once, Accepted Everywhere*". This sub-element refers to the phase, crucial for access to global markets, in which the compliance of a product with the specified requirements is confirmed. In recent years, the TABD has made less effort to gain acceptance of its idea of transferring the New Approach to technical harmonization and standardization to the international level, and to the formulation and clarification of the conditions necessary for this transfer, and

222 Cf. Harelss, *ibid*, 262.

instead has attempted to influence the definition of technical requirements in specific product sectors.

- The TABD emphasizes the reference of technical regulations to international standards which have been brought about by market forces. National regulators should therefore select the appropriate basis for reference from the available international standards offered by competing standards organizations. Conversely, the New Approach to technical harmonization and standardization is based upon the premise that the national regulators responsible for the protection of elementary legal rights formulate the key constraints for standardization activity through the essential requirements, i.e. they lay down binding objectives of protection.
- The concept of exploiting the European “New Approach” as a basis for the development of international basic safety requirements essentially exhibits two flaws:
 - a) The formulation of essential requirements at international level involves adoption of only one key element from the New Approach to technical harmonization and standardization. The efficacy and legitimacy of the New Approach, however, is attributable to the careful co-ordination of a number of elements. Besides the specification in directives of essential requirements binding upon manufacturers, importers, standards bodies, certification bodies and market surveillance authorities, these elements include the issuing of standardization mandates by the European Commission, close co-ordination between the technical committees and the Commission by *New Approach Consultants*, the facility for the raising of objections that the standards drafted fail to meet the essential requirements, the safeguarding clause in the event of deficits detected at a later stage, and co-ordination of the activities of certification bodies and inspection bodies.
 - b) The formulation of essential requirements remains, with good reason, the prerogative of the legislative bodies holding political responsibility. What party might assume this task at international level, and by means of which instruments, remains unclear.
- Assumption by the WTO of political control of the framework of international standardization is out of the question. To date, no proposals to this effect have been submitted for preparation of a new World Trade Conference or within the WTO Committee on Technical Barriers to Trade. The international model of the UN/ECE entrusts control of the framework for specific product sectors to the groups of countries indicating a wish to co-operate. The UN/ECE cannot be considered for a global co-ordination task, as it is aligned too closely to Europe and the industrialized nations.

7. Definition of “international standard”

Question: *What stage has been reached by discussion of the definition of “international standard”?*

a) Discussion in the WTO Committee on Technical Barriers to Trade

Discussion of the definition of an “international standard” reached a substantial conclusion in the form of a constructive development with submission in November 2000²²³ of the second triennial report²²⁴ on Application of the TBT Agreement.²²⁵ Following long and informative debate²²⁶, the WTO Committee on Technical Barriers to Trade adopted a decision regarding the principles to be observed during development of international standards, guides and recommendations. The decision was based chiefly²²⁷ on two position documents submitted by the USA²²⁸ and the European Commission²²⁹ and synthesis papers submitted by the Secretariat²³⁰ concerning *i.a.* the information of international organizations²³¹ of their role in the drafting of international standards. The principles can be characterized by the key

223 G/L/412, 14 November 2000.

224 Cf. Schwamm, Henri, Reducing technical trade barriers. Second Triennial Review of the WTO Agreement on Technical Barriers to Trade (TBT) –Results and Scope, ISO Bulletin 2001-2, 5-10.

225 Cf. the position statements in G/TBT/M/22, 2-5 signalling general satisfaction.

226 G/TBT/M/8, 14-18; G/TBT/M/12, 11-15; G/TBT/M/13, 13-16; G/TBT/M/14, 11-13; G/TBT/M/15, 13-20; G/TBT/M/16, 11-14; G/TBT/M/17, 8-15; G/TBT/M/18, 14-16; G/TBT/M/20, 13-17; G/TBT/M/21, 8-14.

227 Further important position papers were the following: First Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade of the World Trade Organization. Communication from Mexico, G/TBT/W/50, 5 August 1997; Philippine Paper on the First Triennial Review. Communication from the Philippines, G/TBT/W/54, 30 September 1997; Issues Concerning International Standards and International Standardization Bodies. Submission from Japan, G/TBT/W/113, 15 June 1999; Amendment of the TBT Agreement. Proposal by Japan, G/TBT/W/121, 7 October 1999; Second Triennial Review of the Agreement, International Standards. Contribution by Australia, G/TBT/W/139, 28 July 2000; Brazilian Proposal to the Second Triennial Review of the Agreement on Technical Barriers to Trade. Contribution from Brazil, G/TBT/W/140, 28 July 2000; Issues concerning International Standards. Submission by Japan, G/TBT/W/144, 2 October 2000.

228 Transparency in International Standards, Draft U.S. Proposal for a Decision. Contribution from the United States, G/TBT/W/75; revised version: 3 September 1998. Cf. previously Transparency in International Standards Development, Contribution from the United States, G/TBT/W/64, 2 April 1998.

229 On the Conditions for Acceptance and Use of International Standards in the Context of the WTO Technical Barriers to Trade Agreement, Note from the European Commission, G/TBT/W/87, 14 September 1998; revised version: 30 September 1999; cf. also Second Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade. Note from the European Community, G/TBT/W/133, 11 April 2000. See also Commission Staff Working Paper, European Policy Principles on International Standardisation, SEC (2001) 1296 of 26 July 2001.

230 Secretariat Paper (Job 3937) on principles for international standards development, July 2000. – The Secretariat had already presented two influential papers: Information Provided by Bodies Involved in the Preparation of International Standards (Information Session – 19 November 1998). Synthesis Paper by the Secretariat, G/TBT/W/106, 26 March 1999. Cf. also Factual Comparison between the Annex 3 of the WTO/TBT Agreement – Code of Good Practice for the Preparation, Adoption and Application of Standards – and the ISO/IEC Guide 59 – Code of Good Practice for Standardization, G/TBT/W/132, 29 March 2000.

231 The organizations concerned being the most important organizations for international standardization, i.e. the Codex Alimentarius Commission (Codex), International Electrotechnical Commission (IEC), International Organization for Standardization (ISO), International Telecommunications Union (ITU), Organisation for Economic Cooperation and Development (OECD), Office International des Epizooties (OIE), International Organization of Legal Metrology (OIML), UN Economic Commission for Europe (UN/ECE) and World Health Organization (WHO).

concepts of transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and consideration of the needs of developing countries.

During this debate, which lasted some two years, the developing countries' demand for better support in active participation in international standardization activity was not the subject of controversy. The USA had emphasized the requirements of transparency, openness and impartiality in the procedures very strongly in its position documents.²³² The parties were in general agreement regarding the criteria for the standards development procedure, namely those of efficiency and suitability for the market in addition to the criteria stated. These criteria can be met by a number of standards organizations. This would open up the opportunity for standards organizations in the USA and other countries who draw up their procedures accordingly and whose products find corresponding favour to be considered as the originators of national standards, guides and recommendations.

In order to reinforce the consistency and coherence of the international body of standards and the position of the international standards organizations such as ISO, IEC and ITU, which are undisputedly recognized as such, the EC called more vocally from the outset for institutional criteria which are to ensure the indisputable world-wide representation and consistency of the body of standards. It argued that the process-oriented criteria should apply as a matter of principle to all types of standards, i.e. also to national and regional standards. In order to promote international trade, international standards should meet further criteria. In the interests of impartiality and coherence, only international standards adopted by an international standards organization should be deemed international standards. These organizations should in turn draft international standards only, and should not simultaneously develop standards for regional or national use. The exclusive concentration upon international standardization activity is an essential condition for assurance of impartial treatment of national positions, and for the guaranteeing of consistency in the international standards. The products of the traditional international standards organizations ISO, IEC, ITU and certain other UN specialized agencies should therefore be granted a certain monopoly status. Conversely, the standards of other *Standards Developing Organisations*, which are *de facto* used world-wide, should be excluded in the interests of coherence of the body of standards. The decisive commitment of the EC to the criteria of coherence and singularity²³³ was supported by the argument that reference in technical regulations to international standards would be a suitable means to the elimination of barriers to trade only if a situation did not exist in which competing international standards were available for selection. The criteria of coherence and singularity are reflected in the approved document however only in the substantially weakened form of co-operation and avoidance of duplicated activity.

Criteria for the definition of an "international standards organization" in the context of the TBT Agreement could not be carried through. As far as can be established, no attempt was made to implement parallels to the SPS Agreement, namely a list of approved products of "international standards" agreed by certain organizations. In addition, no direct link can be established to the terminological distinction contained in ISO/IEC Guide 2²³⁴ between "*standardising body*" and "*standards body*". "*Standardising bodies*" are institutions which

232 Transparency in International Standards, Draft U.S. Proposal for a Decision. Contribution from the United States, G/TBT/W/75, 30 June 1988; revised version: 3 September 1998.

233 Cf. esp. Principles of Coherence and Singularity to be observed by International Standardizing Bodies. Contribution from the European Communities, G/TBT/W/149, 1 November 2000. See also Commission Staff Working Paper, European Policy Principles on International Standardization, S/Ec (2001) 1296 of 26 July 2001, Ref. 14.

234 ISO/IEC Guide 2:1991 – General terms and their definitions concerning standardization and related activities, 4.3, 4.4.

conduct recognized activities in the field of standardization; the UN/ECE is a prominent example. “*Standards bodies*” are standardising bodies recognized at national, regional or international²³⁵ level, that have as their principal function, by virtue of their statutes, the preparation, approval or adoption of standards that are made available to the public. Examples at international level are ISO and IEC, at regional level CEN and CENELEC, and at national level AFNOR, BSI and DIN.

b) Principles for the development of international standards, guides and recommendations

The principles for the development of international standards, guides and recommendations, which were agreed by the WTO Committee on Technical Barriers to Trade in conjunction with adoption of the Second Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade, are listed below.²³⁶ They place strict requirements on the procedures to be followed in international standardization activity. By open and transparent processes, which are open to all interested national standards organizations for involvement without discrimination, and by the reaching of decisions by consensus, international standards are to be assured as an effective instrument recognized by all parties for the avoidance and/or elimination of technical barriers to trade. The principles should also be observed where international standards organizations delegate a part of their activities.

A. Transparency:

3. All essential information regarding current work programmes, on proposals for standards, guides and recommendations under consideration and on the final results, should be made easily accessible to all interested parties in the territories of all WTO members. Adequate time and opportunities are to be provided for written comments.
4. The following minimum requirements apply to the procedures for assurance of transparency:
 - A notice is to be published at an early appropriate stage, in such a manner as to enable interested parties to become acquainted with it, that an international standardizing body proposes to develop a particular standard.
 - Members of international standardizing bodies are to be notified of the scope and the objective of the proposed standard.
 - Notification is to take place at a sufficiently early stage for amendments to be made and comments taken into account.
 - Members of an international standards organization are to be provided promptly with the text of the draft standard upon request.
 - Sufficient time is to be provided for interested parties in the territory of all members of an international standards organization to make comments in writing, and for these comments to be taken into account in the further consideration of the standard.
 - A standard is to be published promptly upon its adoption.

²³⁵ Only standards organizations whose membership is open to the relevant institutions of all countries are deemed “international”; *ibid.*, 4.4.3.

²³⁶ Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with relation to Articles 2, 5 and Annex 3 of the Agreement, Second Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade, Annex IV, G/TBT/9, 13 November 2000, 24-26.

- A work programme containing information on the standards currently being prepared and adopted is to be published periodically.
5. The Internet is a suitable communication medium for the making available of all information, texts and comments referred to in a timely fashion. As the necessary technical facilities may not be available in all cases (for example in developing countries), hard copies of documents are to be made available upon request.
- B. Openness:**
6. Membership of an international standardizing body is to be open to all relevant bodies of WTO members without discrimination at any stage of standard development.
 7. Any interested member of an international standardizing body, in particular from a developing country, with an interest in a specific standardization activity should be provided with meaningful opportunities to participate at all stages of standard development. Participation in a particular international standardization activity in the territory of a member is to be performed where practical through a delegation representing all standardizing bodies in the territory that have adopted, or expect to adopt, standards for the subject-matter to which the international standardization activity relates.
- C. Impartiality and consensus:**
8. All relevant bodies of WTO members are to be provided with meaningful opportunities to contribute to the elaboration of an international standard such that the standard development process will not favour the interests of particular suppliers, countries or regions. Consensus-forming procedures²³⁷ are to be established that seek to take into account the views of all parties concerned and to reconcile any conflicting arguments.
 9. Impartiality is to be the decisive yardstick throughout the standards development process with respect *i.a.* to access to participation in work, submission of comments on drafts, consideration of views and comments made, obtaining of information and documents, dissemination of the international standard, fees charged for documents, the right to transpose the international standard into a regional or national standard, and revision of the international standard.
- D. Effectiveness and relevance:**
10. In order to facilitate international trade and to prevent unnecessary trade barriers, international standards must be relevant, and must effectively respond to regulatory and market needs as well as to scientific and technological developments in various countries. They should not distort the global market, nor have adverse effects on fair competition, nor stifle innovation and technical development. In addition, they should not give preference to the characteristics or requirements of specific countries or regions when different needs or interests exist in other countries or regions. Wherever possible, international standards should be performance-based rather than being based upon design or descriptive characteristics.
 11. International standardizing bodies should:
 - take account of relevant regulatory or market needs as well as scientific and technological developments in the elaboration of standards;

237 In accordance with EN 45020, Item 1.7, consensus is defined as General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. Consensus need not imply unanimity. On the requirement for consensus in standardization, cf. most recently Allan R. Mears, Konsens, DIN-Mitteilungen. 80 (2001), 761-763.

- put in place procedures aimed at identifying and reviewing standards that for various reasons have proved obsolete, inappropriate or ineffective;
- employ procedures aimed at improving communication with the WTO.

E. Coherence:

12. In order to avoid the development of conflicting international standards, international standardizing bodies should co-operate with other relevant international organizations, in order to avoid overlap and duplication of activities.

F. Development dimension:

13. Constraints on developing countries, in particular, to participate effectively in standards development, should be taken into consideration; ways must be sought to facilitate their effective participation. The impartiality and openness of any international standardization process requires that developing countries not be excluded *de facto* from it. Measures for technical assistance in line with Article 11 of the TBT Agreement are to be used to improve participation by developing countries.

c) Summary

- Discussion of the definition of an “international standard” reached a substantial conclusion in November 2000 with submission of the Second Triennial Report on Application of the TBT Agreement. Following long and informative debate, the WTO Committee on Technical Barriers to Trade adopted a decision concerning the principles to be observed in the development of international standards, guides and recommendations, namely those of transparency, openness, impartiality and consensus, effectively and relevance, coherence, and consideration of the needs of developing countries.
- The decisive commitment of the EU to the criteria of coherence and singularity was supported by the argument that reference in technical regulations to international standards would be a suitable means to the elimination of barriers to trade only if a situation did not exist in which competing international standards were available for selection. The criteria of coherence and singularity are reflected in the approved document however only in the substantially weakened form of co-operation and avoidance of duplicated activity.

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Annex A: Comparative overview of organizations developing international standards

1. Codex Alimentarius Commission of the WHO and FAO (CAC)

Internet address:	http://www.codexalimentarius.net/
Founded:	By resolution by the FAO (1961) and the WHO (1963)
Membership:	165 member states world-wide
Mission:	Establishment of standards for all basic foodstuffs (including hygienic requirements, nutritional value, marking, preparation, analysis methods)
Standards:	Approximately 5,000 Codex standards, including standards governing individual foods, standards for hygiene or foodstuffs technology, assessment of pesticides, threshold values for pesticide residues, guidelines for contaminants, assessment of foodstuff additives, assessment of veterinary pharmaceuticals
Technical committees:	Nine general committees for certain categories of foodstuffs or other aspects; 5 co-ordinating committees for the regions Africa, Asia, Latin America/Caribbean, North America/South-West Pacific, Europe; numerous working groups
Languages:	English, French, Spanish
Headquarters:	Geneva and Rome
Procedural rules:	Rules of Procedure of the Codex Alimentarius Commission; Procedures for the Elaboration of Codex Standards and Related Texts (The Codex “Step Procedure”)
New projects:	Proposals from the governments of the member states; “Criteria for the Establishment of Work Priorities and for the Establishment of Subsidiary Bodies” apply
Procedures:	Generation of a preliminary draft by the Commission Secretariat, request of position statements from the governments of the member states, evaluation of the position statements and generation of a final draft by a dedicated working group
Formal decision:	By the governments of the member states, following a multi-structured preparatory procedure; attempt is made to reach agreement by consensus; decisions are reached by simple majority in the event of disagreement
Time required:	Several years are required on average for development and adoption of a standard.
Revision:	No routine period; a revision is launched in order to take into account the latest scientific findings and other relevant information
Legal force:	Voluntary; the categories full acceptance, acceptance with specified deviations, free distribution apply to acceptance
Co-operation	Close collaboration with the FAO and the WHO

2. International Electrotechnical Commission (IEC)

Internet address:	http://www.iec.ch/
Founded:	1906
Membership:	Fifty-two national standards organizations world-wide in the field of electrical engineering; a further 9 associate members
Mission:	Promotion of international co-operation in all issues of standardization and conformity assessment in the fields of electrical engineering, electronics, and related technology
Standards:	At the end of 2000: 4,557 IEC publications (of which 362 first appeared in 2000); 1,683 current projects
Technical committees:	Approximately 200 technical committees and sub-committees, and around 700 working groups
Languages:	English, French, Russian
Headquarters:	Geneva; committee meetings are held throughout the world.
Procedural rules:	ISO/IEC Directives, Part 1: Procedures for the technical work; ISO/IEC Directives, Part 2: Methodology for the development of International Standards; ISO/IEC Directives, Part 3: Rules for the structure and drafting of International Standards
New projects:	Proposals by national standards organizations; commencement of activity requires formal acceptance by the interested members by simple majority and the active involvement of at least 5 members in the standardization activity
Procedures:	Drafting of a standard by the responsible sub-committee or a working group; comments by the national standards organizations involved in the standardization project concerned, who must first provide all interested parties with the opportunity to comment; completion of the final text
Formal decision:	Voting by the national standards organizations; quorum: acceptance by two-thirds of the member organizations actively involved in the standardization process; the number of “no” votes from all national standards organizations must not exceed one-quarter of all votes cast
Time required:	Five years on average
Revision:	Routine revision after five years; where necessary, earlier adaptation to progress in the state of the art
Legal force:	Voluntary
Co-operation:	Close collaboration with ISO (ISO and IEC Joint President’s Coordination Group, ISO and IEC Joint Technical Advisory Board, Joint Technical Committee on Information Technology) and to ITU, but also to the WHO, the ILO and to the UN/ECE; co-operation agreements with CENELEC (Dresden Agreement) and ETSI

3. International Maritime Organization (IMO)

Internet address: <http://www.imo.org/>

Founded: 1948 as the IMCO – Inter-Governmental Maritime Consultative Organisation;
has been the International Maritime Organisation since 1982

Membership: 158 member states world-wide, including all major shipping states and also including flags of convenience; two associate members;
co-operation agreements with 37 international non-governmental organizations (INGOs);
Fifty-six international non-governmental organizations participate in the activity in an advisory capacity

Mission: The IMO is the United Nations' dedicated organization for promotion of safety in ocean shipping and prevention of marine pollution by ocean shipping

Body of rules: In addition to binding statutory agreements and protocols, which have legal force for the countries which have ratified them, the IMO has drawn up a large number of other standards which are recognized as international standards with no formal legal force. These include the hundreds of codes of practice, recommendations and guidelines for the areas of loading, ship safety and ship technology, marine pollution, navigation, search and rescue, radio at sea, and training.

Selection of agreements and protocols:

a) Maritime Safety:

International Convention for the Safety of Life at Sea (SOLAS), 1974;
Convention on the International Regulations for Preventing Collisions at Sea (COLREG), 1972;

Convention on the International Maritime Satellite Organization (INMARSAT), 1976;

International Convention for Safe Containers (CSC), 1972;

The Torremolinos International Convention for the Safety of Fishing Vessels (SFV), 1977;

International Convention on Standards of Training, Certification and Watchkeeping for Seafarers (STCW), 1978;

International Convention on Standards of Training, Certification and Watchkeeping for Fishing Vessel Personnel (STCW-F), 1995;

International Convention on Maritime Search and Rescue (SAR), 1979;

b) Marine Pollution:

International Convention for the Prevention of Pollution from Ships (MARPOL), 1973, 1978;

International Convention Relating to Intervention on the High Seas in Cases of Oil Pollution Casualties (INTERVENTION), 1969;

Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter (LDC), 1972;

International Convention on Oil Pollution Preparedness, Responses and Co-operation (OPRC), 1990;

Protocol on Preparedness, Response and Co-operation to Pollution Incidents by Hazardous and Noxious Substances (HNS-Protocol), 2000;

c) Liability and Compensation:

International Convention on Civil Liability for Oil Pollution Damage

(CLC), 1969;
 International Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage (FUND), 1971;
 Convention on Limitation of Liability for Maritime Claims (LLMC), 1976;
 International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea (HNS), 1996;
 International Convention on Civil Liability for Bunker Oil Pollution Damage, 2001;

d) Other Subjects:

Convention on Facilitation of International Maritime Traffic (FAL), 1965;
 International Convention on Tonnage Measurement of Ships (TONNAGE), 1969;
 International Convention on Salvage (SALVAGE), 1989;

Selection of other standards:

International Maritime Dangerous Goods Code (IMDG Code), 1965;
 Code of Safety for Fishermen and Fishing Vessels, 1974;
 Code on Noise Levels on Board Ships, 1981;
 Code of Safety for Special Purpose Ships, 1981;
 International Safety Management Code (ISM Code), 1993

Committees: Assembly of the member states (at least biennial);
 Council (32 selected members);
 Maritime Safety Committee (MSC);
 Marine Environment Protection Committee (MEPC);
 Legal Committee;
 Technical Co-operation Committee;
 Facilitation Committee

Languages English

Headquarters: London

Procedural rules: IMO Convention

Procedures: The committees encourage the drafting of new agreements and other rules and the adaptation of existing agreements and other rules in their own particular areas. Following agreement by the Council and Assembly, they or their sub-committees draft detailed text proposals; the support of co-operating INGOs and NGOs is welcomed at this stage. The final texts are presented to the Council and the Assembly for launching of the procedure for formal adoption. Formal adoption takes place at a conference of all member states of the IMO, at which not only the prepared texts, but also the comments received from member states and interested organizations are available. As comprehensive a consensus as possible is the objective. The agreement texts adopted by majority voting at the Assembly are generally open for signature for one year. The conditions which must be met before a particular agreement may enter into force are defined in the agreement concerned; at present, IMO Conventions come into force on average five years after their adoption.

The agreements have binding legal force upon states which ratify them. Some of the most important conventions are ratified sufficiently widely to cover 95% of the total world-wide tonnage of ocean shipping. The resolutions adopted by the Assembly have the status of

recommendations and are treated as internationally recognized standards. They may however acquire legal force by virtue of reference within other legislation.

Implementation is the responsibility of the member states. The concept of port state control is a response to the issue of flags of convenience. IMO has set up a sub-committee dedicated to issues relating to flags of convenience. IMO is authorized to monitor the training and examination of seamen.

Revision: Continual; changes are frequent owing to technical development, and enter into force in accordance with the simplified “tacit acceptance” procedure.

Co-operation: Co-operation agreements with 37 INGOs (including ALADI, Arab League, CARICOM, EU, OAPEC, OAS, OAU; CEPT, ESA, INTELSAT, OECD, UNIDROIT, WTO)

56 international NGOs may participate in the IMO’s activities with advisory status (including European Chemical Industry Council [CEFIC], Friends of the Earth, Greenpeace International, International Association of Classification Societies [ICAS], International Association of Ports and Harbors [IAPH], International Bar Association [IBA], International Chamber of Commerce [ICC], International Confederation of Free Trade Unions [ICFTU], International Council of Marine Industry Associations [ICOMIA], IEC, International Navigation Association [INA], International Shipping Federation [ISF], ISO, International Union of Marine Insurance [IUMI], WWF)

4. International Organization for Standardization (ISO)

Internet address: <http://www.iso.ch/>

Founded: 1947

Membership: 138 organizations world-wide, who are most representative of standardization activity in their respective countries (of which 91 are full members, 36 are corresponding members, and 11 are subscriber members)

Mission: Promotion of international co-operation in all issues of standardization and conformity assessment in the technical fields which do not fall within the scope of the IEC

Standards: 13,025 International Standards (as of: 31 December 2000), of which 986 were published in 2000; 4,789 current projects

Technical committees: 187 technical committees, 552 sub-committees, approximately 2,100 working groups, and 19 ad-hoc groups

Languages: English, French, Russian

Headquarters: Geneva; committee meetings are held throughout the world.

Procedural rules: ISO/IEC Directives, Part 1: Procedures for the technical work; ISO/IEC Directives, Part 2: Methodology for the development of International Standards; ISO/IEC Directives, Part 3: Rules for the structure and drafting of International Standards

New projects: Proposals from national standards organizations, but also from ISO committees, international organizations, certain bodies within ISO and IEC, and notified bodies; formal selection of an issue by the ISO Technical Management Board; at least 5 member organizations must be involved in the activity

Procedures: Drafting of a standard by the responsible sub-committee or a working group; comments by the national standards organizations involved in the standardization project concerned, who must first provide all interested parties with the opportunity to comment; completion of the final text

Formal decision: Voting by the national standards organizations; quorum: acceptance by two-thirds of the member organizations actively involved in the standardization process; the number of "no" votes from all national standards organizations must not exceed one-quarter of all votes cast

Time required: Five years on average

Revision: Routine revision after five years; where necessary, earlier adaptation to progress in the state of the art

Legal force: Voluntary

Co-operation: Close working contact to ISO (ISO and IEC Joint President's Coordination Group, ISO and IEC Joint Technical Advisory Board), co-operation agreements with CEN (Vienna Agreement); close contacts to the WHO and the FAO, and to the International Atomic Agency

5. International Telecommunication Union (ITU)

Internet address:	http://www.itu.int/
Founded:	1865 (International Telegraph Union), a UN Organization in its own right since 1947
Membership:	189 member states, 144 telecommunications administrations (network operators and service providers), 182 scientific and industrial organizations, 50 regional and other international organizations, 11 regional telecommunications organizations, 7 organizations for satellite issues, financing and development organizations
Mission:	World-wide standardization and co-ordination in the areas of ITU-T: Telecommunication Standardization Sector, ITU-R: Radiocommunication Sector, ITU-D: Telecommunication Development Sector
Standards:	ITU-T: 2,876 recommendations and other publications (as of 1 December 1999), including 290 joint ISO and ITU-T texts
Technical committees:	ITU-T: 14 study groups
Languages:	Arabic, Chinese, English, French, Russian, Spanish
Headquarters:	Geneva; meetings may be held world-wide
Procedural rules:	ITU-T: Rules of Procedure of the ITU Telecommunication Standardization Sector (ITU-T); for accelerated procedures: Alternative approval procedure for new and revised Recommendations
New projects:	ITU-T: The programmes of the study groups are revised continually and adapted to current market requirements; a consensus of the relevant study group, the Telecommunication Standardization Advisory Group or the World Telecommunication Standardization Conference is required for this purpose.
Procedures:	ITU-T: Creation of a draft in a study group or a working group formed by it, consultation of the member states, final discussion, and formal decision in the study group
Formal decision:	ITU-T: Seventy percent of the member states must agree to an ITU-T recommendation prior to final discussion in the study group concerned; the latter must reach agreement with no remaining conflicting positions.
Time required:	ITU-T: On average, 9 months for drafting and a further 6-12 months for publication
Revision:	ITU-T: continual revision of the body of Recommendations by the study groups
Legal force:	ITU-T Recommendations are not binding, but are generally adhered to for reasons of compatibility.
Co-operation:	ITU-T: working contact to ISO, IEC and to the Postal Operations Body of the Universal Postal Union; Memorandum of Understanding on Electronic Business between IEC, ISO, ITU, and UN/ECE

6. Organization for Economic Co-operation and Development (OECD)

Internet address: <http://www.oecd.org/>

Founded: 1960

Membership: Thirty member states world-wide (including all EU member states), who have committed themselves to the principles of the market economy, democratic pluralism, and respect for human rights; according to the OECD itself, “the OECD is a club of like-minded countries”. Over 50 members participate in certain OECD activities in some form or other in an associate capacity. The EU is represented with a seat and a vote in the key decision-making body, the OECD Council.

Mission: The OECD regards itself as a forum for discussion and consultation on issues of economic and social policy, and supports the negotiation of international agreements and voluntary guidelines in virtually all areas of policy with the exception of military security.

Standards: The OECD has adopted the following body of product-related standards and guidelines:

- OECD Guidelines for the Testing of Chemicals (1981),
- OECD Principles of Good Laboratory Practice (GLP) (1981),
- Council Decision related to the Mutual Acceptance of Data in the Assessment of Chemicals (1981),
- OECD Scheme for the Application of International Standards for Fruits and Vegetables (1962) – in co-operation with UN/ECE,
- OECD Schemes for the Varietal Certification of Seed Moving in International Trade, current text from 2000,
- OECD Standard Codes for the Official Testing of Agricultural and Forestry Tractors (1959),
- OECD Scheme for the Control of Forest Reproductive Material Moving in International Trade (1974).

Technical committees: OECD Council, comprising government representatives of the member states; meets once every two weeks. The activity proper is performed by some 200 committees, working groups and panels of experts.

Languages: English, French

Headquarters: Paris

Procedural rules: Convention on the Organisation for Economic Co-operation and Development

New projects: Proposals by the member states

Procedures: Drafting by groups of experts (representatives of governments, enterprises, unions, environment bodies, other NGOs, scientists, nominated in each case by the member states); the principle of consensus applies

Formal decision: Decisions and recommendations are adopted by mutual agreement by the members, unless arrangements to the contrary are agreed for special cases.

Revision: No routine revision at specific intervals.

Legal force: Decisions are binding upon OECD members who have participated in voting as soon as the required internal conditions are met. Recommendations are not binding. The application of OECD standards is open to both members and non-members.

Co-operation: Standards are developed in co-operation with the relevant international organizations such as the WHO, ISO and ILAC. International organizations and NGOs are invited to attend OECD meetings in an observer and expert capacity.

7. International Office of Epizootics (OIE)

Internet address: <http://www.oie.int/>

Founded: 1924

Membership: One hundred and fifty-seven member states world-wide

Mission: Provision of information to governments on the incidence and progress of animal diseases world-wide and on the possibilities for their control; international co-ordination of studies into the outbreak of animal diseases and their control; harmonization of the sanitary requirements for international trade in animals and animal products, and adoption of international standards in the area of animal health

Standards: International Animal Health Code, 2000 (with 141 sub-chapters), Manual of Standards for Diagnostic Tests and Vaccines, 4th ed., 2000 (with 101 sub-chapters), International Aquatic Animal Health Code and Diagnostic Manual for Aquatic Animal Diseases (with 55 sub-chapters)

Technical committees: Specialized commission for specific aspects of animal health; five regional commissions (Africa, North and South America, Asia, Far East and Oceania, Europe and the Middle East)

Languages: Arabic, English, French, German, Russian, Spanish

Headquarters: Paris

New projects: Launched regularly in response to reports by one or more member states of acute problems concerning animal health

Procedures: Production of drafts by the relevant specialized commissions, opportunity for comment by the member states, production of final drafts by the responsible commission

Formal decision: Adoption by the member states in the International Committee, generally by consensus (“absence of strong and motivated opposition of one member country”). The chief functions stated for the International Committee include the following:

- to adopt international standards in the fields of animal health, especially for international trade,
- to adopt resolutions on the control of major animal diseases.

Revision: As required; no routine revision at specific intervals

Legal force: Voluntary

Co-operation: Working contacts to the FAO, the WHO, the WTO, the Inter-American Institute for Cooperation on Agriculture and the Pan American Health Organization

8. International Organization of Legal Metrology (OIML)

Internet address:	http://www.oiml.org/
Founded:	1955
Membership:	Fifty-seven member states and 51 corresponding members world-wide
Mission:	Harmonization of national and regional measurement regulations regarding the required accuracy of measurement and the measuring instruments employed
Standards:	Over 110 OIML International Recommendations
Technical committees:	18 technical committees and 49 sub-committees; two main groups are represented in the technical committees, namely the regulatory bodies and the manufacturers of measuring instruments
Languages:	French, English
Headquarters:	Paris
Procedural rules:	Convention establishing an International Organisation of Legal Metrology
Procedures:	Production of drafts by the relevant committees and sub-committees, opportunity for comment by the member states, production of final drafts by the responsible committees
Formal decision:	Quorum for formal adoption of OIML International Recommendations: consent by two-thirds of the members actively involved in drafting, abstentions by not more than one-fifth and rejection by not more than one fifth of all voting members
Time required:	Three to six years
Revision:	No routine revision at specific intervals
Legal force:	Voluntary – “Member States are morally obliged to implement OIML Recommendations as far as possible”. A member is not however obliged to implement a regulation solely because a corresponding OIML recommendation exists; should it implement a regulation, however, derogation from the OIML recommendations is not permitted.
Co-operation:	Collaboration with over 100 international and regional organizations in the area of metrology; collaboratory agreements with ISO and IEC, in order to avoid discrepancies and duplication of activity

9. United Nations, Economic Commission for Europe (UN/ECE)

Internet address: <http://www.unece.org/>

Founded: 1947

Membership: 55 member states (including all EU member states) in Europe, North America (Canada, USA) and parts of Asia (Armenia, Azerbaijan, Georgia, Kazakhstan, Kirghizia, Tajikistan, Turkmenistan, Uzbekistan), Israel

Mission: Promotion of greater economic creation between member states; activities include economic analyses, development of conventions, regulations and standards, and technical support.

The activities of the UN/ECE of relevance to products include:

- standardization and technical harmonization policy,
- quality standards for agricultural produce,
- design requirements for vehicles,
- standards for the facilitation of trade.

Standards: 113 UN/ECE Regulations concerning the construction of vehicles, approximately 100 quality standards for perishable foodstuffs and other agricultural produce, 28 UN/ECE Recommendations for trade facilitation, a total of 30 conventions and protocols, over 250 regulations and standards

Technical committees: – UN/ECE Working Party on Technical Harmonization and Standardization Policies (WP.6): does not itself develop standards, but instead supports the development, adoption and application of harmonized technical rules and procedures for conformity assessment in the member states; it also maintains a UN/ECE standardization list in which the need for standardization is recorded and the international standards organizations responsible for the required activity are named;

- UN/ECE Working Party on Standardization of Perishable Produce and Quality Development: defines quality standards for perishable produce such as foodstuffs, plants and cut flowers for the purpose of facilitating international trade;
- Working Party on Construction of Vehicles (WP.29): develops technical requirements for all individual components and aspects required for uniform type approval of passenger vehicles, goods vehicles, tractors and two-wheeled motor vehicles, together with rules for regular review of the safety and environmental requirements;
- Centre for Facilitation of Procedures and Practices for Administration, Commerce and Transport (CEFACT): develops standards and recommendations for simplification of the bureaucracy associated with trade and for the development of electronic commerce
- Inland Transport Committee: the following dedicated working groups operate under the auspices of this committee:
 - the Working Party on Road Transport (SC1),
 - the Working Party on Road Traffic Safety (WP.1),
 - the World Forum for Harmonization of Vehicles Regulations (WP.29),
 - the Working Party on Rail Transport (SC.2),
 - the Working Party on Inland Water Transport (SC.3),
 - the Working Party on Combined Transport (WP.24),
 - the Working Party on the Transport of Dangerous Goods (WP.15).

Languages:	English, French, Russian
Headquarters:	Geneva; meetings are in some cases held by invitation in the member countries
Procedural rules:	Terms of Reference and Rules of Procedure of the United Nations Economic Commission for Europe (UN/ECE)
New projects:	Authority of interested parties (member states, international or intergovernmental organizations, international trade organizations) to launch initiatives; establishment and updating of work programmes by the responsible working groups
Revision:	No routine revision at specific intervals; revisions are however undertaken at frequent intervals
Legal force:	Application is voluntary, but many of the standards adopted by the UN/ECE have formed the basis for binding EU or OECD provisions
Co-operation:	Co-ordination of activity with ISO and IEC in the area of electronic commerce; co-operation with the FAO, the WHO and the Codex Alimentarius Commission in the sphere of foodstuffs; involvement in an advisory capacity of relevant non-governmental organizations in the relevant areas of activity

10. World Health Organization (WHO)

Internet address: <http://www.who.org/>

Founded: 1948

Membership: One hundred and ninety-one members world-wide

Mission:

- world-wide support and instruction in health policy,
- Development and promotion of international standards in the area of health (including water quality, hygiene standards, food quality and safety, pharmaceuticals, pesticides, contagious diseases, examination methods, requirements for laboratory equipment and procedures, requirements for hospitals),
- Support of national health programmes,
- Development and transfer of suitable technologies, information and standards for the promotion of health

Languages: English

Headquarters: Geneva

Procedural rules: Rules of Procedure of the World Health Assembly, Rules of Procedure of the Executive Board of the WHO, Regulations for Expert Advisory Panels and Committees

New projects: Proposals and initiatives from the health authorities of the member states, the WHO committees or panels of experts

Procedures: Development of initial drafts by the WHO Secretariat; opportunity for governments, relevant bodies in the member states, NGOs and bodies co-operating with the WHO to comment; revision in consideration of the comments, with an endeavour to reach consensus; formulation of the final text by a committee of experts

Formal decision: Binding standards require a majority decision of the member states in the WHO Assembly; non-binding standards are established at technical level by publication of the reports of the expert committee sessions or at intergovernmental level by decision by the WHO Assembly

Time required: One to six years

Revision: No routine revision at specific intervals

Legal force: Observance of the majority of WHO standards is voluntary. Observance of the International Health Regulations (IHR) adopted at the 22nd WHO Assembly in 1969 is obligatory for the signatory states.

Co-operation: Co-operation with UNICEF, FAO, UNEP, ILO and other relevant UN organizations, and with NGOs
Owing to its expertise in science and medicine, the WHO is responsible for the development and adoption of methods for risk assessment; these in turn form the basis for the standards, guidelines and recommendations of the Codex Alimentarius Commission.

Compiled in accordance with WTO, Committee on Technical Barriers to Trade, Information provided by Bodies Involved in the Preparation of International Standards (Informal Session – 19.11.1998), Synthesis Paper by the Secretariat, G/TBT/W/106, 26.3.1999, supplemented and updated with information available on the Internet pages indicated.

Annex B: Supporting of technical regulations by standards in Community Law outside the New Approach

Table 15: References to ISO standards in current Community law, and comparison with the current body of ISO standards (as of 30 April 2001)

No.	Act etc.	References to standards	Current ISO standards
1	370 L 0156	ISO/R 586:1963 (E)	D Withdrawn
2	374 L 0150	ISO/R 612:1967	D ISO 612:1978
		ISO/R 1176:1970	D ISO 1176:1990
		ISO/R 789:1968	D Withdrawn
3	375 L 0106	ISO 2859	ISO 2859-0:1995, ISO 2859-1:1999, ISO 2859-2:1985, ISO 2859-3:1991, ISO 2859-4:1999
4	375 L 0323	ISO/R 1724:1970	D ISO 1724:1997
5	376 L 0211	ISO 2859	ISO 2859-0:1995, ISO 2859-1:1999, ISO 2859-2:1985, ISO 2859-3:1991, ISO 2859-4:1999
6	376 L 0891	ISO/R 75:1958	D Withdrawn
7	378 L 0507	ISO 3779:1977	D ISO 3779:1983
		ISO 3780:1976	D ISO 3780:1983
8	378 L 0933	ISO/R 1724:1970	D ISO 1724:1997
		ISO/R 1185:1970	D ISO 1185:1997
9	379 L 0113	ISO 3741:1975	D ISO 3741:1999
10	379 L 0489	ISO 3583:1975	D ISO 3583:1984
11	380 L 0181	ISO 2955:1974	D ISO 2955:1983
		ISO 31-1:1965	D ISO 31-1:1992
12	380 L 0779	ISO 4219:1979	D ISO 4219:1979
		ISO/DP 6767:1979	D ISO 6767:1990
		ISO/DIS 4219	ISO 4219:1979
		ISO/DIS 6349	ISO 6349:1979
13	381 L 1051	ISO 5353:1978	D ISO 5353:1985
14	382 L 0319	ISO/R 105-B02:1978	D ISO 105-B02:1994
		ISO/R 6487:1980	D ISO 6487:2000
15	383 L 0351	ISO 970	Withdrawn
16	383 L 0514	ISO 5725	ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
17	383 R 1354	ISO 1184	Withdrawn
		ISO 2206	ISO 2206:1987
		ISO 2233	ISO 2233:2000
		ISO 2248	ISO 2248:1985
		ISO 2872	Withdrawn
		ISO 2874	Withdrawn
18	384 L 0449	ISO 1218 (E)	Withdrawn
		ISO/R 918	ISO 918:1983

No.	Act etc.	References to standards	Current ISO standards
		ISO/DIS 4626	ISO 4626:1980
		ISO 387	ISO 387:1977
		ISO/R 649	ISO 649-1:1981, ISO 649-2:1981
		ISO/R 1185	ISO 1185:1997
		ISO/R 1183	ISO 1183:1987
		ISO/R 91	ISO 91-1:1992, ISO 91-2:1991
		ISO/R 758	ISO 758:1976
		ISO/R 3507	ISO 3507:1999
		ISO 304	ISO 304:1985
		ISO 1516	ISO 1516:1981
		ISO 3680	ISO 3680:1983
		ISO 1523	ISO 1523:1983
		ISO 3679	ISO 3679:1983
		ISO 2719	ISO 2719:1988
19	384 L 0533	ISO 1217:1975	D ISO 1217:1996
20	384 L 0535	ISO/R 700:1968	D Withdrawn
21	384 L 0537	ISO/R 1180	ISO 1180:1983
		ISO/R 1571	Not locatable
22	384 L 0538	ISO/R 4046	ISO 4046:1978
		ISO 354:1985	ISO 354:1985
23	385 L 0203	ISO/DIS 7996	ISO 7996:1985
24	385 L 0490	ISO 5725	ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
25	385 L 0503	ISO 3310-1:1975	D ISO 3310-1:2000
26	385 L 0591	ISO 5725:1981	D ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
27	385 L 0647	ISO 3583:1982	D ISO 3583:1984
		ISO 7638:1985	D ISO 7638-1:1997, ISO 7638-2:1997
		ISO 3731	ISO 3731:1997
		ISO 1185	ISO 1185:1997
28	386 L 0188	ISO 6189:1983 [V] [+] D	ISO 6189:1983
		ISO 389:1975	D ISO 389-1:1998, ISO 389-2:1994, ISO 389-3:1994, ISO 389-4:1994, ISO 389-5:1998, ISO 389-7:1996
29	386 R 2429	ISO 937:1978	D ISO 937:1978
		ISO 1442:1973	D ISO 1442:1997
		ISO 1443:1973	D ISO 1443:1973
		ISO 936:1978	D ISO 936:1998
30	386 R 2930	ISO 3046-1:1981	D ISO 3046-1:1995
31	386 X 0666	ISO/DIS 6309-2:1985	D ISO 6309: 1987
32	387 X 0142	ISO/TR 5090:1977	D ISO/TR 5090:1977
33	388 L 0642	ISO/TR 7708:1983	D ISO 7708:1995

No.	Act etc.	References to standards	Current ISO standards
34	389 L 0173	ISO 730-1 ISO 8759-2 ISO 5676:1983 ISO 1728:1980	ISO 730-1:1994 ISO 8759-2:1998 D ISO 5676:1983 D ISO 1728:1980
35	389 L 0491	ISO 2575:1982	D ISO 2575:2000
36	389 R 0226	ISO 1442:1973 ISO 936:1978	D ISO 1442:1997 D ISO 936:1998
37	390 D 0515	ISO 3534:1977 ISO 5725:1986	D ISO 3534-1:1993, ISO 3534-2:1993, ISO 3534-3:1999 D ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
38	390 L 0207	ISO 5725	ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
39	390 L 239	ISO 4387 ISO 3400 ISO 8243	ISO 4387:2000 ISO 3400:1997 ISO 8243:1991
40	390 L 0630	ISO 6549:1980 ISO 4130:1978	D ISO 6549:1999 D ISO 4130:1978
41	391 L 0410	ISO 8317:1989	D ISO 8317:1989
42	391 L 0422	ISO 9128:1987 ISO 3583:1984 ISO 7638	D ISO 9128:1987 D ISO 3583:1984 ISO 7638-1:1997, ISO 7638-2:1997
43	391 L 0441	ISO 970	Withdrawn
44	391 L 0662	ISO 6487:1987	D ISO 6487:2000
45	391 X 0337	ISO/DIS 639 ISO 2014 ISO 3166 ISO 4217:1978	ISO 639:1988, ISO 639-2:1998 Withdrawn ISO 3166-1:1997, ISO 3166-2:1998, ISO 3166-3:1999 D ISO 4217:1995
46	392 D 0242	ISO/DIS 7498-2	ISO 7498-2:1998
47	392 L 0053	ISO 612:1978	D ISO 612:1978
48	392 L 0062	ISO 612:1978 ISO 1402:1984 ISO 6605:1986 ISO 7751:1983	D ISO 612:1978 D ISO 1402:1994 D ISO 6605:1986 D ISO 7751:1991
49	392 L 0069	ISO 1218 (E) ISO 2207 ISO 1392 ISO 3016 ISO/R 918 ISO 387 ISO 649-2 ISO 1183	Withdrawn ISO 2207:1980 ISO 1392:1977 ISO 3016:1994 ISO 918:1983 ISO 387:1977 ISO 649-2:1981 ISO 1183:1987

No.	Act etc.	References to standards	Current ISO standards
		ISO 901	ISO 901:1976
		ISO 758	ISO 758:1976
		ISO 3507	ISO 3507:1999
		ISO 304	ISO 304:1985
		ISO 1516	ISO 1516:1981
		ISO 3680	ISO 3680:1983
		ISO 1523	ISO 1523:1983
		ISO 3679	ISO 3679:1983
		ISO 2719	ISO 2719:1988
		ISO 4833	ISO 4833:1991
		ISO 8692	ISO 8692:1989
50	392 L 0097	ISO/DIS 10534 ISO/DIS 10844	ISO 10534-1:1996, ISO 10534-2:1998 ISO 10844:1994
51	393 D 0256	ISO 3534:1977	D ISO 3534-1:1993, ISO 3534-2:1993, ISO 3534-3:1999
		ISO 5725:1986	D ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
52	393 L 0021	ISO/DP 7225 ISO 10156:1990	ISO 7225:1994 D ISO 10156:1996
53	393 L 0073	ISO 5725	ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
54	393 L 0091	ISO 2575:1982	D ISO 2575:2000
55	393 L 0092	ISO 6742-1	ISO 6742-1:1987
56	393 R 2891	ISO 1442 ISO 937	ISO 1442:1997 ISO 037:1978
57	394 L0020	ISO/R 468 ISO 1302 ISO 337	Withdrawn ISO 1302:1992 ISO 337:1981
58	394 L 0037	ISO 8317 ISO/TR 9122	ISO 8317:1898 ISO/TR 9122-1:1989, ISO/TR 9122-2:1990, ISO/TR 9122-3:1993, ISO/TR 9122-4:1993, ISO/TR 9122-5:1993, ISO/TR 9122-6:1994
59	394 L 0055	ISO 9001 ISO 9002	ISO 9001:1994, ISO 9001:2000 ISO 9002:1994
60	394 X 0820	ISO 7372 ISO 9735	ISO 7372:1993 ISO 9735:1988
61	395 L 0008	ISO 4793	ISO 4793:1980
62	395 L 0032	ISO 5725	ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994

No.	Act etc.	References to standards	Current ISO standards
63	396 D 703	ISO 1043	ISO 1043-1:1997, ISO 1043-2:2000, ISO 1043-3:1996, ISO 1043-4:1998
64	396 L 0027	ISO 6487:1987	D ISO 6487:2000
65	396 L 0037	ISO 6487:1987	D ISO 6487:2000
66	396 L 0046	ISO 5725	ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
67	396 L 0047	ISO 7810 ISO 7816-1 ISO 10373	ISO/IEC 7810:1995 ISO/IEC 7816-1:1998 ISO/IEC 10373:1993, ISO/IEC 10373-1:1998, ISO/IEC 10373-2:1998, ISO/IEC 10373-3:2001, ISO/IEC 10373-5:1998
68	396 L 0049	ISO 10156:1990 ISO/DIS 10298:1995 ISO 2431:1984 ISO 1750:1981 ISO/R 148 ISO 3679:1983 ISO 3680:1983 ISO 1523:1983 ISO 1516:1981 ISO 2719:1988 ISO 2592:1973 ISO 2137:1985 ISO 3574:1986 ISO 535:1976 ISO 1183 ISO 1133 ISO 3036:1975	D ISO 10156:1996 D ISO 10298:1995 D ISO 2431:1993 D ISO 1750:1981 ISO 148:1983, ISO 148-2:1998, ISO 148-3:1998 D ISO 3679:1983 D ISO 3680:1983 D ISO 1523:1983 D ISO 1516:1981 D ISO 2719:1988 D ISO 2592:2000 D ISO 2137:1985 D ISO 3574:1999 D ISO 535:1991 ISO 1183:1987 ISO 1133:1997 D ISO 3036:1975
69	396 L 0050	ISO 7810	ISO/IEC 7810:1995
70	396 L 0054	ISO 3104 ISO 3105 ISO 3219 ISO/DP 7225	ISO 3104:1994 ISO 3105:1994 ISO 3219:1993 ISO 7225:1994
71	396 L 0098	ISO 8729 ISO 449 ISO 2269 ISO 10316 ISO 8728 ISO 9875 ISO 6182	ISO 8729:1997 ISO 449:1997 ISO 2269:1992 ISO 10316:1990 ISO 8728:1997 ISO 9875:2000 ISO 6182-1:1993, ISO 6182-2:1993, ISO 6182-3:1993, ISO 6182-4:1993, ISO 6182-5:1995

No.	Act etc.	References to standards		Current ISO standards
72	396 R 0322	ISO 3356:1975	D	ISO 3356:1975
		ISO 707		ISO 707:1997
		ISO 1924-2:1985	D	ISO 1924-2:1994
73	297 A 1217 (01)	ISO 9002		ISO 9002:1994
74	397 D 0265	ISO 14001:1996	D	ISO 14001:1996
75	397 D 0278	ISO 6579:1993 [R]	D	ISO 6579:1993
76	397 D 0836	ISO 9002		ISO 9002:1994
77	397 L 0024	ISO 105		ISO 105 [currently comprises 97 parts]
		ISO 3310-1		ISO 3310-1:2000
		ISO 2599		ISO 2599:1983
		ISO/DIS 10534		ISO 10534-1:1996, ISO 10534-2:1998
		ISO/DIS 10844		ISO 10844:1994
		ISO/R 468		Withdrawn
		ISO 1302		ISO 1302:1992
		ISO/TR 1417		ISO/TR 1417:1974
78	397 L 0027	ISO 612:1978	D	ISO 612:1978
79	397 L 0068	ISO 8174-4		ISO 8174-4:1997
		ISO 3046-3		ISO 3046-3:1989
		ISO 5165		ISO 5165:1998
		ISO 3675		ISO 3675:1998
		ISO 3405		ISO 3405:2000
		ISO 8574		ISO 8574:1990
		ISO 2719		ISO 2719:1988
		ISO 2160		ISO 2160:1998
		ISO 10370		ISO 10370:1993
80	298 A 0214 (02)	Future ISO standard		ISO 10990-4:1999, ISO 10990-5:1999
81	298 A 1016	ISO/DIS 13590		ISO 13590:1997
82	398 D 0094	ISO 6060 [G]		ISO 6060:1989
		ISO 9562 [G]		ISO 9562:1998
83	398 D 0227	ISO 6579:1993 [R]	D	ISO 6579:1993
84	398 D 0483	ISO 1043		ISO 1043-1:1997, ISO 1043-2:2000, ISO 1043-3:1996, ISO 1043-4:1998
85	398 D 0634	ISO 14001		ISO 14001:1996
		ISO/DIS 11466 [V]		ISO 11466:1995
		ISO 105-E04		ISO 105-E04:1994
86	398 D 0701	ISO 7810:1995	D	ISO 7810:1995
87	398 L 0012	ISO 9128:1987	D	ISO 9128:1987
		ISO 3583:1984	D	ISO 3583:1984
		ISO 7638-1985	D	ISO 7638-1:1997, ISO 7638-2:1997
		or ISO/DIS 7638:1996		ISO 7638-1-1997, ISO 7638-2:1997
		ISO 1185		ISO 1185:1997
		ISO 6310:1981	D	ISO 6310:2001
88	398 L 0014	ISO 612:1978	D	ISO 612:1978
		ISO 2416:1992	D	ISO 2416:1992

No.	Act etc.	References to standards	Current ISO standards
		ISO 10011-1,2,3:1991	D ISO 10011-1:1990, ISO 10011-2:1991, ISO 10011-3:1991
89	398 L 0068	ISO/DIS 15031-7	ISO 15031-7:2001
		ISO 8422:1991	D ISO 8422:1991
		ISO/DIS 15031-6	Not locatable
		ISO 2575:1982	D ISO 2575:2000
		ISO 9141-2	ISO 9141-2:1994
		ISO 11519-4	Not locatable
		ISO/DIS 15031-3	ISO/DIS 15031-3:2000
		ISO/DIS 15031-4	ISO/DIS 15031-4:2000
		ISO/DIS 15031-5	Not locatable
90	398 L 0069	ISO 3675:1995	D ISO 3675:1998
91	398 L 0083	ISO 7899-2	ISO 7899-2:2000
		ISO 5725	ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
92	398 L 0098	ISO 2431	ISO 2431:1993
		ISO 3104	ISO 3104:1994
		ISO 3105	ISO 3105:1994
		ISO 3219	ISO 3219:1993
93	398 R 2135	ISO 7810	ISO/IEC 7810:1995
		ISO 7816-1	ISO/IEC 7816-1:1998
		ISO 7816-2	ISO/IEC 7816-2:1999
		ISO 7816-3	ISO/IEC 7816-3:1997
		ISO/DIS 7816-4	ISO/IEC 7816-4:1995
		ISO/DIS 10373	ISO/IEC 10373:1993, ISO/IEC 10373-1:1998, ISO/IEC 10373-2:1998, ISO/IEC 10373-3:2001, ISO/IEC 10373-5:1998
94	399 D 0010	ISO 6504-1	ISO 6504-1:1983
		ISO 2813	ISO 2813:1994
		ISO 2812-1	ISO 2812-1:1993
95	399 D 0178	ISO 14001	ISO 14001:1996
		ISO 139	ISO 139:1973
		ISO 6060	ISO 6060:1989
		ISO 11480:1997	D ISO 11480:1997
		ISO 7827	ISO 7827:1994
		ISO 9887	ISO 9887:1992
		ISO 9888	ISO 9888:1999
		ISO 9439	ISO 9439:1999
		ISO 10707	ISO 10707:1994
		ISO 10708	ISO 10708:1997
		ISO 9408	ISO 9408:1999
		ISO 14593	ISO 14593:1999
		ISO 11733	ISO 11733:1995

No.	Act etc.	References to standards	Current ISO standards
		ISO 9562	ISO 9562:1998
		ISO 8288	ISO 8288:1986
		ISO 9174	ISO 9174:1998
		ISO 105-E04	ISO 105-E04:1994
		ISO 5077	ISO 5077:1984
		ISO 105-C06	ISO 105-C06:1994
		ISO 105-X12	ISO 105-X12:1993
		ISO 105-B02	ISO 105-B02:1994
96	399 D 0179	ISO 14001	ISO 14001:1996
		ISO 6060	ISO 6060:1989
97	399 D 0205	ISO 11469	ISO 11469:2000
98	399 D 0427	ISO 1043	ISO 1043-1:1997, ISO 1043-2:2000, ISO 1043-3:1996, ISO 1043-4:1998
99	399 D 0476	ISO 14001	ISO 14001:1996
		ISO 1043	ISO 1043-1:1997, ISO 1043:2:2000, ISO 1043-3:1996, ISO 1043-4:1998
100	399 D 0554	ISO 14001	ISO 14001:1996
		ISO 6060 [G]	ISO 6060:1989
		ISO 9562 [G]	ISO 9562:1998
		ISO 9001	ISO 9001:1994, ISO 9001:2000
		ISO 9002	ISO 9002:1994
101	399 D 0698	ISO 14001	ISO 14001:1996
		ISO 11469	ISO 11469:2000
102	399 L 0030	ISO 5725-1:1994	D ISO 5725-1:1994
		ISO/FDIS 10498	ISO/DIS 10498:1999
		ISO 7996:1985	D ISO 7996:1985
		ISO 9855:1993	D ISO 9855:1993
103	399 L 0032	ISO 8754:1992	D ISO 8754: 1992
		ISO 4259:1992	D ISO 4259:1992
104	399 L 0045	ISO 6503:1984	D ISO 6503:1984
105	399 L 0047	ISO 1750:1981 [N]	ISO 1750:181
106	399 L 0051	ISO 8666	DIN EN ISO 8666:2000
107	399 L 0096	ISO 5725	ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
		ISO 8422:1991	ISO 8422:1991
		ISO/DIS 11614	ISO 11614:1999
		ISO 6974	ISO 6974-1:2000, ISO 6974-2:2001, ISO 6974-3:2000, ISO 6974-4:2000, ISO 6974-5:2000
		ISO 6326-5	ISO 6326-5:1989
		ISO 7941	ISO 7941:1988
		ISO 8819	ISO 8819:1993
		ISO 6251	ISO 6251:1996
108	399 L 0102	ISO/DIS 15031-7:1998 D	ISO 15031-7:2001
		ISO 9141-2	ISO 9141-2:1994

No.	Act etc.	References to standards	Current ISO standards
		ISO/FDIS 11519-4	Not locatable
		ISO/FDIS 14230-4	ISO 13230-4:2000
		ISO/WD 15765-4	ISO/DIS 15765-4:2000
		ISO/DIS 15031-4:1998 D	ISO/DIS 15031-4:2000
		ISO/DIS 15031-5:1998 D	Not locatable
		ISO/DIS 15031-6:1998 D	Not locatable
		ISO/DIS 15031-3:1998 D	ISO/DIS 15031-3:2000
109	399 L 0103	ISO 31-1:1992 D	ISO 31-2:1992
110	399 R 2799	ISO 5725	ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
		ISO 707	ISO 707:1997
111	300 D 0040	ISO 11469	ISO 11469:2000
112	300 D 0045	ISO 14001	ISO 14001:1996
113	300 D 0368	ISO 2431	ISO 2431:1993
		ISO 3104	ISO 3104:1994
		ISO 3105	ISO 3105:1994
		ISO 3219	ISO 3219:1993
		ISO/DP 7225	ISO 7225:1994
114	300 D 0728	ISO 14001	ISO 14001:1996
115	300 L 0014	ISO 8528-1:1993 D	ISO 8528-1:1993
		ISO 3744:1995 D	ISO 3744:1995
		ISO 3746:1995 D	ISO 3746:1995
		ISO 10844:1994 D	ISO 10844:1994
		ISO 7960:1995 D	ISO 7960:1995
		ISO 9207:1995 D	ISO 9207:1995
		ISO 6395:1988 D	ISO 6395:1988
		ISO 11094:1991 D	ISO 11091:1991
		ISO 8528-10:1998 D	ISO 8528-10:1998
116	300 L 0032	ISO 3104	ISO 3104:1994
		ISO 3105	ISO 3105:1994
		ISO 3219	ISO 3219:1993
		ISO 8317:1989	ISO 8317:1989
		ISO 11683:1997 D	ISO 11683:1997
117	300 L 0060	ISO 5667-3:1995 D	ISO 5667-3:1994
118	300 L 0069	ISO 5725:1994 D	ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
119	300 L 0071	ISO 4259:1995 D	ISO 4259:1995
120	300 R 0824	ISO 712:1998 D	ISO 712:1998
		ISO 9648:1988 D	ISO 9648:1988
		ISO 5529:1992 D	ISO 5529:1992
		ISO 3093:1982 D	ISO 3093:1982
		ISO 7971-2:1995 D	ISO 7971-2:1995
121	300 R 1072	ISO 1442	ISO 1442:1997
		ISO 937	ISO 937:1978

No.	Act etc.	References to standards	Current ISO standards
122	300 R 1980	ISO 14001	ISO 14001:1996
123	300 R 2801	ISO 3781 ISO 5636-5	ISO 3781:1983 ISO 5636-5:1986
124	300 R 2870	ISO 3534-1 ISO 3696:1987 ISO 3507	ISO 3534-1:1993 D ISO 3696:1987 ISO 3507:1999
125	300 X 0053	ISO 4513 [N] ISO 2575 [N] ISO 4040 [N] ISO 3958 [N] ISO/DIS 15005 [N] ISO/DIS 15006 [N] ISO/DIS 15008 [N] ISO/DIS 11429 [N]	ISO 4513:1978 ISO 2575:2000 ISO 4040:1997 ISO 3958:1996 ISO/DIS 15005:2000 ISO/DIS 15006-1:1998 ISO/DIS 15008-1:1998 ISO 11429:1996
126	2000/C312/01 Ä	ISO 711 ISO 712 ISO 6450 ISO 3093 ISO 5529 ISO 7305 ISO 7301 ISO 662 ISO 663 ISO 660 ISO 5508 ISO 5509 ISO 6799 ISO 3961 ISO 3960 ISO 6463	ISO 711:1995 ISO 712:1998 ISO/DIS 6450:1991 ISO 3093:1982 ISO 5529:1992 ISO 7305:1998 ISO 7301:1998 ISO 662:1998 ISO 663:2000 ISO 660:1996 ISO 5508:1990 ISO 5509:2000 ISO 6799:1991 ISO 3961:1996 ISO 3960:1998 ISO 6463:1982
127	301 L 0003	ISO 789-10 ISO 612:1978 ISO 4004:1983 ISO 789-3:1993 ISO 789-6	ISO 789-10:1996 D ISO 612:1978 D ISO 4004:1983 D ISO 789-3:1993 ISO 789-6:1982
128	301 L 0027	ISO/DIS 16183:2000 ISO 6245 ISO 2719 ISO 1388-2 ISO 1388-4 ISO 759 ISO 760 ISO 4259 ISO 6974	D ISO/DIS 16183:2000 EN ISO 6245:1995 ISO 2719:1988 ISO 1388-2:1981 ISO 1388-4:1981 ISO 750:1981 ISO 760:1978 ISO 4259:1992 ISO 6974-1:2000, ISO 6974-2:2001, ISO 6974-3:2000, ISO 6974-4:2000, ISO 6974-5:2000

No.	Act etc.	References to standards	Current ISO standards
		ISO 6326-5	ISO 6326-5:1989
		ISO 7941	ISO 7941:1988
		ISO 8819	ISO 8819:1993
		ISO 6251	ISO 6251:1996
129	301 R 0213	ISO 3356:1975	D ISO 3356:1975
		ISO 5725:1994	D ISO 5725-1:1994, ISO 5725-2:1994, ISO 5725-3:1994, ISO 5725-4:1994, ISO 5725-5:1998, ISO 5725-6:1994
		ISO 8528:1991	D ISO 8528-1:1993, ISO 8528-2:1993, ISO 8528-3:1993, ISO 8528-4:1993, ISO 8528-5:1993, ISO 8528-6:1993, ISO 8528-7:1994, ISO 8528-8:1995, ISO 8528-9:1995, ISO 8528-10:1998, ISO 8528-12:1997
		ISO 707	ISO 707:1997
		ISO 648	ISO 648:1977
		ISO/R 835	ISO 835-1:1981, ISO 835-2:1981, ISO 835-3:1981, ISO 835-4:1981
130	301 R 0214	ISO 707	ISO 707:1997

Key:

- D** Reference to a specific date of issue of a standard (last column but one)
- Ä** Where reference is made to an international standard, any changes or revocation must be taken into account.
- G** Reference to an ISO standard or equivalent standards
- N** Stipulation that the most recent version of the standards in question are to be applied, or that the current version is applicable
- R** Reference to an ISO standard or a revised version of this standard
- V** Reference to an ISO standard or equivalent standard
- +** The standard is to be applied only with a certain amendment

Table 16: References to ISO standards in current proposals for Community legislation, and comparison with the current body of ISO standards (as of 30 April 2001)

No.	Proposal (COM doc.)	References to standards		Current ISO standards
1	(1999) 125	ISO 5725-1:1994	D	ISO 5725-1:1994
		ISO/FDIS 13694		ISO 13694:2000
2	(1999) 594	ISO 4387		ISO 4387:2000
		ISO 10315		ISO 10315:2000
		ISO 8454		ISO 8454:1995
		ISO 8243		ISO 8243:1991
3	(2000) 172	ISO 12098:1994	D	ISO 12098:1994
		ISO 7638:1985	D	ISO 7638-1:1997, ISO 7638-2:1997
		ISO 3795:1989	D	ISO 3795:1989
4	(2000) 179	ISO 9001:2000	D	ISO 9001:2000
		ISO 10011:1991	D	ISO 10011-1:1990, ISO 10011-2:1991, ISO 10011-3:1991
5	(2000) 468	ISO 1996-1:1982	D	ISO 1996-1:1982
		ISO 1996-2:1987	D	ISO 1996-2:1987
		ISO 9613-2		ISO 9613-2:1996
		ISO 8297:1994	D	ISO 8297:1994
6	(2000) 529	ISO 11784		ISO 11784:1996
		ISO 11785		ISO 11785:1996
7	(2000) 840	ISO 8178-4		ISO 8178-4:1996
		ISO/DIS 8168-4:1996	D	Standard not yet adopted [ISO 8168:1988]
		ISO/DIS 8258-1:1993	D	Standard not yet adopted [ISO 8258:1991]
		ISO 3046-3		ISO 3046-3:1989
		ISO 8178-1		ISO 8178-1:1996
		ISO 3675:1995	D	ISO 3675:1998
		ISO 4259		ISO 4259:1992

Table 17: References to IEC standards in current Community law, and comparison with the current body of IEC standards (as of 30 April 2001)

No.	Act etc.	References to standards		Current IEC standards
1	370 L 0157	IEC 179:1965	D	Replaced by IEC 60651 (1979)
2	370 L 0388	IEC 179:1965	D	Replaced by IEC 60651 (1979)
3	374 L 0151	IEC 179:1965	D	Replaced by IEC 60651 (1979)
4	376 L 0761	IEC 7004-95-1		Not locatable
		IEC 7004-95A-1		Not locatable
		IEC 7004-95B-1		Not locatable
5	376 L0891	IEC 28		IEC 60028 (1925-01)
		IEC 60:1962	D	IEC 60060-1 (1989-11); IEC 60060-2 (1984-11), last amended by IEC 60060-2-am1 (1996-03)
6	377 L 0311	IEC 179:1965	D	Replaced by IEC 60651 (1979)
7	379 L 0113	IEC 179:1973	D	Replaced by IEC 60651 (1979)
8	381 L 0334	IEC 179:1973	D	Replaced by IEC 60651 (1979)
9	381 L 1051	IEC 179:1973	D	Replaced by IEC 60651 (1979)
10	382 L 0130	IEC 61-2		IEC 60061-2 (1969-01), last amended by IEC 60061-2-am23 (2001-02)
11	384 L 0449	IEC 79-4		IEC 60079-4 (1975-01), last amended by IEC 60079-4-am1 (1995-07)
12	385 L 0405	IEC 651:1979	D	IEC 60651 (1979-01), last amended by 60651-am2 (2000-10)
		IEC 179:1973	D	Replaced by IEC 60651 (1979)
13	386 L 0188	IEC 651		IEC 60651 (1979-01), last amended by IEC 60651-am2 (2000-10)
		IEC 804		IEC 60804 (2000-10)
14	392 L 0097	IEC 179:1973	D	Replaced by IEC 60651 (1979)
15	393 L 0030	IEC 651:1979	D	IEC 60651 (1979-01), last amended by IEC 60651-am2 (2000-10)
		IEC 225:1966	D	Replaced by IEC 61260 (1995)
16	395 L 0056	IEC 529:1989	D	IEC 60529 (2001-02) Ed. 2.1 (consoli- dated edition)
		IEC 68-2-30:1980	D	IEC 60068-2-30:1980
		IEC 68-2-11:1981	D	IEC 60068-2-11:1981
		IEC 651:1979	D	IEC 60651 (1979-01), last amended by 60651-am2 (2000-10)
		IEC 225:1966	D	Replaced by IEC 61260 (1995)
17	396 L 0098	IEC 945		IEC 60945 (1996-11)
		IEC 936		IEC 60936-1 (1999-12), IEC 60 936-2 (1998-10)
		IEC 872		IEC 60872-1 (1998-09), IEC 60872-2 (1999-01), IEC 69872-3 (2000-08)
		IEC 1023		IEC 61023 (1999-07)

No.	Act etc.	References to standards	Current IEC standards
		IEC 1010	IEC 61010-1 (2001-02), IEC 61010-2-010 (1992-09), last amended by IEC 61010-2-010-am1 (1996-01), IEC 61010-2-020 (1992-09), last amended by 61010-2-020-am1 (1996-01), IEC 61010-2-031 (1993-02), IEC 61010-2-032 (1994-12), IEC 61010-2-041 (1995-12), IEC 61010-2-042 (1997-04), IEC 61010-2-043 (1997-04), IEC 61010-2-045 (2000-09), IEC 61010-2-051 (1995-08), IEC 61010-2-061 (1995-09), IEC/TR3 61010-3 (1997-07), IEC/TR3 61010-3-1 (1997-07), IEC/TR 61010-3-010 (1999-02), IEC/TR 61010-3-020 (1999-04), IEC/TR 61010-3-032 (2000-01), IEC/TR 61010-3-041 (1999-10), IEC/TR 61010-3-042 /1999-10), IEC/TR 61010-3-051 (1999-02), IEC/TR 61010-3-061 (1999-02)
		IEC 1075	IEC 61075 (1991-07)
		IEC 1135	IEC 61135 (1992-05)
		IEC 1108-1	IEC 61108-1 (1996-06)
		IEC 1097-1	IEC 61097-1 (1992-07)
		IEC 1097-2	IEC 61907-2 (1994-12)
		IEC 1097-3	IEC 61097-3 (1994-06)
		IEC 1097-4 (draft)	IEC 61097-4 (1994-11)
		IEC 1097-5 (draft)	IEC 61097-5 (1997-11)
		IEC 1097-6	IEC 61097-6 (1995-02)
		IEC 1097-7	IEC 61097-7 (1996-10)
		IEC 1097-8	IEC 61097-8 (1998-09)
		IEC 1097-9	IEC 61097-9 (1997-11)
		IEC 1097-10	IEC 61097-10 (1999-06)
		IEC 1097-11 (draft)	Not locatable
		IEC 1097-12 (draft)	IEC 61097-12 (1996-12)
		IEC 1097-15	Not locatable
18	397 L 0024	IEC 809	IEC 60809 (1996-01), last amended by IEC 60809-am1 (1996-09)
		IEC 61 (in preparation)	IEC 60061-1 (1969-01), last amended by IEC 60061-1-am26 (2001-02) IEC 60061-2 (1969-01), last amended by IEC 60061-2-am23 (2001-02)

No.	Act etc.	References to standards	Current IEC standards
			IEC 60061-3 (1969-01), last amended by IEC 60061-3-am25 (2001-02)
			IEC 60061-4 (1990-02), last amended by IEC 60061-4-am6 (2000-05)
		IEC 179:1973	D Replaced by IEC 60651 (1979)
19	298 A 1016	IEC 02/1992-05	D Not locatable
20	398 L 0018	IEC 92	IEC 92 [currently comprises 69 parts, e.g. IEC 60092-101:1994 and IEC 60092-507:2000]
21	399 L 0035	IEC 61996	IEC 61996 (2000-07)
22	301 D 0068	IEC 61619	IEC 61619 (1997-04)

Table 18: References to IEC standards in current proposals for Community laws, and comparison with the current body of IEC standards (as of 30 April 2001)

No.	Proposal (COM doc.)	References to standards	Current IEC standards
1	(1997) 644	IEC 92-504 IEC 801-2 IEC 801-3 IEC 801-4 IEC 801-5	Not locatable Replaced by IEC 61004-2 (1995) Replaced by IEC 61004-3 (1995) Replaced by IEC 61004-4 (1995) Not locatable
2	(1997) 680	IEC 651:1979 IEC 942	D IEC 60651 (1979-01), last amended by IEC 60651-am2 (2000-10) IEC 60942 (1997-11), last amended by IEC 60942-am1 (2000-10)
3	(1999) 328	IEC 555	Not locatable
4	(2000) 172	IEC 529	IEC 60529 (2001-02) Ed. 2.1 (consolidated version)
5	(2000) 802	IEC 61996	IEC 61996 (2000-07)

Table 19: References to ISO/IEC standards in current Community law and comparison with the current body of ISO/IEC standards (as of 30 April 2001)

No.	Act etc.	References to standards	Current ISO/IEC standards
1	300 R 2082	ISO/IEC TR 10000-1:1992 ISO/IEC TR 10000-2:1994 ISO/IEC 7776:1994 ISO/IEC 8208:1993 ISO/IEC ISP 10609-9:1992 ISO/IEC 7498-1:1994 ISO/IEC 8348:1993 ISO/IEC 8072:1994 ISO/IEC 8878:1992 ISO/IEC 9646-1:1994	ISO/IEC TR 10000-1:1998 ISO/IEC TR 10000-2:1998 ISO/IEC 7776:1995 ISO/IEC 8208:2000 ISO/IEC ISP 10609-9:1992 ISO/IEC 7498-1:1994 ISO/IEC 8348:1996 ISO/IEC 8072:1996 ISO/IEC 8878:1992 ISO/IEC 9646-1:1994
2	300 R 2729	ISO/IEC 17025	ISO/IEC 17025:1999

Table 20: References to European standards in current Community law and comparison with the current body of European standards (as of 30 April 2001)

No.	Act etc.	References to standards		Current European Standards
1	379 L 0196	EN 50014:1977	D	EN 50014:1997
		EN 50015:1977	D	EN 50015:1998
		EN 50016:1977	D	EN 50016:1995
		EN 50017:1977	D	EN 50017:1998
		EN 50018:1977	D	EN 50018:1994
		EN 50019:1977	D	EN 50019:1994
		EN 50020:1977	D	EN 50020:1994
2	379 L 0531	HD 376:1978	D	Not locatable
3	382 L 0130	EN 50014:1977	D	EN 50014:1997
		EN 50015:1977	D	EN 50015:1998
		EN 50016:1977	D	EN 50016:1995
		EN 50017:1977	D	EN 50017:1998
		EN 50018:1977	D	EN 50018:1994
		EN 50019:1977	D	EN 50019:1994
		EN 50020:1977	D	EN 50020:1994

(The directive itself reproduces amendments to the text of the standards verbatim and contains amendments to them!

– likewise directives 88/35/EWG, 91/269/EEC, 94/44/EC and 98/65/EC)

4	384 L 0449	EN 57		Not locatable
5	384 L 0539	HD 395-1:1979 [M]	D	Not locatable
6	390 L 0487	EN 50028:1987	D	EN 50028:1987
		EN 50039:1980	D	Not locatable
		EN 50050:1986	D	EN 50050:1986
		EN 50053-1:1987	D	EN 50053-1:1987
		EN 50053-2:1989	D	EN 59953-2:1989
		EN 50053-3:1989	D	EN 50053-3:1989
7	392 L 0053	EN 29002		EN ISO 9002:1994
8	392 L 0069	EN 57		Not locatable
9	392 R 2081	EN 45011:1989	D	EN 45011:1998
10	392 R 2082	EN 45011:1989	D	EN 45011:1998
11	393 D 0465	EN 45000 series		EN 45000 series
		EN 29001 [B]		EN ISO 9001:1994
		EN 29002 [B]		EN ISO 9002:1994
		EN 29003 [B]		EN ISO 9003:1994
12	394 L 0002	EN 153:1990	D	EN 153:1995
13	394 L 0057	EN 45004		EN 45004:1995
		EN 29001		EN ISO 9001:1994
14	394 X 0780	EN 10020		EN 10020:2000
15	394 X 0820	EN 29735		EN 29735:1992
		EN 27372		Not locatable

No.	Act etc.	References to standards	Current European Standards
16	395 L 0016	EN 29001 [B] EN 29002 [B] EN 29003 [B]	EN ISO 9001:1994 EN ISO 9002:1994 EN ISO 9003:1994
17	395 L 0047	I-ETS 300 352 I-ETS 300 250	ETS 300 352:1994 ETS 300 250:1993
18	395 R 1935	EN 45011:1989	D EN 45011:1998
19	395 Y 1011	prENV GDF 2.1	Not locatable
20	396 D 0703	EN 28960 EN 45001 series	EN 28960:1993 EN 45001 series
21	396 L 0049	EN 417:1992 EN 22719:1994	D EN 417:1992 D EN 22719:1994
22	396 L 0057	EN 153:1995	D EN 153:1995
23	396 L 0098	EN 3	EN 3-1:1996, EN 3-2:1996, EN 3-3:1994, EN 3-4:1996, EN 3-5:1996, EN 3-6:1996
24	396 R 1524	prENV 278/9/#62 prENV 278/9/#64 prENV 278/9/#65 I-ETS 300 674	[V] Not locatable [V] Not locatable [V] Not locatable [V] Not locatable
25	397 D 0265	EN ISO 14001:1996	D EN ISO 14001:1996
26	397 D 0283	prEN 1948	EN 1948-1:1996, EN 1948-2:1997, EN 1948-3:1997
27	397 L 0051	ETS 300 686 ETS 300 687 ETS 300 688	ETS 300 686:1996 ETS 300 687:1996 ETS 300688:1996
28	397 L 0053	EN 50014:1992 EN 50015:1994 EN 50016:1995 EN 50017:1994 EN 50018:1994 EN 50019:1994 EN 50020:1994	D EN 50014:1997 D EN 50015:1998 D EN 50016:1995 D EN 50017:1998 D EN 50018:1994 D EN 50019:1994 D EN 50020:1994
29	397 L 0068	EN 29002 EN 24260 EN 116 EN ISO 6245	EN ISO 9002:1994 EN ISO 24260:1994 EN 116:1997 EN ISO 6245:1995
30	397 R 1427	EN ISO 661 EN ISO 5555	EN ISO 661:1995 EN ISO 5555:1995
31	397 R 1932	EN 45001	EN 45001:1989
32	398 D 0080	ETS 300 247 ETS 300 247/A1 ETS 300 288 ETS 300 288/A1 ETS 300 289 ETS 300 418	ETS 300 247:1994 ETS 300 247/A1:1995 ETS 300 288:1994 ETS 300 288/A1:1995 ETS 300 289:1994 ETS 300 418:1995

No.	Act etc.	References to standards	Current European Standards
		ETS 300 419	ETS 300 419:1995
		ETS 300 448	ETS 300 448:1996
		ETS 300 449	ETS 300 449:1996
		ETS 300 451	ETS 300 451:1996
		ETS 300 452	ETS 300 452:1996
33	398 D 0094	EN 420	EN 420:1994
		prEN ISO 14184-1	EN ISO 14184-1:1998
34	398 D 0483	EN 50242	EN 50452:1998
		EN 45001	EN 45001:1989
35	398 D 0634	prEN ISO 14184-1	EN ISO 14184-1:1998
		EN 312-1	EN 312-1:1996
		EN 622-1	EN 622-1: 1997
		prEN 1957:1997	D EN 1957:2000
36	398 L 0010	ETSI ETR 207	Not locatable
37	398 L 0014	EN ISO 9002:1994	D EN ISO 9002:1994
		EN 45012	EN 45012:1998
38	398 L 0069	EN 25163:1993	D EN 25163:1993
		EN 25164:1993	D EN 25164:1993
		EN 12:1993	D EN 12:1993
		EN ISO 3405:1988	D EN ISO 3405:2000
		prEN 12177	EN 12177:1998
		EN ISO 7536:1996	D EN ISO 7536:1996
		EN 1601:1997	D EN 1601:1997
		EN ISO 6246:1997	D EN ISO 6246:1997
		prEN ISO/DIS 14596	EN ISO 14596:1998
		EN ISO 2160:1995	D EN ISO 2160:1998
		EN 237:1996	D EN 237:1996
		EN ISO 5165:1998	D EN ISO 5165:1998
		EN ISO 3675:1995	D EN ISO 3675:1998
		EN 22719:1993	D EN 22719:1993
		EN 116:1981	D EN 116:1997
		EN ISO 3104:1996	D EN ISO 3104:1996
		EN ISO 10370:1995	D EN ISO 10370:1995
		EN ISO 6245:1995	D EN ISO 6245:1995
		EN ISO 12937:1998	D prEN ISO 12937:2000
		EN ISO 12205:1996	D EN ISO 1205:1996
		EN 12196:1997	D EN 12196:1997
39	398 R 2248	EN ISO 661	EN ISO 661:1995
40	398 R 2402	EN 1753:1997	D EN 1753:1997
41	399 D 0178	prEN ISO 14184-1	EN ISO 14184-1:1998
42	399 D 0179	prEN ISO 14184-1	EN ISO 14184-1:1998
		EN 1392	EN 1392:1998
		prEN 12769	prEN 12769:1997
		prEN 12770	EN 12770:1999
		prEN 12746	EN 12746:2000
		prEN 13072	prEN 13072:1997

No.	Act etc.	References to standards	Current European Standards
43	399 D 0205	EN 45001	EN 45001:1989
44	399 D 0303	ETSI EG 201 121	Not locatable
45	399 D 0427	EN 45001 [G]	EN 45001:1989
46	399 D 0568	EN 50285	EN 50285:1999
		EN 60064	EN60064:1995
		EN 60901	EN 60901:1996
		EN 60969	EN 60969:1993
		EN 60081	EN 60081:1998
		EN 60929	EN 60929:1992
47	399 D 0698	EN 45001	EN 45001:1989
48	399 L 0030	EN 12341	EN 12341:1998
49	399 L 0032	prEN ISO 14596	EN ISO 14596:1998
		EN ISO 24260:1987 D	EN 24260:1994
50	399 L 0096	EN 437:1993 D	EN 437:1993
		EN ISO 5165:1998 D	EN ISO 5165:1998
		EN ISO 3675:1995 D	EN ISO 3675:1998
		EN ISO 3405:1998 D	EN ISO 3405:2000
		EN 27719:1993 D	EN 22719:1993
		EN 116:1981 D	EN 116:1997
		EN ISO 3104:1996 D	EN ISO 3104:1996
		prEN ISO/DIS 14596:1998	EN ISO 14596:1998
		EN ISO 2160:1995 D	EN ISO 2160:1998
		EN ISO 10370	EN ISO 10370:1995
		EN ISO 6245:1995 D	EN ISO 6245:1995
		EN ISO 12937:1995 D	pr EN ISO 12937:2000
		EN ISO 12205:1996 D	EN ISO 1205:1996
		EN 12916:1997 D	EN 12196:1997
		EN 589	EN 589:2000
		EN 24260	EN ISO 24260:1994
51	399 R 0379	EN ISO 661	EN ISO 661:1995
		EN ISO 5555	EN ISO 5555:1995
52	399 R 2316	EN ISO 9167-1:1995 D	EN ISO 9167-1:1995
		EN ISO 9167-2:1997 D	EN ISO9167-2:1997
		EN ISO 5508:1995 D	EN ISO 5508:1995
53	300 D 0040	EN 153	EN 153:1995
		EN 28960	EN 28960:1993
54	300 D 0045	EN 60456:1999 D	EN 60456:1999
55	300 D 0368	EN 417	EN 417:1992
56	300 D 0637	ETS 300 698	ETS 300 698:1997
57	300 L 0014	EN ISO 3744:1995 D	EN ISO 3744:1995
		EN ISO 3746:1995 D	EN ISO 3746:1995
		EN 500-4 Rev. 1:1998 D	EN 500-4 Rev. 1:1998
		EN 791:1995 D	EN 791:1995
		EN 840-1:1997 D	EN 840-1:1995

No.	Act etc.	References to standards	Current European Standards
58	300 L 0032	EN 862:1997 D	EN 862:2000
		EN ISO 11683:1997 D	EN ISO 11683:1997
59	300 L 0055	EN 50294:1998 D	EN 50294:1998
		EN 60920	EN 60920:1991
60	300 L 0060	EN 27828:1994 D	EN 27828:1994
		EN 28265:1994 D	EN 28265:1994
		EN ISO 9391:1995 D	EN ISO 9391:1995
		EN ISO 8689-1:1999 D	EN ISO 8689-1:2000
		EN ISO 8689-2:1999 D	EN ISO 8689-2:2000
61	300 L 0071	EN 25163:1993 D	EN 25163:1993
		EN 25164:1993 D	EN 25164:1993
		prEN 1306-1:1997 D	prEN 1306-1:1997
		prEN ISO 3405:1998 D	EN ISO 3405:2000
		EN 12177:1998 D	EN 12177:1998
		EN 238:1996 D	EN 238:1996
		EN 1601:1997 D	EN 1601:1997
		prEN 13132:1998 D	EN 13132:2000
		EN ISO 14596:1998 D	EN ISO 14596:1998
		EN ISO 8754:1995 D	EN ISO 8754:1995
		EN 24260:1994 D	EN 24260:1994
		EN 237:1996 D	EN 237:1996
		EN ISO 5165:1998 D	EN ISO 5165:1998
		EN ISO 3675:1998 D	EN ISO 3675:1998
		EN ISO 12185:1996 D	EN ISO 12185:1996
62	300 R 1760	EN 45001	EN 45001:1989
63	300 R 1980	EN ISO 14040	EN ISO 14040:1997
		EN ISO 14024	EN ISO 14024:2000
64	300 R 2729	EN 45001	EN 45001:1989
65	300 R 2801	EN ISO 1924-2	EN ISO 1924-2:1994
66	300 S 0283	EN 10011	Not locatable
		EN 10025	EN 10025:1990
67	300 S 0284	EN 10011	Not locatable
		EN 10025	EN 10025:1990
68	301 D 0022	ETSI EG 201 769-1	Not locatable
69	301 D 0068	EN 12766-1 [N]	EN 12766-1:2000
		prEN 12766-2 [N]	prEN 12766-2:2000
70	301 D 0148	ETS 300 718	ETS 300 718:1997
71	301 L 0022	prEN 13804	Not locatable
72	301 L 0027	EN 589	EN 589:2000
		EN 24260	EN ISO 24260:1994
73	301 R 0214	EN 770	EN 770:1994
74	301 R 0455	EN ISO 661	EN ISO 661:1995
		EN ISO 5554	EN ISO 5555:1995
75	301 R 0761	EN ISO 14001:1996 D	EN ISO 14001:1996

No.	Act etc.	References to standards	Current European Standards
76	301 X 0290	EN 50121	EN 50121:2000, EN 50121-2:2000, EN 50121-3-1:2000, N 50121-3-1:2000, EN 50121-4:2000, EN 50121-5:2000
77	301 X 0337	EN ISO 11290-1 EN ISO 11290-2	EN ISO 11290-1:1996 EN ISO 11290-2:1998

Key:

- [B]** Standard is amended as required in order to take into account the particular features of the products to which it applies.
- [G]** The requirements of these standards or standards of equivalent systems are to be complied with.
- [M]** The directive itself contains amendments to the content of the standard referred to.
- [N]** Reference is made not only to the standard, but also to its subsequently amended versions.
- [V]** Should the standards specify stricter requirements, the conditions contained therein take precedence.

Table 21: References to European standards in current proposals for Community law, and comparison with the current body of European standards (as of 30 April 2001)

No.	Proposal (COM doc.)	References to standards	Current European Standards
1	(1997) 276	EN 3-1	EN 3-1:1996
2	(1997) 644	EN 1305 EN 395 EN 711 EN 1306	EN 1305:1996 EN 395:1993 EN 711:1995 EN 1306:1996
3	(1998) 526	prEN 1949:1995 prEN 722-1:1995	D EN 1949:1995 D EN 722-1:1995
4	(2000) 172	EN 50014 EN 50015 EN 50016 EN 50017 EN 50018 EN 50019 EN 50020 EN 50028	EN 50014:1997 EN 50015:1998 EN 50016:1995 EN 50017:1998 EN 50018:1994 EN 50019:1994 EN 50020:1994 EN 50028:1987
5	(2000) 181	EN 50294:1998	D EN 50294:1998
6	(2000) 392	ETSI ETR 207 ETSI EG 201 769-1:2000	Not locatable Not locatable
7	(2000) 468	EN ISO 3744:1995 EN ISO 3746:1995	D EN ISO 3744:1995 D EN ISO 3746:1995
8	(2000) 818	EN 12438:1998 EN 1753:1997	D Not locatable D EN 1753:1997
9	(2000) 840	EN 25163:1993 EN 25164:1993 EN 12:1993 EN ISO 3405:1988 EN 12177:1998 EN ISO 7536:1996 EN 1601:1997 EN ISO 6246:1997 EN ISO 14596:1998 EN ISO 2160:1995 EN 237:1996	D EN 25163:1993 D EN 25164:1993 D EN 12:1993 D EN ISO 3405:2000 D EN 12177:1998 D EN ISO 7536:1996 D EN 1601:1997 D EN ISO 6246:1997 D EN ISO 14596:1998 D EN ISO 2160:1998 D EN 237:1996

Table 22: References to anticipated European standards in Community law or in proposals for the same (as of 30 April 2001)

No.	Document		References to anticipated European standards
a) Current Community law:			
1	388 L 0642		<ul style="list-style-type: none"> – CEN standards with general requirements for the performance of measuring procedures and devices for workplace measurements together with provisions on testing – CEN specifications for the collection of suspended material at the workplace
2	394 L 0027		CEN standards on all the test methods used in demonstrating the conformity of products with this Directive (Member States must comply with the Directive not later than six months after publication by the Commission in the Official Journal of the European Communities of the standards adopted by CEN.)
3	394 L 0067	N	CEN standards (elaborated on the basis of orders placed by the Commission) on the incineration of hazardous waste (sampling and analysis of all pollutants including dioxins and furans as well as reference measurement methods to calibrate automated measurement systems)
4	300 L 0060		<ul style="list-style-type: none"> – Relevant CEN/ISO standards for macrophyte sampling when developed – Relevant CEN/ISO standards for fish sampling when developed – Relevant CEN/ISO standards for diatom sampling when developed – All relevant CEN/ISO standards for physico-chemical parameters – Any relevant CEN/ISO standards for hydromorphological parameters
5	300 L 0069	A	– CEN standards with detailed test protocols for the measurement of air pollution with benzene and carbon monoxide
		N	– CEN standard for a reference method for the sampling/analysis of benzene
		N	– CEN standard for a reference method for the analysis of carbon monoxide
b) Current legislative proposals:			
6	(1998) 415		<ul style="list-style-type: none"> – CEN standards for discontinuous measurements of the emission of certain pollutants into the air from large combustion plants
		N	– CEN standards for continuous measurements of the emission of certain pollutants into the air from large combustion plants (i.e. sampling and analysis of relevant pollutants and process parameters as well as reference measurement methods to calibrate automated measurement systems)

7	(2000) 177	N	Standards of CEN or ISO for the measurement of air pollution on heavy metals (sampling and analysis of all pollutants as well as reference measurement methods to calibrate automated measurement systems)
8	(2000) 393		Standards and/or specifications (adopted by European standardisation bodies such as ETSI or the Joint European Standards Institution CEN/CENELEC) for the provision of services, technical interfaces and/or network functions [In the absence of such standards and/or specifications, Member States shall encourage the implementation of international standards or recommendations adopted by the International Telecommunications Union (ITU), the International Organisation for Standardisation (ISO) or the International Electrotechnical Committee (IEC). Where international standards exist, Member States shall take all reasonable measures to ensure that European standardisation bodies, such as ETSI or CEN/CENELEC use them, or the relevant parts of them, as a basis for the standards they develop, except where such international standards or the relevant parts of them would be ineffective.]
9	(2000) 613		CEN standards for a reference method for analysis of ozone and calibration of ozone instruments

A Until CEN standards are adopted, the Commission will issue certain guidelines.

N While awaiting the elaboration of CEN standards, national standards shall apply.

Table 23: References to IMO provisions in current Community law (as of 30 April 2001)

No.	Act etc.	References to IMO provisions
1	391 R 0613	IMO Resolution A.212 (VII): Bulk Chemical Code IMO Resolution A.328 (IX): Bulk Gas Carrier
2	393 L 0075	IMDG Code: International Maritime Dangerous Goods Code [A] IBC Code: IMO International Code for the construction and equipment of ships carrying dangerous chemicals in bulk [A] IGC Code: IMO International Code for the construction and equipment of ships carrying liquefied gases in bulk [A] IMO Resolution A.648 (16) of 19 October 1989: General principles for ship reporting systems and ship reporting requirements, including guidelines for reporting incidents involving dangerous goods, harmful substances and for marine pollutants [A]
3	393 Y 1007	IMO Resolution A.722 (17) on the application of tonnage measurement of segregated ballast tanks in oil tankers IMO Resolution on the IMO identification number for ships
4	394 L 0057	IMO Resolution A.739 (18) on guidelines for the authorization of organizations acting on behalf of the administration [A]
5	394 R 2978	IMO Resolution A.722 (17) of 6 November 1991 on the application of tonnage measurement of segregated ballast tanks in oil tankers IMO Resolution A.747 (18) of 4 November 1993 on the application of tonnage measurement of segregated ballast tanks in oil tankers
6	394 Y 1231 (06)	IMO Resolution A.741 (18): International Management Code for the safe operation of ships and for pollution prevention IMO Resolution A.581 (14): Mooring of road vehicles on roll-on/roll-off passenger ferries
7	395 L 0021	IMO Resolution A.741 (18): International Management Code for the safe operation of ships and for pollution prevention IMO Resolution A.466 (XII): Procedures for the control of ships IMO Resolution A.481 (XII): Principles of safe manning IMO Resolution A.542 (13): Procedures for the control of ships and discharges under annex I to Marpol 73/78 IMO Resolution MEPC 26 (23): Procedures for the control of ships and discharges under annex II to Marpol 73/78 IMO Resolution A.742 (18): Procedures for the control of operational requirements related to the safety of ships and pollution prevention IMO Resolution A.744 (18): Survey report file
8	395 R 3051	ISM Code: International Safety Management Code for the safe operation of ships and for pollution prevention (IMO Resolution A.741 (18) of 4 November 1993)
9	396 L 0098	<u>International Testing Standards:</u> IMO Resolution A.689 (17) IMO Resolution A.658 (16)

No.	Act etc.	References to IMO provisions
		IMO Resolution A.762 (18)
		IMO Resolution A.530 (13)
		IMO Resolution A.697 (17)
		IMO Resolution A.694 (17)
		IMO Resolution A.384 (X)
		MEPC 60 (33)
		MEPC 5 (XIII)
		IMO Resolution A.444 (XI)
		IMO Resolution A.586 (14)
		MEPC 2 (VI)
		IMO Resolution A.214 (VII)
		IMO Resolution A.687 (17)
		IMO MSC/Circular 549
		IMO Resolution A.382 (X)
		IMO Resolution A.424 (XI)
		IMO Resolution A.477 (XII)
		IMO Resolution A.422 (XI)
		IMO Resolution A.478 (XII)
		IMO Resolution A.526 (13)
		IMO Resolution A.665 (16)
		IMO Resolution A.479 (XII)
		IMO Resolution A.524 (13)
		IMO Resolution A.609 (15)
		IMO Resolution A.525 (13)
		IMO Resolution A.570 (14)
		IMO Resolution A.664 (16)
		IMO Resolution A.700 (17)
		IMO Resolution A.662 (16)
		IMO Resolution A.763 (18)
		IMO Resolution A.696 (17)
		IMO Resolution A.661 (16)
		IMO Resolution A.383 (X)
		IMO Resolution A.421 (XI)
		IMO Resolution A.571 (14)
		IMO Resolution A.610 (15)
		IMO Resolution A.613 (15)
		IMO Resolution A.698 (17)
		IMO Resolution A.663 (16)
		IMO Resolution A.613 (15)
		IMO Resolution A.753 (18)
		IMO Resolution A.123 (V)
		IMO Resolution A 754 (18)
		IMO MSC/Circular 373/Rev. 1
		IMO MSC/Circular 450/Rev. 1
		IMO Resolution A.472 (XII)
		IMO Resolution A.612 (15)

No.	Act etc.	References to IMO provisions
10	397 L 0058	IMO Resolution A.789 (19) on specifications on the survey and certification functions of recognized organizations acting on behalf of the administration
11	398 L 0018	<p>Code on Intact Stabilities for all types of ships covered by IMO Instruments Contained in IMO Resolution A.749 (18) of 4 November 1993 [A]</p> <p>International Code for Safety of High Speed Craft contained in Resolution MSC 36 (63) of 20 May 1994 [A]</p> <p>Code for Safety of Dynamically Supported Craft contained in IMO Resolution A.373 (X) of 14 November 1977, as amended by Resolution MSC 37 (63) of 19 May 1994 – DSC Code</p> <p>IMO Resolution A.746 (18) of 4 November 1993 on survey guidelines under the harmonized system of survey and certification</p> <p>IMO Resolution A.167 (IV)</p> <p>IMO Resolution A.562 (14)</p> <p>Calculation procedure to assess the survivability characteristics of existing ro-ro passenger ships when using a simplified method based upon IMO-Resolution A.265 (VIII)</p> <p>IMO Resolution A.799 (19) „Revised recommendations on test methods for qualifying marine construction materials as non-combustible“</p> <p>IMO Resolution A.754 (18)</p> <p>IMO Resolution A.653 (16): Test methods for bulkhead, ceiling and deck finishing materials</p> <p>IMO Resolution A.471 (XII)</p> <p>IMO Resolution A.563 (14)</p> <p>IMO Resolution A.652 (16): Fire test procedures of upholstered furniture</p> <p>MSC/Circular 668 Of 30 December 1994</p> <p>IMO Resolution A.757 (18)</p> <p>IMO Resolution A.752 (18)</p> <p>IMO Resolution A.760 (18): Symbols related to life-saving appliances and arrangements</p> <p>IMO Resolution A.653 (16): Test procedure for the resistance to the propagation of flame</p> <p>IMO Resolution A.687 (17): Fire test procedures for material which will not readily ignite</p> <p>IMO Resolution A.800 (19): Guidelines for an approved equivalent sprinkler system</p> <p>IMO Resolution A.123 (V)</p> <p>IMO Resolution A.686 (17): Code on alarms and indicators</p> <p>IMO Resolution A.691 (17)</p> <p>IMO Resolution A.656 (16)</p> <p>IMO Resolution A.771 (18)</p> <p>IMO Resolution A.229 (VII): Recommendations for an helicopter pick-up area</p> <p>IMO Resolution A.600 (15): IMO ship identification number</p>

No.	Act etc.	References to IMO provisions
12	398 L 0042	IMO Resolution A.787 (19) IMO Resolution A.481 (XII): Principles of safe manning
13	398 L 0055	IMO Resolution A.748 (18): Code for the safe carriage of irradiated nuclear fuel, plutonium and high-level radioactive wastes in flasks on board (INF Code)
14	398 L 0074	IMO Resolution A.851 (20) General principles for ship reporting systems and ship reporting requirements, including guidelines for reporting incidents involving dangerous goods, harmful substances and/or marine pollutants
15	399 L 0035	International Code for Safety of High-Speed Craft contained in Resolution MSC 36 (63) of 20 May 1994 [A] IMO Resolution A.849 (20): Code for investigation of marine casualties and incidents IMO Resolution A.746 (18) on survey guidelines under the harmonised system of survey and certification [A] IMO Resolution A.861 (20) on performance standards for voyage data recorders IMO Resolution A.795 (19) on shore-based navigational guidance systems and other information schemes IMO Resolution A.852 (20) on guidelines for a structure of an integrated system of contingency

Explanation:

- A** Reference to an IMO provision as it stands at the date of adoption of the relevant Directive or Regulation

Table 24: References to IMO provisions in current proposals for Community laws (as of 30 April 2001)

No.	Proposal (COM doc.)	References to IMO provisions
1	(2000) 179	Code of Practice for the safe loading and unloading of bulk carriers, as contained in the annex to IMO Assembly Resolution A.862 (20) – BLU Code IMO Code of safe practice for solid bulk cargoes
2	(2000) 802 (01)	Resolution A.851 (20) „General principles for ship reporting systems and ship reporting requirements including guidelines for reporting incidents involving dangerous goods, harmful substances and/or marine pollutants“ ISM Code: International Safety Management Code providing for the safe operation of ships and for pollution prevention IMDG Code: International Maritime Dangerous Goods Code IBC Code: IMO International Code for the construction and equipment of ships carrying dangerous chemicals in the bulk IGC Code: IMO International Code for the construction and equipment of ships carrying liquefied gases in bulk BC Code: IMO Code of safe practice for solid bulk cargoes INF Code: IMO Code for the safe carriage of irradiated nuclear fuel, plutonium and high-level radioactive waste in flasks and ships Any ship (...) must (...) be fitted with an automatic identification system which meets the performance standards drawn up by the IMO (...) IMO Resolution A.861 (20): Performance standards for voyage data recorders (black boxes)
3	(2000) 848	IMO Resolution MEPC 64 (36) IMO Resolution A.746 (18): Survey guidelines under the harmonised system of survey and certification
4	(2000) 849	IMO Resolution A.847 (20) on guidelines to assist flag states in the implementation of IMO instruments IMO Resolution A.739 (18) on guidelines for the authorisation of organizations acting on behalf of the administration IMO-MSC/Circular 710 MEPC Circular 307 on model agreement for the authorisation of recognised organizations acting on behalf of the administration IMO Resolution A.746 (18) on survey guidelines under the harmonized system of survey and certification IMO Resolution A.788 (19) on guidelines on implementation of the International Safety Management (ISM) Code by administrations
5	(2000) 850	IMO Resolution A.744 (18) on assessment of the construction and equipment of ships
6	(2001) 46	IMO FAL Convention on Facilitation of Marine Traffic

Table 25: References to ASTM standards in current Community law (as of 30 April 2001)

No.	Act etc.	References to ASTM standards	M.?	Content of the ASTM standards
1	369 L 0493	ASTM E 92-65	M	Measurement of Vickers hardness
2	370 L 0220	ASTM D 908-67	M	Technical data of the reference fuel to be used testing vehicles equipped with a gasoline-fuelled engine: determination of the octane number
		ASTM D 1298-67	M	ditto: determination of density
		ASTM D 323-58	M	ditto: determination of the Reid vapour pressure
		ASTM D 86-67	M	ditto: measurement of distillation
		ASTM D 1319-66 T	M	ditto: hydrocarbon analysis
		ASTM D 525-55	M	ditto: measurement of oxidation stability
		ASTM D 381-64	M	ditto: measurement of existent gum
		ASTM D 1266-64 T	M	ditto: measurement of sulphur content
		ASTM D 526-66	M	ditto: measurement of lead content
3	372 L 0306	ASTM D 1298-67	M	Specifications of reference fuel prescribed for approval tests and to verify conformity of production: determination of density
		ASTM D 86-67	M	ditto: measurement of distillation
		ASTM D 976-66	M	ditto: determination of the Cetane index
		ASTM D 445-65	M	ditto: measurement of kinematic viscosity
		ASTM D 129-64	M	ditto: measurement of sulphur content
		ASTM D 93-71	M	ditto: determination of the flash-point
		ASTM D 2500-66	M	ditto: determination of the cloud point
		ASTM D 611-64	M	ditto: determination of aniline point
		ASTM D 524-64	M	ditto: measurement of carbon residue
		ASTM D 482-63	M	ditto: measurement of ash content
		ASTM D 95-70	M	ditto: measurement of water content
		ASTM D 130-68	M	ditto: copper-corrosion test
		ASTM D 2-68 (ap. VI)	M	ditto: determination of net calorific value
		ASTM D 974-64	M	ditto: determination of the strong acid number
4	373 L 0146	ASTM D 93-66	A	Method of operation for the measurement with the Pensky-Martens apparatus
		ASTM D 56-70	M	Method of operation for the measurement with the Tag apparatus

No.	Act etc.	References to ASTM standards	M.?	Content of the ASTM standards
5	377 L 0537	ASTM D 1298-67	M	Specifications of reference fuel prescribed for approval tests and to verify conformity of production: determination of density
		ASTM D 86-67	M	ditto: measurement of distillation
		ASTM D 976-66	M	ditto: determination of the Cetane index
		ASTM D 445-65	M	ditto: measurement of kinematic viscosity
		ASTM D 129-64	M	ditto: measurement of sulphur content
		ASTM D 93-71	M	ditto: determination of the flash-point
		ASTM D 2500-66	M	ditto: determination of the cloud point
		ASTM D 611-64	M	ditto: determination of aniline point
		ASTM D 524-64	M	ditto: measurement of carbon residue
		ASTM D 482-63	M	ditto: measurement of ash content
		ASTM D 95-70	M	ditto: measurement of water content
		ASTM D 130-68	M	ditto: copper-corrosion test
		ASTM D 2-68 (ap.VI)	M	ditto: determination of net calorific value
		ASTM D 974-64	M	ditto: determination of the strong acid number
6	377 L 0541	ASTM D 735	M	Characteristics of the absorbing material
		ASTM D 736	M	Measurement of the low-temperature brittleners
		ASTM D 573	M	Determination of ageing in air
		ASTM No. 1 Oil	M	Test method of immersion in oil
		ASTM No. 3 Oil	M	Test method of immersion in oil
7	383 L 0351 *	ASTM D 2699	M	Technical data of the reference fuel to be used testing vehicles equipped with a gasoline-fuelled engine: determination of the octane number
		ASTM D 1298	M	ditto: determination of density
		ASTM D 323	M	ditto: determination of the Reid vapour number
		ASTM D 86	M	ditto: measurement of distillation
		ASTM D 1319	M	ditto: hydrocarbon analysis
		ASTM D 525	M	ditto: measurement of oxidation stability
		ASTM D 381	M	ditto: measurement of existent gum
		ASTM D 1266, 2622, 2785	C	ditto: measurement of sulphur content
		ASTM D 3341	M	ditto: measurement of lead content
		ASTM D 1298	M	Technical data of the reference fuel to be used testing vehicles equipped with a Diesel engine: determination of density
		ASTM D 976	M	ditto: determination of the Cetane index
		ASTM D 86	M	ditto: measurement of distillation

No.	Act etc.	References to ASTM standards	M.?	Content of the ASTM standards
		ASTM D 445	M	ditto: determination of viscosity
		ASTM D 1266, 2622, 2785	C	ditto: measurement of sulphur content
		ASTM D 93	M	ditto: determination of the flash point
		ASTM D 189	M	ditto: determination of the Conradson carbon residue
		ASTM D 482	M	ditto: measurement of ash content
		ASTM D 95, ASTM D 1744	C	ditto: measurement of water content
		ASTM D 130	M	ditto: measurement of copper corrosion
		ASTM D 974	M	ditto: determination of the neutralization number
		ASTM D 3244	M	Defining a basis for petroleum product quality disputes
8	383 R 1354	ASTM D 1709	M	Resistance of a Polyethylene film to a dart impact test
9	384 L 0449	ANSI/ASTM D 3451-76	B	Standard recommended practices for testing polymeric powder coatings with the Kofler hot-bar
		ASTM E 1-71	A, G	Requirements for thermometers
		ASTM E 324-69	B	Standard method for relative initial and final melting points and the melting range of organic chemicals
		ANSI/ASTM D 2133-66	B	Standard specification for acetal resin injection moulding and extrusion materials
		ASTM D 1120-72	B	Determination of the molecular weight by boiling point evaluation with ebulliometers
		ASTM D 2879-75	B	Isoteniscope
		ASTM D 792	B	Specific gravity and density of plastics by displacement
		ASTM D 949-55, ASTM D 1296-67, ASTM D 1481-62, ASTM D 1298	B	Hydrostatic balance for liquid substances: density, specific gravity or API gravity of crude petroleum and liquid petroleum products by hydrometer methods
		ASTM D 297	B	Pycnometer methods for liquid substances: chemical analysis of rubber products
		ASTM D 2111	B	Pycnometer methods for liquid substances: halogenated organic compounds
		ASTM D 56	A	Non-equilibrium method for measurements with the Tag apparatus

No.	Act etc.	References to ASTM standards	M.?	Content of the ASTM standards
		ASTM 8013, ASTM D 33	A	Non-equilibrium method for measure- with the Pensky-Martens apparatus
		ASTM E 659-78	A	Test conditions for the determination of the temperature of self-ignition of volatile liquids and of gases
10	388 L 0077 *	ASTM D 613	M	Test methods for the determination of technical characteristics of reference fuel prescribed for approval tests and to verify conformity of production: determination of the Cetane number
		ASTM D 1298	M	ditto: determination of density
		ASTM D 86	M	ditto: measurement of distillation
		ASTM D 93	M	ditto: determination of the flash point
		ASTM D 445	M	ditto: determination of viscosity
		ASTM D 1266, 2622, 2785	C	ditto: measurement of sulphur content
		ASTM D 130	M	ditto: measurement of copper corrosion
		ASTM D 189	M	ditto: determination of the Conradson carbon residue
		ASTM D 482	M	ditto: measurement of ash content
		ASTM D 95, ASTM D 1744	C	ditto: measurement of water content
		ASTM D 2274	M	ditto: measurement of the oxidation stability
		ASTM D 3244	M	Defining a basis for petroleum product quality disputes
11	389 L 0491 *	ASTM D 613	M	Test methods for the determination of technical characteristics of reference fuel prescribed for approval tests and to verify conformity of production: determination of the Cetane number
		ASTM D 1298	M	ditto: determination of density
		ASTM D 86	M	ditto: measurement of distillation
		ASTM D 93	M	ditto: determination of the flash point
		ASTM D 445	M	ditto: determination of viscosity
		ASTM D 1266, 2622, 2785	C	ditto: measurement of sulphur content
		ASTM D 130	M	ditto: measurement of copper corrosion
		ASTM D 189	M	ditto: determination of the Conradson carbon residue
		ASTM D 482	M	ditto: measurement of ash content
		ASTM D 95, ASTM D 1744	C	ditto: measurement of water content
		ASTM D 2274	M	ditto: measurement of the oxidation stability

No.	Act etc.	References to ASTM standards	M.?	Content of the ASTM standards
		ASTM D 3244	M	Defining a basis for petroleum product quality disputes
12	391 L 0441 *	ASTM D 2699	M	Technical data of the reference fuel to be used for testing vehicles equipped with positive-ignition engines: research octane number
		ASTM D 2700	M	ditto: motor octane number
		ASTM D 1298	M	ditto: determination of density
		ASTM D 323	M	ditto: determination of the reid vapour pressure
		ASTM D 86	M	ditto: measurement of distillation
		ASTM D 1319	M	ditto: analysis of olefins
		ASTM D 3606, ASTM D 2267	C	ditto: analysis of aromatics
		ASTM D 1319	M	ditto: analysis of saturates
		ASTM D 525	M	ditto: measurement of the oxidation stability
		ASTM D 1266, 2622, 2785	C	ditto: measurement of sulphur content
		ASTM D 130	M	ditto: measurement of the copper corrosion
		ASTM D 3237	M	ditto: measurement of lead content
		ASTM D 3231	M	ditto: measurement of phosphorous content
		ASTM D 3244	M	Defining a basis for petroleum product quality disputes
		ASTM D 613	M	Technical data of the reference fuel to be used for testing vehicles equipped with a Diesel engine: determination of the Cetane number
		ASTM D 1298	M	ditto: determination of density
		ASTM D 86	M	ditto: measurement of distillation
		ASTM D 93	M	ditto: determination of the flash point
		ASTM D 445	M	ditto: determination of viscosity
		ASTM D 1266, 2622, 2785	C	ditto: measurement of sulphur content
		ASTM D 130	M	ditto: measurement of the copper corrosion
		ASTM D 189	M	ditto: determination of the Conradson carbon residue
		ASTM D 482	M	ditto: measurement of ash content
		ASTM D 95, ASTM D 1744	C	ditto: measurement of water content
		ASTM D 2274	M	ditto: measurement of the oxidation stability

		ASTM D 3244	M	Defining a basis for petroleum product quality disputes
13	391 R 2568	ASTM STP No. 440	M	Intensity rating test for analyzing olive oil
14	392 L 0069	ASTM E 537-76, ASTM E 473-85, ASTM E 472-86	A	Differential thermal analysis, differential scanning calorimetry
		ASTM D 97-66	M	Standard test method for pour point of petroleum oils
		ASTM E 1-71	A, G	Requirements for thermometers
		ASTM E 324-69	B	Standard test method for relative initial and final melting points and the melting range of organic chemicals
		ANSI/ASTM D 3451-76	B	Standard recommended practices for testing polymeric powder coatings with the Kofler hot-bar
		ANSI/ASTM D 2133-66	B	Standard specification for acetal resin injection moulding and extrusion materials
		ASTM D 1120-72	B	Determination of the molecular weight by boiling point evaluation with ebulliometers
		ASTM D 792	A	Specific gravity and density of plastics by displacement
		ASTM D 941-55, ASTM D 1296-67, ASTM D 1481-62, ASTM D 1298	A	Hydrostatic balance for liquid substances: density, specific gravity or API gravity of crude petroleum and liquid petroleum products by hydrometer method
		ASTM D 297,	A	Pycnometer methods for liquid substances: chemical analysis of rubber products
		ASTM D 2111		Pycnometer methods for liquid substances: halogenated organic compounds
		ASTM D 2879-86	A	Standard test method for vapour pressure
		ASTM D 56	B	Determination of the flash point with the Tag apparatus
		ASTM D 93	A	Determination of the flash point with the Pensky-Martens apparatus
		ASTM E 659-78	A	Determination of the auto-ignition temperature of liquids and gases
15	392 R 3576	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
16	393 R 3665	ASTM D 86	M	Distillation of petroleum products
17	394 R 3254	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
18	396 L 0049	ASTM D 4359-90	A	Test for determining fluidity

No.	Act etc.	References to ASTM standards	M.?	Content of the ASTM standards
		ASTM G 31-72 (extended in 1990)	Z	Test for determining the potential of substances to destruct skin tissue
		ASTM D 56-93	B	Non-equilibrium method for measurements with the Tag apparatus
		ASTM D 93-94	A	Non-equilibrium method for measurements with the Pensky-Martens apparatus
19	297 A 0222 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
20	297 A 0716 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
21	297 A 1218 (02)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
22	297 D 0123	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
23	297 D 0407 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
24	297 D 0524 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
25	297 D 0723 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
26	297 D 0723 (02)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
27	297 D 0723 (03)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
28	297 D 0805 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
29	297 D 0811 (05)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
30	397 L 0068	ASTM D 4052	A	Determination of density
		ASTM D 482	M	Determination of ash content
		ASTM D 95, D 1744	C	Determination of water content
		ASTM D 2274	M	Measurement of the oxidation stability
		ASTM D 3244	A	Determination of the Cetane number
31	298 A 0202 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
32	298 A 0220 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
33	298 A 0309 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
34	298 A 0330 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products

No.	Act etc.	References to ASTM standards	M.?	Content of the ASTM standards
35	398 L 0069	ASTM D 1319-95	M	Method for analysing olefins, aromatics and salucates in petrol
		ASTM D 3231-94	M	Method for the determination of the phosphorous content of petrol
		ASTM D 974-95	M	Method for the determination of the neutralisation number of Diesel fuel
		ASTM D 3536-91	B	Method for the determination of the molecular weight in case manual digitisation is used
36	398 L 0070	ASTM D 3536-91	M	Method for analysing olefins and aromatics in petrol
		ASTM 1319-95	M	Method for analysing aromatics in petrol
37	398 L 0073	ASTM D 3536-91	B	Method for the determination of molecular weight in case manual digitisation is used
38	299 A 0226	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
39	299 A 0313 (01)	ASTM A 516	M	Water-hydrogen sulphide exchange process in steel
40	299 A 1204 (02)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
41	399 L 0032	ASTM D 86	M	Distillation of petroleum products
42	399 L 0096	ASTM D 974-95	M	Method for the determination of the neutralization number of Diesel fuel
43	399 R 0046	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
44	399 R 2204	ASTM D 86	M	Distillation of petroleum products
		ASTM D 874	M	Determination of the viscosity of petroleum products
		ASTM D 939-54	M	Determination of the saponification index
		ASTM D 97	M	Determination of the viscosity of petroleum products
		ASTM D 445	M	Determination of the kinematic viscosity
		ASTM D 1500	M	Determination of colour after dilution of petroleum products
		ASTM D 721	M	Determination of oil content
45	200 A 0318 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
46	200 A 0621 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
47	200 A 1215 (01)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products

No.	Act etc.	References to ASTM standards	M.?	Content of the ASTM standards
		ASTM D 1003-16	M	Method for the measurement of optical clouding of films
48	297 D 0630 (02)	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
49	300 L 0003	ASTM D 735	M	Characteristics of the absorbing material
		ASTM D 736	M	Measurement of the low-temperature brittleners
		ASTM D 573	M	Measurement of ageing in air
		ASTM No. 1 Oil	M	Test method of immersion in oil
		ASTM No. 3 Oil	M	Test method of immersion in oil
50	300 L 0071	ASTM D 1319-95	M	Method for analysing olefins and aromatics in petrol
51	300 R 1602	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
52	300 R 2388	ASTM D 86	M	Distillation of petroleum products
		ASTM D 874	M	Determination of viscosity of petroleum products
		ASTM D 939-54	M	Determination of the saponification index
		ASTM D 97	M	Determination of viscosity of petroleum products
		ASTM D 445	M	Determination of the kinematic viscosity
		ASTM D 1500	M	Determination of colour after dilution of petroleum products
		ASTM D 721	M	Determination of oil content
53	300 R 2801	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 3417	M	Method for the determination of the melting point of polypropylene
		ASTM D 638	M	Method for the determination of the elongation at break
		ASTM D 817-72	M	Method for the determination of the propionyl content and of the viscosity of cellulose acetate propionate
		ASTM D 638	M	Method for the determination of tensile strength at break
		ASTM D 882	M	Method for the determination of the elongation at break
		ASTM D 1204	M	Method for the determination of the shrinkage of a polyethylene film
		ASTM D 257-93	M	Method for the determination of the surface resistivity of a polyethylene film
		ASTM D 523	M	Method for the determination of the degree of gloss of a polyethylene film
		ASTM D 751	M	Method for the determination of the grab breaking strength

No.	Act etc.	References to ASTM standards	M.?	Content of the ASTM standards
		ASTM D 2584-94	M	Method for the determination of the loss on ignition
54	301 L 0027 *	ASTM D 5501	M	Determination of the mass of alcohol
		ASTM D 4052	M	Determination of the density of ethanol
		ASTM D 1209	M	Determination of the colour of ethanol
		ASTM D 5453	M	Determination of the sulphur content of ethanol
		ASTM D 1617	M	Determination of the ester content of ethanol
55	301 R 0082	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products

Key:

- M Only the ASTM indicated applies to the corresponding requirements and test/measurement procedures.
- A The ASTM standard indicated is only one of a number of alternatives which are expressly stated.
- B The ASTM standard indicated applies alone to the measurement/test procedure stated; a selection may however be made from a number of different procedures.
- C A selection may be made from several ASTM standards for the measurement/test procedure concerned.
- G Other equivalent standards which are however not stated explicitly may be considered for fulfilment of the relevant requirements in addition to the standards stated.
- Z The standard stated describes a permissible test procedure.
- * Announcement that equivalent ISO procedures are to be adopted as soon as they are published for all characteristics stated.

Table 26: References to ASTM standards in current proposals for Community laws (as of 30 April 2001)

No.	Act etc.	References to ASTM standards	M.?	Content of the ASTM standards
1	(1998) 526	ASTM D 2156	M	Method for the determination of the absorption coefficient of exhaust emissions
2	(1999) 622	ASTM D 455	M	Method for the determination of the viscosity of synthetic poly-alpha-olefin
3	(2000) 63	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
		ASTM D 1003-16	M	Method for the measurement of optical clouding of films
4	(2000) 432	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
5	(2000) 732	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
		ASTM D 1003-16	M	Method for the measurement of optical clouding of films
6	(2000) 840	ASTM D 1319-95	M	Methods for analysing olefins, aromatics and saturates in petrol
		ASTM D 3231-94	M	Method for the determination of the phosphorous content of petrol
7	(2001) 90	ASTM D 1266-59 T	M	Desulphurization with hydrogen
		ASTM D 86	M	Distillation of petroleum products
		ASTM D 1003-16	M	Method for the measurement of optical clouding of films

M Reference is made only to ASTM standards for the measurement/test procedure concerned.