

Unclassified

TD/TC/WP(98)36/FINAL



Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

OLIS : 28-Jan-1999

Dist. : 29-Jan-1999

PARIS

Or. Eng.

**TRADE DIRECTORATE
TRADE COMMITTEE**

**TD/TC/WP(98)36/FINAL
Unclassified**

Working Party of the Trade Committee

REGULATORY REFORM AND INTERNATIONAL STANDARDISATION

73893

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Acknowledgement

This document was prepared for discussion in the Trade Committee Working Party. It was prepared by Akira Kawamoto of the Trade Directorate, based on work by Raymond Schonfeld, consultant, under the supervision of Anthony Kleitz. The OECD secretariat wishes to thank the many organisations which contributed data in this project, notably the World Trade Organisation, ISO, and other national and international standardisation bodies.

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1. Executive Summary

1. The leading players in the field of international standards share the perception that trade liberalisation has moved on from its earlier focus on tariffs, quotas, and related issues, and into the area of NTBs (non-tariff barriers); that standardisation forms a legitimate area of study in that context; and specifically that increasing attention needs to be devoted to making standards more relevant to the needs of trade and of the market. In the words of the president-elect of ISO: *standards should be economic instruments with technical content*. The attempt by OECD to contribute to that goal is broadly welcomed.

2. The scope of this report covers not only voluntary texts (**standards *stricto sensu***) but also standards that have been incorporated in texts with regulatory force (**technical regulations**). It considers only those with an identifiable link to products traded, where the goal of *one product, one test, accepted everywhere*, could be postulated. Other standards not directly related to trade, such as those for in-factory health and safety, or for processes beyond quality management affecting the product, are excluded here.

3. In this field, there is no trade-based justification for OECD to concentrate on specific sectors, such as high technology, to the exclusion of others. The impact of standards on trade is so widespread that, on purely economic grounds, almost all sectors would justify attention; one estimate claims that up to 80% of trade (equivalent to around \$4 trillion annually) is affected by standards or associated technical regulations.

4. Attempts to optimise the contribution of international standards to trade liberalisation must deal with a more diversified world than is conventionally imagined. The standards world is not homogeneous and dominated by a limited number of Geneva-based international bodies and their affiliates (notably ISO). Instead, the world shows a diverse mixture of organisations, in many of which the primary role is played by government or industry. It is not their number which is striking, but the diversity of their structure and mission. Such diversity is demonstrated by the three groups of standards bodies listed in detail in Appendix 1: classic international standards bodies; formal standardisers, some of whose standards are used internationally; ad hoc standardisers, some of whose standards are used internationally.

5. The involvement of regulators as direct players in international standardisation is one important and additional element in the diversity. In the ISO model, the participation of regulators is today not automatic (national delegations may or may not include them, and no regulator participates automatically and *ipso facto* in policy-making councils or technical committees). Nevertheless, some international standards bodies involve regulators as of right, with the stated objective of elaborating standards suitable for regulatory harmonisation. Global examples include chemicals, pharmaceuticals, automotive parts, telecommunications, foods, and measuring instruments.

6. Outside the regulatory field, the emergence of standardisation *consortia* is also striking: ad hoc groups with a clear, short-term purpose, often in a fast-moving area of technology with massive impact, but without any evident permanent mission. Some of the more established standardisation bodies deliberately try to develop mechanisms for co-operating with these fast-moving outsiders, while others prefer to ignore them.

7. The variety evident in the players in standardisation suggests a need for closer analysis of exactly how they operate. Is there an “optimum” model? No consensus emerges, and this study suggests that it will only be possible for the players in this field to decide what is “optimum” if there is total transparency about how the different models operate and what they achieve. In other words, transparency is a valid goal in its own right.

8. Beyond the issue of structure, several variables in standardisation activity deserve attention. The activities are those of regulators, the standardisation bodies themselves, and industry.

9. At government level, regulators adopt a range of approaches. In any given area, their work may 1) concern product standards, or conformity assessment, or both; 2) deal only with issues of the protection of the consumer or the worker (safety, hygiene, health, prevention of fraud) or aim wider, as in the example of foods, where mandatory, *quality standards* co-exist alongside hygiene standards; 3) use any of a number of models for linking standards to regulations and 4) develop agreements either at multilateral level (in the WTO or other bodies), or bilaterally (e.g., USA/EU).

10. The efficiency of the standardisation process in the established standards bodies is perceived as a particular area for attention. Today, that attention focuses on 1) the nature of the product line (categories of standards document); 2) the depth and scope of the standards, and notably the distinction between criteria for end-performance and related testing and other descriptive specifications developed for the convenience of industry; 3) the inherent speed and complexity of the standards development process (while classic standardisation bodies emphasise the value of electronic data interchange to speed up what remains a highly formalised system, others concentrate on making the process itself less formal); 4) the implementation of adopted standards, since standards only have value if they are used; and 5) the ability to weed out obsolete or irrelevant texts.

11. The commitment of industry to standardisation is also perceived as a critical variable. Paradoxically, however, the strongest industry participation in standards development doesn't seem to lead to closer involvement with the classic standards bodies, but to side-stepping them: industry leadership is achieved through organisations that are completely industry-run. Again, there is no consensus on whether there is an optimum model, or whether diversity should be encouraged.

2. Purpose of this report

12. Past analysis from the trade policy perspective in the context of the OECD regulatory reform project¹ has revealed that use of internationally harmonised standards is an important way to overcome national regulatory barriers. It has also been pointed out that the issue of the quality of international standards and the standardisation process is increasingly attracting the attention of policy-makers, and in some cases there is a recognised need for improvement. Such recognition led to one of the policy recommendations produced at the time of the 1997 OECD Ministerial meeting:

Develop and use wherever possible internationally harmonised standards as a basis for domestic regulations, while collaborating with other countries to review and improve international standards to assure that they continue to achieve intended policy goals efficiently and effectively.

¹ *Product Standards, Conformity Assessment and Regulatory Reform*, chapter 6, The OECD Report on Regulatory Reform, Vol. I: Sectoral Studies (1997), OECD.

13. The current report represents the outcome of initial research responding to this recommendation. It attempts to present an analytical inventory of standardising activities that affect international trade. It provides an overview of the issues involved, identifies the players, and highlights elements that are felt to determine the quality of international standards themselves and of the process behind their development.

14. In this, the essential fact-finding nature of the report is emphasised. The primary goal is not to provide independent judgement on the effectiveness of standardisation or of regulators. Rather, it is a stocktaking, or inventory, of what the players themselves are doing and what the players perceive to be important.

15. These factual findings are intended to provide a basis for discussion and definition of focused action programmes, hopefully contributing to a better functioning of standardisation.

3. Definitions

3.1 *The need for focus*

16. The scope of standardisation is vast. For example, standards can cover raw, unprocessed products; manufactured products from toys to the most complex aerospace specifications; services covering anything from hotel star-ratings to complex standards for financial services; production processes for those products or services; testing, conformity assessment, certification, or quality assurance procedures for them; health and safety at the workplace, and the environment. Some of those subjects are highly sensitive politically: for example, developing countries have expressed public resentment of attempts by the industrialised world to impose its own standards of environmental practice or worker protection.

17. While the breadth of the field suggests a need for focus, the need is reinforced by discussion over the meaning of the term *standard* and *international standard*, and in particular over whether regulations can constitute standards and vice versa.

18. It is therefore appropriate to attempt to define with some precision the areas which offer the most practical opportunities for OECD to make a significant contribution. A summary of conclusions appears in Section 3.5 below.

3.2 *The activities to be targeted*

19. Standards considered here are those **with a directly identifiable link to products traded:** notably, descriptive standards for products; standards for product function and performance (including safety, health, hygiene and interconnectivity issues); and quality assurance standards for products. The report also focuses on procedures for testing, conformity assessment and certification of those products, because of the part they play in the market operation of standards.

20. External evidence confirms the importance attributed to that category of standard. The goal of *one product, one test, accepted everywhere* is widely referred to in trade discussions (e.g., in the current Trans-Atlantic Business Dialogue, or TABD, between the EU and North America, or in APEC).

21. Several other categories of standard are not covered here: those concerning services, processes (except when directly linked to the quality of the final product), health and safety at the workplace, and the environment. Their exclusion does not imply that they are unsuitable for international co-ordination -- indeed, many of them are used or applied by manufacturing industry; however, for a variety of reasons related to practicality or political sensitivity, they seem to offer fewer opportunities for concrete results under the current research project.

3.3 *What is a standard?*

22. Although many elements of the definition appear widely accepted, there is confusion about whether a *standard* can be developed or subsequently used as a regulatory instrument or not. Since this project, within OECD, has a clear link with *Regulatory Reform*, it is appropriate to consider whether any work by OECD should include activities which lead to documents with regulatory force.

23. If standardisation is taken to encompass regulatory activities, then there must be consequences both for the involvement of regulatory authorities in standards development and for the co-ordination between regulation and standardisation. Conversely, if standardisation is defined as an activity entirely separable from regulatory development, led by industry and with complete independence from regulators, then involvement and co-ordination are less relevant. However, even in the hypothesis of completely independent standardisation activities, it should not be forgotten that their end-products may often be subsequently used for regulatory purposes.

24. Faced with varied definitions on this issue,² one can notice a number of common elements, which are essential for a technical specification to be considered a standard, such as its elaboration by **consensus** and its subsequent **consistent use**. Definitions are less unanimous on the voluntary or mandatory nature of standards, since WTO and EU definitions stress their **voluntary** nature, while ISO definitions encompass both voluntary and mandatory requirements, even if the voluntary character of the entire standards development process is emphasised.

25. For the purposes of this report it appears thus important to focus on specifications which are market-driven, actually used by the market and elaborated through some sort of agreement, whether exclusively by industry or with the involvement of regulators; excluding any specifications that are decided by regulatory authorities and imposed upon the market. However, technical specifications that correspond to those criteria will be covered by this report even in the cases where these specifications have been subsequently given a mandatory status that departs from their original status as voluntary documents.

3.4 *What is an “international standard”?*

26. One of the goals of this work defined by OECD is to “*use harmonised standards and rigorously review international standards*”. So what does the term “*international standard*” mean? Whose standards are these? This question is essential given the commitments taken by OECD Member States in the context of the WTO TBT Agreement.

² See **Appendix 3** to this report for fuller details

27. Definition here is also difficult, and complicated by the fact that standardisers themselves do not agree on the definition. The central element in the disagreement is whether an *international standard* is simply one which benefits from *de facto* or *de jure* international acceptance and use by the industry, or whether it must come from a demonstrably *international* body in the sense of one which has an international representation of national members and an international voting structure based on those national members. Some of the most reputable organisations in the standardisation world have contradictory views on the subject.

28. This report uses the former definition. There exist indeed technical specifications which have been elaborated at a national or regional level, yet are widely used by industry. Although they do not qualify as international standards under the latter definition, such standards are covered by this report because of their considerable impact on the operation of some industrial sectors. Discarding them would compromise the accuracy of this fact-finding survey.

3.5 *Conclusions: the coverage of this report*

29. **The areas or subjects of standardisation** covered in this report are those with a directly identifiable link to products traded: notably, descriptive standards for products themselves; standards for product function and performance (including safety, health, hygiene and interconnectivity issues); quality assurance standards for those products; and procedures for testing, conformity assessment and certification of those products.

30. **A standard** is considered to be a document which meets the criteria common to ISO, WTO/TBT and EU definitions: *a document approved by a recognised body that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.* For the purposes of this report no distinction will be made between documents which are incorporated in some form into regulatory instruments (standards incorporated into technical regulations) and those whose use remains entirely voluntary (standards *stricto sensu*); both are covered within the scope of the report.

31. An **international standard** is considered to be a standard with a significant *de facto* international use and acceptability. The scope will not be limited to standards produced by the major, recognised international standards bodies of which ISO is the most widely respected example.

4. **Standardisation and Trade**

32. If standards are judged to have an impact on global trade liberalisation, what is the trade that is affected, and for which products are standards developed and/or used, and where should the analysis of the role and potential of standardisation be directed?

4.1 *Current values of trade*

33. Since this research has concentrated on trade in products,³ figures for world merchandise exports provide a base: US \$5 trillion in 1996.

Global merchandise trade in 1996	<u>billion in US\$</u>
Agricultural and food products	586
Minerals	574
Manufactured products	3750
Chemicals	474
Iron and steel	141
Other semi-manufactures	393
Machinery and transport equipment*	1985
Textiles	150
Clothing	163
Other consumer goods	444

* machinery includes office and telecommunications equipment and automotive products (62% of total), as well as machinery and transport equipment.

Source: OECD Annual Report

4.2 *The value of eliminating technical barriers*

34. Separately, attempts are made to estimate the effects of barriers to trade, or of their elimination. These are generally less precise, and quantitative analysis of that kind is outside the scope of this work. It may suffice to quote the WTO, which has tried to give a short, public answer to the question: *What is the effect of the WTO on world trade?* It does not distinguish between category of barrier, and answers: *“Obtaining a precise figure is difficult. In 1994, economists at what was then GATT estimated that the [WTO] agreements could contribute \$184 to \$510 billion to the world economy by 2005.”*⁴

35. No global calculation is known to the writer of this report which quantifies the benefits of the elimination of global *technical* barriers, or barriers caused by standardisation specifically. Attempts tend to concentrate on specific sectors for specific countries (for example, the US government has put a value on US agricultural exports which are affected by technical barriers⁵; and the EU and its trading partners have conducted extensive research into the potential benefits of MRAs, or Mutual Recognition Agreements, in the field of conformity assessment).

³ See Chapters 3.2 and 3.5 above for the definition of the scope of the work in this sense.

⁴ Internet, at <http://www.wto.org/wto/faqs/faq.htm>

⁵ In a 1997 Staff Paper of the Economic Research Service of the Commercial Agriculture Division of the US Department of Commerce (Staff Paper Number AGES-9705), it was estimated (p. 21) that technical barriers to trade deprived U.S. exporters of \$5 billion annually in sales. 90% of that total was attributed to SPS regulations (i.e., sanitary and phytosanitary), and the remaining 10% was due to other regulations such as packaging or labelling.

36. However, one important recent calculation offers a figure which may give an indirect basis for order-of-magnitude global extrapolation. A 1996 study commissioned by the EU included an evaluation of the economic importance of technical barriers to trade in the EU. Although the EU itself regards the study as broad-brush only, and feels that its figures cannot be presented as hard fact, the study estimated that:

- 76% of all intra-EU trade was affected by technical regulations (both national and harmonised at the European level).
- sectors affected by regulatory trade barriers accounted for 21% of intra-EU trade and 29% of gross value added.

37. That study treated technical specifications – for the products themselves (including packaging, marking, or labelling) or for associated activities, such as testing and conformity assessment– as the central element, beyond the texts of regulations, in these intra-EU technical barriers.

38. Also in 1996, the US government estimated that EU harmonisation of national technical regulations would by then have covered over half of US exports to the EU.⁶

39. Even if no direct extrapolation is possible from these figures to the global level, the percentages are significant, and show the breadth of the impact of standardisation.

4.3 Sectors affected by standardisation

40. If up to 80% of trade is affected by standards -- as the previous section suggests -- then automatically most sectors must be covered, and any effort by OECD to improve the standardisation process must be broad and multi-sectoral in scope. That conclusion can be reinforced from a number of sources.

41. For example, the standards organisations themselves – and notably ISO - produce sectoral breakdowns of their standards. ISO's main breakdown is the *International Classification System* for standards.⁷ It covers most sectors of trade.

42. Separately from ISO, the practical example of the EU provides evidence of the sectoral breadth of the impact of standardisation. In around 30 sectors, the EU has developed some form of harmonised technical regulation EU experience is highly relevant in the context of this study, since the EU has over 30 years of experience, in the most developed regional trade liberalisation programme in the world to date.

43. Other examples exist to demonstrate the wide range of sectors affected by standardisation in international efforts towards trade liberalisation. In APEC, a wide-ranging programme has been launched. The USA has this year successfully negotiated its first multi-sectoral mutual recognition agreement with the EU (limited to conformity assessment), and the EU has negotiated or is negotiating similar agreements with several other countries.

⁶ 1996 US Dept. of Commerce Trade Estimate Report on Foreign Trade Barriers, European Union chapter USAT TR6, April 1996, p.7.

⁷ The list is accessible on the ISO Internet site: <http://www.iso.ch/cate/cat.html>

44. All this means, in addition, that in any work in this field, there is no reason to concentrate attention on high technology to the exclusion of traditional products. Indeed, it would be dangerous to do so, and a review of a separate, recent OECD report illustrates well the need for technical programmes to cover a wide range of trade and economic activity:

*“Industrial countries devote too much effort to promoting new technology in the small “high-tech” sector, rather than fostering innovation and technology diffusion more broadly through the economy, ministers heard yesterday.....The OECD....insisted in a report to its ministerial meeting that new technology should promote jobs rather than destroy them.....Technology policies continue to be piecemeal, with insufficient attention given to linkages within national innovation systems and to the broader structural reform agenda.”*⁸

45. So many of these sectors are of great economic importance that there is little justification for attempting to use economic criteria for selecting priority areas for assessing standardisation: most sectors would qualify. Selection of any sectoral priorities should therefore be based on other considerations, such as identifiable opportunities for action in the field of standardisation.

46. In addition to a search for sectoral opportunities, opportunities should be sought for multi-sectoral action aimed at the process of standardisation or the use of standards.

5. The players in international standardisation

5.1 The first impression of international standardisation

47. To many people – from global organisations like the WTO downwards – *international standardisation* concentrates on activities managed from an area in or within 100 metres of a single, short street in Geneva: the Rue de Varembe, which is within easy walking distance of both the United Nations and the World Trade Organisation, and where three of the best-known global organisations are located: ISO (International Organisation for Standardisation), IEC (International Electrotechnical Commission), and ITU (International Telecommunications Union).

48. In simplistic terms, IEC and ITU are considered to be responsible for standardisation in their limited sectors, and ISO for everything else. *ISO 9000*⁹ is a good example of a term which illustrates the general perception that ISO covers “everything.”

⁸ Financial Times, 28.4.1998

⁹. “ISO 9000” is a family of generic standards for quality management systems. ISO defines “generic” in this context to mean that they can be applied in any organisations, large or small, whatever its product ... in any sector. It adds that the standards concern processes (the way an organisation goes about its work) and not products – at least not directly. A fuller explanation, including these terms, can be found on ISO’s *Magical Demystifying Tour of ISO 9000*, available on its web-site www.iso.ch. In its most recent report on use of the standards (*ISO 9000 News*, November/December 1998 edition), ISO reports that over 211,000 ISO 9000 certificates had been issued to organisations world-wide.

The evidence from the WTO

49. The paramount importance of ISO and IEC is illustrated by the central document in the Uruguay Round of the WTO which deals with this field: the *Agreement on Technical Barriers to Trade*, or *TBT Agreement*, which at the global level represents the most wide-ranging operational system yet developed for attacking technical barriers to trade.

50. In this document, and notably in its *Code of Good Practice for the Preparation, Adoption and Application of Standards*, it appears to accept that ISO and IEC are the dominant bodies in this field. It centralises with them the notification of acceptance of the code. Most of its definitions are taken from ISO/IEC documents. And where it deviates from ISO/IEC definitions – as it does on the question of whether standards can be regulatory instruments¹⁰ – it invents its own, rather than preferring those of any other standards body.

51. The same bodies dominate in the actual operation of the WTO TBT Agreement. The Agreement is overseen by a TBT Committee, with representatives from every WTO member, and which may grant observer status to international standards bodies. Apart from the three organisations above, observer status has only been granted to four other bodies which fit the definition of global standardisation body. Although international standards bodies may, and often do, contribute to trade liberalisation even if they do not hold observer status in the TBT Committee, that committee plays a central role in the elimination of technical barriers, and participation or non-participation in it must be considered significant.

The evidence from ISO

52. ISO tries to act as a central clearing house for standardisation activity (for example, it negotiates memoranda of understanding with any individual international body which wishes to achieve wider global recognition), and it has no sectoral limitation on its activity. In the introductory section of its current Internet web-site, ISO states:

The scope of ISO is not limited to any particular branch. It covers all standardisation fields except electrical and electronic engineering, which is the responsibility of IEC.

53. The impression that ISO, IEC and ITU are the dominant players in international standardisation is strengthened by the fact that the EU, in much of its technical regulation, grants a privileged role to harmonised European standards, and in its central definition of such standards, it lists those developed by the three regional European bodies which are members or close associates of the three global, Geneva-based bodies highlighted here: ISO, IEC, and ITU.

54. In this “classical” model, these few dominant bodies do not work in isolation. They seek and promote strong partnership with two main groups: government and industry. And they seek dialogue with other interested parties, such as consumers and trade unions.

55. The partnership, and the role of both government and industry as players in the process, is important. Indeed, the standards bodies repeatedly stress that their work will only be effective if government and industry representatives participate fully. The partnership is most visible at the level of the *technical committees* which develop the texts of the standards. Representatives on these committees are designated by the national member standards bodies, who are not only free to designate but

¹⁰ See the chapter of this report on definitions.

encouraged to nominate representatives from industry and government, as appropriate, and those representatives choose their presidents and secretaries from among their number. As a result, the detailed work of international standards development frequently involves industry and government representatives as active partners.

56. However, in this model, standards bodies have an independent existence, traditions, and power.

5.2 A wider picture

57. However, even though this may not be clear at this first impression, international standardisation is a diverse, bubbling world, with many other significant players and a high degree of decentralisation.

5.2.1 Who are the other bodies?

58. To identify the standards bodies which develop texts for specific sectors in global trade, it is only necessary to go to any sectoral breakdown of trade, and to ask which bodies of international importance exist in those sectors. Simply scratching the surface of technical regulation affecting trade reveals significant standardisation activities which appear to be outside the relatively homogeneous, ISO-dominated world described above.

59. A list appears in **Appendix 1** of significant bodies identified in this context during this study. Of the twenty-five bodies listed, only the first eight have formal observer status as international standardisation organisations in the TBT Committee of the WTO.

60. The list shows that major standardisation activity goes on outside ISO and the “big three” Geneva organisations in the following sectors: foods and raw products used in foods, chemicals, automotive parts, measurement instruments, pharmaceuticals, transport equipment and requirements for carrying dangerous goods on them, equipment for mineral exploration, pressure equipment, electronic data transmission, digital audio and video.

61. The list does not claim to be complete. It deliberately omits some organisations which appear in ISO’s own directory of standards bodies, on the grounds that they do not emerge as having a significant impact on major sectors of global trade. And it would not be surprising if other organisations emerged that play a significant role in standards harmonisation. That is because there is a spectrum of public visibility of standards developers, and at the bottom end of the scale the developers are hardly visible at all; inspection of Appendix 1 will confirm that some bodies are better known than others.

62. But this list may provide an adequate first step. It covers some massive activities, in both high technology and older-established sectors.

5.2.2 The significance of the other bodies

63. It is not the fact that these other bodies exist that is important in the context of OECD’s work. Their existence is known to many people, including, in most cases, ISO, which even has formal Memoranda of Understanding with some. Nor does their existence diminish the value of ISO or the other global bodies listed above.

64. **What has emerged as most striking in the work in this project is the diversity of their structure and methods of operation.** The key elements in those differences appear in the table below, which groups 25 sample standards organisations into three lists. Details of standardising bodies under three lists are shown in **Appendix 1**. Apart from the “classical” standards bodies, they include bodies dominated by government regulators; bodies dominated by industry; bodies open to individual international membership but without any established one-per-country national member structure; bodies with long-term sectoral missions; bodies without long-term sectoral missions and concentrating on a clearly defined, short-term task.

CRITERION	List 1: Classic International Standards Bodies	List 2: Formal standardisers, some of whose standards are used internationally (e.g., ASTM)	List 3: Ad-hoc standardisers, some of whose standards are used internationally (e.g., IETF)
Established <i>de facto</i> basis of international acceptance of standards	Yes	Yes	Yes
Long-term mission to develop standards broadly across defined sector(s)	Yes	Yes	No
Membership composed of national members on a one-per-country basis	Yes	No	No
Membership open to any individual or organisation anywhere in the world	No	Yes	Sometimes
Develops multi-sectoral principles for standardisation	Sometimes	No	No

65. Equally significant is evidence that bodies outside the “classical” model are often as effective as those inside it. If a single example exists to prove it, it comes from the USA.

66. The US member of ISO – ANSI, or American National Standards Institute – reports no less than 175 separate entities in the US which it recognises as developers of standards, and other standards development consortia exist even outside the ANSI umbrella. Even for the ones inside it, the ANSI yoke is loose. Yet against that background of diversity, American standards are time and again quoted as a basis for global performance. Internet protocols have swept the world and have been developed largely outside the classic standardisation structure. FAA aircraft safety standards and ASTM material standards are other examples. American standards are a powerful force in the global economy. At the same time, concerns have been raised about the capacity of the bodies in Lists 2 and 3 to take into account the interests of all stakeholders (including governments) outside of the US on equal terms.

67. The diversity suggests that there may be unexploited reserves of experience and case examples of successful performance in the standardisation field.

5.3 Structures for regulators as players in international standardisation

68. It is the varied role of regulators in standardisation that is perhaps the most striking aspect. Both the structure of their involvement (dealt with in this chapter), and the mechanisms of their involvement (dealt with in chapter 6: the variables in standardisation) vary from case to case.

5.3.1 A history of linkage at national level: the traditional model

69. At national level, structural linkage between standardisation and regulation is not new. In many countries, national standards bodies have close, formal links with government authorities. In most cases, the national standards bodies are formally independent of government, although there are still some exceptions, where the national standards bodies are run as departments of government ministries. This model – in which strong linkage at national level is crucial, between standardisers and governments – can be called the traditional, or “ISO/IEC”, model. Relevant features include:

- At the national level:
 - National standards bodies (NSBs) are generally formally independent of government, with heavy involvement of industry.
 - National regulatory authorities and national standards bodies link their activities. Typical linkages oblige national governments to participate in standards development through their local NSBs, and inform those NSBs of regulatory needs. They also oblige the NSBs to take account of those regulatory needs in their standardisation work. These linkages are frequently underpinned by formal Memoranda of Understanding.¹¹
- At the international level:
 - Regulatory authorities are automatically represented in international standardisation only through their participation in national standards activity. Beyond that, inter-governmental groups of regulatory authorities do not participate automatically in the development of international standards, although ISO has an optional “liaison” system which permits such groups to ask or to be invited to participate, and which is quite heavily used¹².
 - Standardisers and industry have no direct right of representation in international groups of regulators developing technical regulations, and at best their representation is limited to that of *observers*, or similar, as happens in the WTO TBT Committee

70. In this model, the theory is that if, in every country, standardisation activity is linked smoothly to regulatory development, national standards bodies will reflect that linkage in their work at international level, in the international standards bodies.

¹¹ An example is the latest (1997) version of a *Memorandum of Understanding between the United Kingdom Government and the British Standards Institution on standards*. Similar examples exist in the USA

¹² The system is described in an ISO publication called “Liaisons”, which lists the bodies concerned, and was published in around 1994/5.

5.3.2 *An alternative model: direct involvement of regulators at international level*

71. Once again, other models exist, in which the most important difference is that regulatory authorities directly control the standardisation process at the international level, either exclusively or with rights of co-decision shared with industry, although in some cases voluntary standards remain important, e.g. to ensure safety. A number of sectoral examples were examined:

- Agri-foods
- Telecommunications
- Chemicals
- Pharmaceuticals
- Automotive parts
- Measuring instruments

72. In most of these cases, regulators control the standardisation process directly at the international level; exceptions in the above list are pharmaceuticals, where regulators participate on an equal basis with representatives of industry, and (partially) telecommunications.

73. Beyond these sectoral cases, the EU provides a regional example of a model in which regulators may be said to control at least a significant part of the standardisation process. And at the inter-regional level, regulators are exercising decisive influence on the standards and conformity assessment field in multi-sectoral agreements, through so-called MRAs (Mutual Recognition Agreements). At present, however, this activity concentrates on testing and conformity assessment, not on the specifications for the products themselves.

74. **Appendix 2** provides additional details of how regulators participate in the process in these cases. It provides no evidence to indicate that these structures, in which regulators play a dominant role, are any less effective than the classical standardisation bodies reviewed above.

5.4 *Structures for industry as leaders in international standardisation*

75. While even in the classical model represented by the traditional standards organisations industry is involved as a partner, other structures show industry dominating.

76. The most striking example of this is perhaps the so-called *consortia: ad hoc* groups with a clear, short-term purpose, often in a fast-moving area of technology with massive impact, but without any permanent mission. These groups may be totally open in membership, or may restrict membership (thus creating potential problems of IPR – who can have access to the results of their work?). Increasingly, they are international.

77. These groups, which represent perhaps the strongest examples of industry leadership of standardisation, sometimes develop their standards completely outside the structures of the classic standardisation bodies, although some of the classic bodies (notably in the telecommunications sector) develop ground-rules for working with them, instead of ignoring them.

78. The existence of these consortia suggests a need to question the assertion that the ideal way forward for international standardisation is for industry to participate more fully in the existing standardisation structures.

5.5 *Conclusions: the players in standardisation*

79. If the world of standardisation were dominated by a few players, with established procedures embodying a large number of common principles and definitions; in which exceptions are either rare or generally unimportant; and in which co-ordination with regulatory authorities and industry is managed through non-governmental national standards bodies, then, in order to improve continuously and meet the changing needs of international trade development, it should identify the ways in which that uniform model can be adapted, or fine-tuned.

80. However, the world of standardisation covers a diverse mixture of organisations, in which alternative models of participation for industry and government exist. The variety evident in the structures used in standardisation, both at sectoral level or in multi-sectoral regional/global programmes, suggests a need for closer analysis of exactly how they operate. Is there an “optimum” model? Can circumstances be defined where industry leadership is more important than government leadership, or vice versa, if standards are to play an effective role in trade liberalisation?

81. While no consensus emerged from this work, the evidence might suggest some guidelines:

- The more significant is a public policy goal such as consumer protection and health, the greater the importance of the government’s role to establish mandatory requirements for industry while minimising trade barriers. An example of this approach is the combination (as in the EU New Approach” which is explained in **Appendix 2**) of generally stated mandatory requirements by government and technical specifications chosen by industries.
- Industry leadership, even outside the classic standardisation structures, may be most helpful where there is a combination of high commercial pressure for speed and relatively few regulatory implications.

82. More importantly, however, the evidence suggests the first, major conclusion from this study: that it will only be possible for the players to decide what is “optimum” in any given area of standardisation if there is total transparency about how the different models operate and what they achieve. This is true with respect to economic stakeholders during the standards setting process so as to ensure legitimacy of the resulting standards; with respect to other affected parties, including consumers, environmentalists, commerce and trade unions; or with respect to standards setting structures with diverging views. Diversity may or may not be good (many players argue for a central core of consistent, uniform principles in standardisation, while others argue for increased flexibility, notably through greater use of publicly-available specifications); and even if there is diversity, some impartial mechanisms may be needed for reconciling conflicts between standards emerging from disparate structures. To deal with issues like those, the players will be better equipped if they have accurate, transparent information about what goes on in the standardisation field. In other words, transparency is a valid goal in its own right.

6. The variables in standardisation

83. Apart from structure, what makes standardisation successful or unsuccessful? What variables need attention if standardisation is to continue to contribute effectively to international trade liberalisation?

84. The fact-finding nature of the presentation in this chapter should be emphasised. The goal here is not to provide independent judgement on what is or is not important, or how effective standards bodies or regulators are. This report is not an evaluation of the state of standardisation in the world. Rather, it is an inventory of what the players themselves are doing and what the players perceive as important. The presentation is consistent with the overall goal of this project defined in Section 2 of this report.

6.1 Methodology: narrowing down the list

85. Some players in the field offer answers concentrating on a single variable. For example: the fundamental need in standardisation is industry leadership. If industry leads it, industry will use it, and trade will benefit. Or: the classic standards bodies are just too slow; they have failed to deliver in time the basic tools that trade liberalisation needs, and we must either speed them up or stop using them.

86. Unsurprisingly, research in this project revealed a wider range of variables than these simple theories suggest, and an important task was to narrow down the list to a significant few. To do this, this project used a checklist of possibilities. It appears in **Appendix 4**.

87. Priorities emerged quickly: issues representing an area of concern or target for new action. This chapter lists the issues which the players believe to be most important.

88. Many areas were felt to be under good control, and are not mentioned here. For example, it is evident that the clarity and technical accuracy of standards are critical if they are to be respected and used. In this research, it emerged that those aspects are regarded as well managed, and their exclusion here therefore indicates simply that they are not issues which the players feel to deserve attention in any new optimisation programme; it does not indicate that they are unimportant.

89. The comments are divided into three sections: the link with regulators, the inherent efficiency of the standardisation process itself, and the link with industry. Those sections correspond to the three “targets” at which the players in the field themselves look: standardisers want industry and government to do more, government wants standardisers and industry to do more, and industry wants governments and standardisers to do more. All three areas are felt to require attention.

6.2 The linkage with regulators

90. In the context of this project – regulatory reform– it is appropriate to consider first the ways in which international regulatory harmonisation to achieve trade liberalisation is linked to standards development. Several characteristics or variables are evident:

- First, it emerges that there are two aspects of international standardisation that regulators seek to influence: product standards and conformity assessment. Regulators may focus exclusively on product standards or on conformity assessment and certification, or intervene directly in both areas at the same time. Examples are 1) legal metrology, where harmonisation has concentrated on product standards and is only beginning, after forty years of existence, to develop harmonised certification systems; 2) the multi-sectoral MRA between the USA and the EU, which has done the opposite, concentrating on certification to the exclusion of product standards and specifications; 3) the EU's regional Single Market programme, which attacked both at the same time.
- Secondly, the areas of standardisation where regulators get involved vary. While, most often this involvement takes place in areas such as protection of the consumer or the worker (safety, hygiene, health, prevention of fraud, or at international level, cross-border interoperability), regulators are sometimes also involved in other areas, where their activities may appear less critical. A prime example is foodstuffs, where mandatory, so-called *quality standards*, dealing with issues as far removed from consumer protection as the shape of vegetables, co-exist alongside hygiene standards.
- Thirdly, the method of regulatory intervention varies greatly. For example: regulators may influence the development (*inter alia* by commissioning standards from external bodies and specifying essential requirements) or directly negotiate common standards, vote on them, and accept them as automatically binding; or they may go through the same development and voting process, but leave freedom as to the use of these standards by industry. And when they work with outside bodies, regulators may or may not provide public finance for the process.
- Finally, regulators work at both bilateral and multilateral levels. Globally, the WTO develops multilateral rules that are followed by regulators across countries, and regionally, the EU, APEC and other groupings try to do the same. But important bilateral agreements also exist, although they are only concerned with conformity assessment, not standards. The first wave of multi-sectoral MRAs (mutual recognition agreements) between the EU and other global trading partners (USA, Australia, Canada, and New Zealand), signed in May/June 1998, was negotiated as a series of bilateral agreements. Many bilateral, sectoral agreements also exist.

91. It appears universally accepted that regulatory involvement in the standardisation process can be helpful. It has worked for years at the national level. It is now proving its value at the regional level, such as in the EU. And many, durable examples of involvement of regulators at the inter-regional or global level, have already been referred to in this report.

92. Against that background, examples of interest in exploring the issues further are:

- 1) Are bilateral negotiations more efficient than multilateral efforts, or less so? The examples of the WTO TBT Agreement (as a multilateral code), and the negotiations between the US and the EU (bilateral) on an MRA (mutual recognition agreement) in the conformity assessment field are instructive. Multilaterally, progress towards clear, binding agreements on mutual recognition of conformity assessment certificates is slow although it is formally encouraged by the current WTO framework. Therefore, trading partners meet bilaterally to accelerate the process, and the US/EU case is a hard example. However, despite the slowness of the multilateral approach, it has evident attractions. The interest has been expressed in help to move the process up to the multilateral level, on the grounds that if the EU continued with its purely bilateral approach, it would need 100 years to cover the world.
- 2) Are new mechanisms needed for involving regulators in the classic international standards bodies such as ISO? Here again, there is evidence of interest in exploring the issue. Since the creation of the WTO, its secretariat and the classic standardisation bodies have proclaimed their interest in collaboration. Contacts appear to be frequent, constructive and friendly. Informally, some key figures express interest in devising formal mechanisms to reinforce the links, for example, between ISO and the WTO (today, the only formal mechanism is through the observer status in the TBT committee granted to a limited number of standards bodies, including ISO/IEC).

93. The interest, however, is not universal, nor is it always active. Two examples:

- The food sector revealed some resistance to “tampering” with an established system of linking standardisation and regulation. While some specialists acknowledged that there were issues deserving attention -- and notably 1) the degree of deviation from the *Codex* standards in current, national regulations and 2) the ability of developing countries to apply the standards -- there was also some opposition, generally on the grounds that “*even if some countries may not be applying the Codex standards, my country should certainly be excluded from such a review, because we do everything possible*”.
- In the classic standardisation world represented by ISO/IEC and their national affiliates, there is considerably less interest in linkage with regulators at global level rather than at national or regional level. Although standardisers frequently establish MoUs with their national government and actively pursue co-operation in the context of their national standards bodies, they are more sceptical as to the merits of an equivalent linkage at the global level, considering that effective global co-ordination is assured if it exists at the national level.

6.3 *The efficiency of the standardisation process itself*

94. There exist, even in some influential voices, deep dissatisfaction with the slow speed of developing harmonised standards in trade liberalisation programmes and serious questioning of the efficiency of standardisation process. On the other hand, there is strong interest in adapting the present process to the changing trade and technology needs. Overall, there is a widespread acknowledgement that, despite any problems, international standardisation has already made enormous contributions to progress and should be helped to continue to do so. The classic standards bodies are, today, frequently

praised for their contribution to progress: two striking examples are the recognition enjoyed by ISO 9000 quality standards, and the fact that an Emmy award was conferred for technical contributions to the standardisation of techniques for digital imaging.

95. Five elements were mentioned most frequently as deserving attention in any efforts at optimisation.

The nature of the “product line”

96. For most business organisations, a definition of the product range is the subject of the most fundamental strategic choices: examples are consideration by a car manufacturer of whether he needs both a luxury and a compact car line in his range, or by a chemicals manufacturer of whether he should be making bulk chemicals for cyclical markets or speciality chemicals for growth markets.

97. Standards bodies are clearly conscious of the importance of the issue. They already have several different *products* today: for example, full standards with detailed specifications, broad guidelines, technical reports, and so on.

98. While the importance of the issue is recognised, little strategic comparison has been made between the product lines of the many players in the field, although there is evidence of interest in increasing the use of *compact* models. In ISO, for example,¹³ an attempt is currently under way to *map* the mix of products in the bodies in the ISO/IEC network. It does not appear, at least yet, to consider product ranges outside the ISO/IEC network.

The depth and scope of standards

99. Notably, this includes the distinction between 1) criteria for end-performance related to issues of public and/or regulatory concern (safety, hygiene, prevention of fraud, interoperability etc.), 2) test criteria and methods, and 3) other descriptive specifications developed for the convenience of industry. In most standards catalogues today, no distinction is made between the two; ISO, for example, feel that their body of around 12000 standards concentrates heavily on methods of testing rather than product standards, but do not quantify the extent of the concentration.

100. Many players in the field feel that a clearer separation would lead to faster definition of core requirements needed for trade liberalisation, and that the corpus of standards available today is confusingly complex.

101. The field of electromagnetic compatibility provides an example. Electromagnetic disturbance can impair the performance of an electrical product; for example, a fuzzy TV screen can be a result. The issue of electromagnetic disturbance is the subject of one of the core harmonisation directives in the EU's regional trade liberalisation programme, and a body of European standards has been developed to support the directive. Broadly, they are a mixture of generic standards (defining general performance requirements for all electrical products), and standards dealing with a specific product or product family. Some observers have expressed the view that greater focus on the few core, generic performance requirements would facilitate implementation.

¹³ At the level of the Technical Management Board

The inherent speed and simplicity/complexity of the standards development process

102. This includes both drafting and voting. Symptoms of today's difficulties include:

- Long average development times, which can be five years or more. This can make standards useless in sectors where product generations last less than five years.
- Development times frequently exceed forecast. Globally, the inability of standards bodies to work to fast schedules is a factor in the emergence of standards-development activities outside the frame of the main standardisation world (as described in Chapter 5 of this report).
- Defined priority programmes are not respected. One major standards body in the ISO network introduced, in the mid-1990s, a rigorous new method for ranking priorities of projects in its work programme. But when, approximately two years after introducing the new system, it verified what its staff were actually working on, it found that the priorities set by the new system were being largely ignored.

103. While recognising that these problems may be due to inherent difficulties of elusive consensus in the standardisation process, they are attacked in various ways. For example, the classic standardisation bodies emphasise the value of electronic data interchange and storage, to achieve massive improvements in speed within a highly formalised system, and wish to invest in that.

104. However, other standardisers – outside the classic structure of the ISO-type bodies – concentrate on making the process altogether less formal, although this does not necessarily mean that they represent the optimal model of standardisation. Perhaps the most striking example of this is the Internet Engineering Task Force (IETF),¹⁴ founded in 1986, whose output includes standard Internet protocols and whose influence on global communication and trade is indisputable. While the goals of IETF are expressed in the most serious and conventional terms, the informality of the procedures is eye-opening. In more detail:

105. The goals of IETF are stated to include:

Identifying and proposing solutions to pressing operational and technical problems in the Internet; specifying the development or usage of protocols and the near-term architecture to solve such technical problems....making recommendations to the Internet Engineering Steering Group (IESG) regarding the standardisation of protocols and protocol usage..... many specifications are produced that become standards....

¹⁴ The quotations in the following paragraphs are reproduced *verbatim* without modification, and are available on the IETF website: www.ietf.org/tao.html

106. The procedures of the IETF include the following statements, and it is important to emphasise that the text is reproduced verbatim :

The IETF is not a traditional standards organisation, although many specifications are produced that become standards. There is no membership in IETF. Anyone may register for and attend any meeting. The closest thing there is to being an IETF member is being on the IETF...mailing lists.....Approximately one third of the attendees are new to the IETF at each meeting..... Since attendees [at meetings] must wear their name tags, they must also wear shirts or blouses. Pants or skirts are also highly recommended.....Many newcomers are ... embarrassed when they show up ... in suits, to discover that everybody else is wearingjeans... and sandals.... The general rule is dress for the weather.

The follow-up and implementation of adopted international standards:

107. Clearly, standards can only have value if they are used. Therefore, mechanisms for achieving widespread diffusion and use are given attention.

108. Unfortunately, except at the regional level in Europe (where new regional standards lead to the automatic withdrawal of earlier, national documents) monitoring of the actual application of international standards appears generally poor, making it impossible to draw any lessons from the use or non-use of individual standards.

109. Three quantitative measures can be highlighted as measures of the progress of international standards: the number transposed at national level (only relevant to the classical standards organisations with national members), the unit purchases of each text, and the number used in national or international regulatory systems.

110. Under all three headings, information is patchy at best. For example:

- On the use of standards in regulations, virtually no quantitative calculations have been made anywhere (geographically or sectorally), with the single exception of standards which are developed by organisations whose statutes give the standards the automatic status of binding regulatory documents (for example, OECD chemicals testing guidelines).
- On transposition, some attempts have been by individual ISO members to calculate the extent of ISO standards in their total body of standards, but no meaningful global summaries were identified in this project. In IEC, a study is currently under way to that end; it is due to last two years. In some standardisation systems, the analysis is complicated by the authorisation of national deviations in various forms.
- On unit sales of standards, no data has been assembled by the main standards organisations, and in one surprising case, when the secretariat of one major global body asked for the information from its members, they refused to supply it, saying that this was a purely national issue.

111. The paucity of the data today leads to the evident question of whether there appears to be general support for data collection. The answer is yes, and it appears likely that initiatives would be supported. The scale of the task (in the case of ISO, comprehensive data collection would cover over 100 locations) might favour selectivity, and concentration on samples rather than a universal exercise.

The ability of standards organisations to weed out texts which are obsolete or irrelevant

112. This problem emerges as especially important whenever exhortations are made to *use international standards more*. If the targeted users of the standards discover (as they have, in identified cases) that some of the standards are unusable, the credibility of international standardisation is damaged severely.

113. The phenomenon has already arisen. The Japanese standards body carried out a test exercise in the steel sector, asking the simple question: *are all ISO standards in this sector appropriate for today's technology?* Their answer was no, and produced a list of up to 40 standards still listed in ISO's catalogue, not removed as obsolete, but which Japanese industry regarded as unsuitable for use.

114. This study did not produce a conclusive answer to the question of whether the Japanese judgement indicates a major, general problem or not. Most standards organisations, including ISO, have established procedures for regular review of older standards, typically including automatic review every five years, with the goal of identifying those no longer used or needed. There appeared to be some recognition of the need to review, critically and in detail, the adequacy of those procedures. Evidence from this study suggested that that could only be done by sectoral case studies.

6.4 The link with industry

115. The way in which industry is involved in standardisation, and the extent of its commitment, is also perceived as a critical variable. Most importantly, the nature of its structural involvement in standardisation activity can vary, as already shown in chapter 5: it may be involved in standardisation through the classic standardisation bodies, or alternatively it may invent its own independent structures to ensure total focus on its own unique goals.

116. Beyond that critical issue of structure, the performance variables in standardisation which affect industry are essentially those of the standardisation process itself, dealt with in Chapter 6.4 above.

6.5 Conclusions

117. The variables which are felt to influence the effectiveness of standardisation relate not only to the working procedures of international standards bodies and follow-up by their members, but also the ways in which government and industry link their activities with standardisation and support it.

118. Within the classic standardisation world itself, a broad consensus emerges on the specific activities requiring attention if standardisation is to continue to contribute to trade development and technological growth. But frequently, data is not yet available to enable conclusions to be drawn on priorities.

REGULATORY REFORM AND INTERNATIONAL STANDARDISATION
-- Inventory of Standardisation Activities --

APPENDIX 1: INTERNATIONAL STANDARDISATION ORGANISATIONS

119. The lists on the following pages contain names of the organisations identified in this project which may be considered to have the most significant impact on global trade, and which produce *international standards* within the frame of the definitions used in this report (detailed in Section 3.5). Of the 25 entries in Lists 1 to 3 of this Appendix, only the first eight (in List 1) have observer status as international standards organisations in the WTO.

120. Although the lists have been prepared with helpful support from ISO they are in no sense “*ISO lists*”. Nor do they claim to be exhaustive, for reasons detailed in the main text of chapter 5 of this report.

121. All bodies in the three lists meet the central criterion of producing standards with a significant *de facto* international use or base of international acceptability,¹⁵ in one or more significant trade sectors.

122. Beyond that central common criterion, the lists differ as follows:

List 1: Classic international standards bodies: contains organisations of international scope with a country-based structure of representation: i.e., with national delegations meeting or voting to develop and/or approve standards to be given an *international* designation. To these can be assimilated regional standardisers composed of national delegations, some of whose standards are used internationally.

List 2: Formal standardisers, some of whose standards are used internationally: contains names of standards organisations which are not composed of national delegations as such. Instead, they are open to membership by individuals or firms from anywhere. To these can be assimilated national standards organisations, some of whose standards are used internationally. Like the organisations in List 1, they have a central, long-term mission to develop standards within a defined field, such as pressure equipment.

List 3: Ad hoc standardisers, some of whose standards are used internationally: contains names of organisations which are generally considered to be consortia rather than formal standards organisations. This category shows a central difference from Lists 1 and 2 above: these organisations are often constituted in order to achieve a more limited objective (in scope or in time), and do not have an evident, permanent mission. For example, a consortium may be established with the specific limited goal of developing the next generation of digital video discs. Beyond that difference, this group may or may not limit membership (for example, to named organisations with common interests), and like List 2 above, its members will normally be individual people or individual companies, not national delegations each grouping all members from a single country.

¹⁵ A fuller definition appears in Chapter 3 of this report.

List 1: Classic-type international standards bodies: organisations with *national* bodies as members

ORGANISATION	SCOPE OF MAJOR, SECTORAL STANDARDISATION ACTIVITIES
ISO (International Organisation for Standardisation)	Almost universal in scope. The only explicit sectoral limitation is the exclusion of electrotechnical standards (left to IEC below). In practice, ISO does not attempt to duplicate the work of bodies which it knows to be respected for developing international standards in a specific sector, although there is occasional duplication (e.g., protocols for electronic data transmission, now dominated by Internet protocols)
IEC (International Electrotechnical Commission)	Electrotechnical sector. Has joint programme with ISO in information technology.
ITU (International Telecommunications Union)	Telecommunications
UNECE (United Nations Economic Commission for Europe)	Automotive vehicle parts; agricultural products (commercial quality standards - e.g., what is a Class I tomato - as opposed to health standards); safety in transport; administrative documentation for international shipments; electronic data interchange
OECD (Organisation for Economic Co-operation and Development)	Chemicals, including in particular laboratory procedures to be followed in order to demonstrate that a product is safe
OIML (Organisation Internationale de la Métrologie Légale)	Instruments used for measurement where verification of accuracy is a legal requirements
Codex Alimentarius (a unit of the FAO)	Food hygiene
OIE (Office International des Epizooties)	Animal health, including methods of demonstrating that animals are disease-free. Therefore also relevant to foods
CEN (European Committee for standardisation)	The scope is similar to ISO, at the European level.
CENELEC (European Committee for Electrotechnical Standards)	The scope is similar to IEC, at the European level.
ETSI (European Telecommunication Standards Institute)	The scope is similar to ITU, at the European level.
IPPC (International Plant Protection Convention - also a unit of the FAO)	Plant health, including fruit and vegetables. Therefore also relevant to foods
International Pharmacopoeia (World Health Organisation)	Pharmaceuticals (essentially, raw materials specifications)
ICH (International Conference on Harmonisation)	Pharmaceuticals: testing procedures to ensure safety, quality, and efficacy
IMO (International Maritime Organisation)	Ship safety
ICAO	Civil aviation safety
Central Office for International Carriage by Rail	Transport of goods by rail

List 2: Formal standardisers, some of whose standards are used internationally: organisations with a long-term sectoral mission but without a network of national, one-per-country member bodies

See first page of this Appendix for detailed criteria for inclusion in this list.

ORGANISATION	SCOPE OF MAJOR, SECTORAL STANDARDISATION ACTIVITIES
ASTM (American Society for Testing of Materials), West Conshohocken, Pennsylvania, USA	Materials (concrete, steel, etc.). The society itself defines its role more broadly: <i>standards on characteristics and performance of materials, products, systems, and services,</i> ” a definition that would make it as broad as ISO in scope. It is not.
API (American Petroleum Institute) Washington, DC, USA	Equipment for mineral exploration
ASME (American Society of Mechanical Engineering), New York, USA	Boilers and pressure vessels
FAA (Federal Aviation Administration), USA	Aircraft

List 3: Ad hoc standardisers, some of whose standards are used internationally: examples of sectors with consortia developing standards

See first page of this appendix for detailed definition of criteria for inclusion on this list

ORGANISATION	SCOPE OF MAJOR, SECTORAL STANDARDISATION ACTIVITIES
IETF (Internet Engineering Task Force)	Protocols for Internet
DAVIC (Digital Video)	Digital video disks
[No formal name: known by the name of system it imposes] QS 9000	Automotive parts (quality assurance)
XOPEN	Interoperability in information technology

**APPENDIX 2: REGULATORS AS PLAYERS
IN STANDARDISATION: AN ALTERNATIVE MODEL
-- REGULATORS IN CHARGE --**

123. Section 5.3 of this report lists sectors where regulators directly control the international standardisation process, in contrast to the ISO-type model where governments intervene indirectly through national delegations of national standards bodies, via memoranda of understanding or other forms of communication.

124. This appendix provides details: first, for the sectors listed, and then for the multi-sectoral examples.

125. **The agri-food sector** provides one of the older alternative models (although not perhaps as old as telecommunications, whose standardisation activity is presented below), and notably the *Codex Alimentarius* Commission,¹⁶ the most important international standardising body in the field of food hygiene. It is the exact opposite of the ISO model above: instead of being a non-government organisation which encourages liaison with government, the *Codex* is a government-controlled organisation which encourages liaison with industry. Its member bodies are governments (163 of them), and governments decide on the composition of its technical working groups and on the adoption of its standards. The same principle applies in the second major standardisation body in the agricultural sector: the OIE¹⁷, the central body developing standards or guidelines for animal health: for example, procedures for determining that a given animal type in a given country is free of a defined disease.

126. In themselves, these standardisation bodies do not require their member governments to apply their standards or guidance documents; they simply encourage them to do so. Slowly, however, the documents are acquiring quasi-regulatory force. Notably, the SPS Agreement in the WTO compels governments to offer a scientific justification for any technical regulation based on any criterion other than those contained in the standards produced by these organisations.¹⁸ The effectiveness of this requirement is currently undergoing trial in the current dispute between the USA and the EU over the presence of hormones in meat.

127. Separately in this sector, the United Nations Economic Commission for Europe (UNECE) produces so-called *quality standards*, which are largely separated from hygiene, and deal with issues such as classification into grades of quality. Like the organisations above, its members are governments.

128. **Pharmaceuticals.** An influential harmonisation body in this sector is ICH, or the International Conference on Harmonisation.¹⁹ In the first sentences of its main public presentation of itself,²⁰ this body states:

¹⁶ FAO, Viale delle Terme di Carcale, I - 00100 Rome.

¹⁷ Office International des Epizoöties, 12 Rue de Prony, F - 75017 Paris.

¹⁸ And by a third organisation in the same context: IPPC (International Plant Protection Convention)

¹⁹ ICH Secretariat, 30 Rue St. Jean, P.O. Box 9, CH - 1211 Geneva. A separate standards harmonisation body exists, the International Pharmacopoeia under the auspices of the WHO, but with a more limited role than ICH.

ICH is a unique project that brings together the regulatory authorities of Europe, Japan, and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration...

The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines. The objective is ... the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety, efficacy, and regulatory obligations to protect public health.

129. The goals in the second paragraph above appear conceptually indistinguishable from the goals of the classic model of standardisation in ISO. The fundamental difference in ICH is the direct involvement of regulators and industry representatives, each as of right, in an international-level forum to develop standards.

130. **Chemicals.** OECD itself is a leader in global standardisation in the chemicals field. Its most voluminous output is a set of around 100 *Guidelines for Testing of Chemicals*, which lay down detailed specifications for individual tests. An example is a test method to prove biodegradability of a chemical. It produces other, supporting documents also: monographs, which define general principles for the *guidelines*, and principles of good laboratory practice, which are used in the accreditation of laboratories to verify the application of the *guidelines*.

131. Much of OECD's activity in this field matches the classic model of standardisation activity (for example, it has a constantly updated work programme, reviews of old documents for obsolescence, has clear voting procedures leading from working group or technical committee up to policy board); however, it shows a fundamental difference in its linkage between regulators and industry representatives.

132. OECD goes even further than ICH in its involvement of regulators. Governments are represented as of right, and form the policy council which must ultimately approve any document (in OECD's case, this must be by unanimity). As a result, governments must not only take account of OECD's standards texts (as governments frequently do, in the case of standards developed by the classic standards bodies): they are obliged to apply them directly and without any possibility of national deviation.

133. This is confirmed by an intergovernmental agreement. In 1981, OECD's Member governments accepted a binding decision (called the *MAD* Decision, or Mutual Acceptance of Data) which requires governments to recognise data generated through use of the *guidelines*.

134. In **telecommunications**, the main global standardisation body (ITU) was initially established as an inter-governmental agency, going back to the very beginnings of telecommunications in the mid-nineteenth century when telegraphic communication needed to be conducted within harmonised technical parameters.

135. Today, ITU has perhaps the largest membership (measured in terms of numbers of countries) in the standardisation world - 187 - although only around 20 are reported to be active in standards development. ITU develops standards covering safety, network security, interoperability of services,

²⁰ On its web-site <http://www.ifpma.org/ich1.html>

interconnectivity of networks, and performance issues. It has only one class of document in this sense, and they are called not standards, but *recommendations*. Unlike chemicals standards presented above, whose recognition is mandatory by inter-government treaty, the use or adoption of ITU *recommendations* into national regulation is not mandatory.

136. Although the ITU has now opened up its membership to include private operators and equipment manufacturers in the field (who now provide an important part of its finance), the fundamental decisions on standards are still taken by government representatives acting alone. Interestingly, the ITU proposes, at its next general assembly in late 1998, to discuss the issue of whether ratification decisions should now be taken by government and industry in partnership, instead of by governments alone; and one of ITU's prime regional sister-organisations in Europe – ETSI, or European Telecommunications Standards Institute – has already introduced this principle of partnership in its decision-making process.

137. The ITU's ability to deal with fast-moving technology is of particular interest in this context. While development of some standards takes years, examples are available of development times as low as one year: for example, for modems for electronic data transmission, where transmission speed increases from generation to generation, where a "generation" of technology is short, and where standards development time has been as low as one year.

138. As a related issue, the ITU is ready to integrate into its process work by industry-led consortia operating separately and outside its direct control. For the consortia, the benefits are significant. A consortium may include in its direct membership a limited number of manufacturers from a few developed countries. Liaison with ITU gives the consortium access to regulatory authorities, and to a wider range of potential user countries.

139. The **automotive parts** sector is again dominated by a government-controlled organisation: in this case UNECE. UNECE's 55 members are governments. They have no binding obligation to incorporate or accept any given standard in their regulations, but a clear process exists in which they are able to do so. Indeed, the texts are called *regulations*, not standards.

140. The effects of this – and their difference from the effects of the traditional ISO model described in Section 5.3.1 of this report – are visible in the texts of regulations. For example, the EU includes the detailed texts of specifications in its technical regulations in this sector, and indicates clearly which UNECE texts are considered identical.²¹

141. **Measuring instruments** also show regulators in a leading role in standardisation. The OIML²² is controlled by government members, one per country, of which it has 55. It has produced 126 standards documents, which it calls *recommendations*, not standards, and which its members are not formally obliged to adopt but often do. For example, the essential requirements or specifications in harmonised EU directives in this sector essentially reproduce the texts of OIML recommendations.²³ At present, it has no harmonised conformity assessment system to back up the technical specifications, but is in the process of developing one.

²¹ In Directive 98/14/EC (OJ L91 25.3.1998), which amends Directive 70/156/EEC (OJ L91 25.3.1976).

²² Organisation Internationale de la Métrologie Légale, 11 Rue Turgot, F - 75009 Paris

²³ There is some slight modification in the EU's *New Approach* directives in this sector, since these contain general *essential requirements* rather than detailed specifications. But there is no other conceptual difference.

142. **At the multi-sectoral level, the EU provides a regional example** of a model in which regulators may be said to work actively with the standardisation process. Responsibilities are divided between regulators and independent standardisers at the regional/national level. Under the EU New Approach to harmonisation all standards are voluntary, while in the EU traditional harmonisation activities, as with motor vehicles and chemicals, standards are mandatory. Outside the harmonised domain all standards are voluntary in accordance with the definition cited in paragraph 38 below.

143. The importance of the elimination of TBT in the EC's Single Market programme is undeniable: it was one of the three core elements in the programme announced in 1985.²⁴ European standardisation in this case played a key role in the programme. The EC's role as a regulator is interesting in this context.

144. Rather than relying on its member governments to lay down technical specifications by regulation to promote intra-Community trade, the European Community has developed standardisation to meet needs from the market and the European legislative authorities. Much has been written by the European Commission on EU standardisation policy, but three central elements can be identified in its direction of standardisation activity:

- It defined the public policy objectives of standardisation (safety, health, environmental protection, interoperability) in what it called *essential requirements*, compliance with which is obligatory. Compliance on a voluntary basis with European standards (specifically presented following an EC mandate) creates a presumption of conformity with those essential requirements. In the words of a European Commission official, it thus "*created a market*" for standards development. In other words, it in effect incited industry to define harmonised standards or harmonised methods of demonstrating compliance with the new, harmonised essential requirements.
- In order to promote the development of a sufficiently strong standardisation infrastructure at the European level, it provided some financial support, linked originally to the development of standards. According to the European Commission, however, this financial support has been subject to severe reductions since a number of years.
- The EU insisted on a level playing field for standards bodies in order to ensure the common nature of the Internal Market, in particular transparency in the activities of national standards bodies, by requiring uniform transposition of European standards, withdrawal of existing conflicting national standards and asking a commitment by national standards bodies to avoid any actions that would jeopardise European regulatory and standardisation activities, and specifically the uncoordinated promulgation of new national standards without an opportunity for EU-level review.²⁵

It may be noted that the third element above corresponds to the approach of the WTO/TBT Agreement, which aims to avoid unnecessary standards-related trade barriers through transparency in national standards-setting and requiring usage of international standards as a basis for national (regional) standards where they exist.

²⁴ The other two categories were physical and fiscal barriers

²⁵ The EU's 83/189 procedure played an important role here, named after the reference number of the EU Directive which defined the procedure.

145. **At the inter-regional level**, regulators are exercising decisive influence on the standards and conformity assessment field in multi-sectoral, bilateral or inter-regional agreements. At present, however, this activity concentrates on testing and conformity assessment, not on the specifications for the products themselves.

146. MRAs (Mutual Recognition Agreements) provide a major example of this. An MRA is a binding agreement under which one country, or trading block (X) agrees to recognise certificates issued by designated bodies in a second country or trading block (Y) as a basis of compliance with its own (i.e., country X) regulations on conformity assessment.

147. The significance of these agreements is potentially great. For example, a manufacturer located in country Y and exporting to country X can, for the first time, arrange all testing, conformity and certification of his product in his home country, with the certainty that the relevant certificates will be recognised by regulatory authorities in his export destination country X. MRAs are a significant step towards the “*one test, accepted everywhere*” goal of industry and trade liberalisation bodies.

148. At present, many sectoral MRAs exist but very few are broad, multi-sectoral in scope. Agreements of the latter sort appear to be limited to the EU and its major trading partners: Australia, New Zealand, Canada and the USA.

149. In developing and negotiating MRAs, the vital importance of strong political direction is apparent. Indeed, it is sometimes not even enough just to involve only the regulatory authorities directly responsible to the public for the adequacy of certification procedures.²⁶

150. It is notable that, in this activity, harmonisation of the product specifications themselves is absent. That contrasts sharply with the history of liberalisation inside the EU itself: there, conformity assessment and the *essential requirements* of the products themselves received equal attention.

²⁶ See for example, the press releases issued by the US government to announce the successful negotiation of MRAs with the EU: they emphasise the condition of an initial phase of confidence-building, or proving that the system can work, before it will be applied in the long-term.

APPENDIX 3: DEFINITIONS IN STANDARDISATION

This appendix cites relevant definitions offered by authoritative bodies in this field.

1. The term *standard*

151. Observation of common parlance shows that ordinary people frequently refer to *standards* to indicate their expectation of the legal minimum performance of a product or service. This does not coincide with the definitions by authoritative bodies (see below), which tend to introduce a distinction between technical specifications with which compliance is voluntary (termed **standards**) and technical specifications with which compliance is mandatory (termed **technical regulations**).

ISO

152. The principal ISO definition of a standard states:²⁷

***Standard:** document, established by consensus and approved by a recognised body that provides, for common and repeated use, rules, guidelines, or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. NOTE: standards should be based on the consolidated results of science, technology and experience, and aimed at the promotion of optimum community benefits.*

153. In another text, ISO offers a simpler definition:²⁸

Standards are documented agreements containing technical specifications or other precise criteria to be used consistently as rules, guidelines, or definitions of characteristics, to ensure that materials, products, processes, and services are fit for their purpose.

154. Those texts mention no connection with regulation, and the WTO states²⁹ that it considers ISO definitions to include both voluntary and mandatory requirements. ISO does not directly contradict this, although its main text above emphasises consensus rather than compulsion, and separately, ISO emphasises the voluntary character of the entire standards development process: “*international standardisation is market-driven and therefore based on voluntary involvement of all interests in the market-place.*”³⁰ ISO offers further support for the view that the fundamental purpose of standardisation has little to do with regulation, since in its primary public list of the benefits of standardisation,³¹ the overcoming regulatory barriers to trade does not appear. Instead, it concentrates on issues such as

²⁷ ISO Guide 2, para. 3.2

²⁸ This definition forms the first sentence on the first page of ISO’s presentation of itself (“Introduction to ISO”) on the Internet: <http://www.iso.ch>

²⁹ In its Annex 1 to the TBT Agreement, on *Terms and their Definitions*

³⁰ ISO, Internet home page

³¹ *International standardisation: what does it achieve?* and *Benefits of International Standardisation*, ISO web-site, chapter *Introduction to ISO*

enhanced product quality and reliability, greater comparability and interoperability, simplification for improved usability and reduction in cost, improved health, safety, and environmental protection. While inevitably some of these benefits – such as improved health and safety – will be of natural interest to regulators, and although in a contiguous text ISO mentions the goal of trade liberalisation, the regulators are apparently not the prime target of the activity.

WTO

155. In the Uruguay Round *Agreement on Technical Barriers to Trade (TBT Agreement)*, the WTO, while explicitly stating that it considers the ISO definition of standards above to cover standards that are mandatory or voluntary, provides its own definitions to ensure that the two categories - standards and technical regulations - are separated in its work:

- A standard is a document approved by a recognised body that provides, for common and repeated use, rules, guidelines or characteristics for products....with which compliance is not mandatory.
- A technical regulation, on the other hand, is a document which lays down product characteristics of their related processes and production methods....with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking, or labelling requirements as they apply to products.....

EU

156. The European Union, which also has a long track record of policy direction in the standards field, uses a definition which is identical to that of the WTO. It insists that standards cannot be regulatory instruments, in a central definition which appears to leave regulation outside the scope of standards development:³²

Standard technical specification approved by a recognised standardisation body for repeated or continuous application, **compliance with which is not compulsory...**

157. However, regulations can make use of standards in different forms. A standard can be wholly incorporated into a regulation : for instance technical regulations may contain specifications which appear conceptually identical to texts produced for purely voluntary use, but which are incorporated directly into the regulations themselves;³³ in this case the standard becomes the regulation. Alternatively a regulation can refer to a standard either in a general manner (as a source of guidance) or in a more specific and prescriptive manner, such as by imposing the use of a given standard from a recognised standards body³⁴.

³² Extract from Article 1.4 of the consolidated version of Directive 83/189/EEC, one of the core EU directives which lays down *a procedure for the provision of information in the field of technical standards and regulations*. The text here comes from COM(96)642 (OJ C78 12.3.1997)

³³ For instance, UN/ECE international standards are made mandatory in Europe via EU automobile harmonisation.

³⁴ Examples abound: for example, regulations which impose IMO codes for ships, or ISO noise measurement standards for determining whether a product meets noise regulations, or European regulations which impose standards specifying methods for measuring energy efficiency.

A standard can therefore be given a more or less mandatory status that departs from its original status as a voluntary document, depending on how its relationship with a regulation has been defined by the legislator.

158. That argument - about the importance and nature of the linkage between standards and regulation - is a major element in the main body of this report. For the purpose of the present report, all technical specifications that correspond to the criteria of market-driven development and subsequent consistent use will thus be considered of interest, even in those cases where these specifications have at a certain point been given a mandatory status that departs from their original status as voluntary documents. At this stage, it will suffice to say that **both regulatory documents and voluntary documents are included within the scope of this report.**

159. By choosing a broad scope, this paper is able to examine the impact of a number of documents and procedures with regulatory force or which are incorporated into regulations. Examples are OECD's own guidelines and monographs for use in the chemical industry, or UNECE specifications for automotive parts (called *regulations*, but in practice indistinguishable from standards). To ignore those documents – and comparable texts – would compromise gravely the ability to survey the range of standards activities undertaken in the world today.

2. What are *international standards*?

160. Again, ISO (International Standards Organisation) can provide a reference point. It defines an international standard as:

a standard that is adopted by an international standardising/standards organisation.... (ISO Guide 2, ch. 3.2.1.1), and defines an international standards organisation as

one whose membership is open to the relevant national body from every country.

161. However, in a December 1997 article entitled *What is an international standard?*, the president of ASTM,³⁵ a US-based standards body with an international reputation at the highest level in its field, stressed that he considered

....a true international standard [to be] a standard that[is] developed by a standardisation bodythat is open to all interested parties regardless of national origin.....has a demonstrated track record of global acceptance and use by the affected industries or regulatory bodies of various nations.....is non-discriminatory by providing equal treatment...without favouring one company or nation over another.

162. This definition insists on the importance of the global acceptance and use by the affected industry of relevant standards, as opposed to their elaboration by standardising bodies benefiting from a global representation. There exist indeed technical specifications which have been elaborated at a national or regional level, yet are widely used by industry. Although their qualification as international standards is controversial, this report treats such documents as equivalent to international standards because of the role they play in the concerned sectors. Many other examples can be identified, beyond ASTM, of bodies which produce standards meeting this definition. Many of them are American, and reflect American

³⁵ ASTM (American Society for Testing and Materials), 100 Barr Harbor Drive, West Conshohocken, Pennsylvania 19428-2959. The article appeared in ASTM Standardization News, December 1997

dominance in technology: sample sectors would include engineering equipment for oil exploration (standards body: API, or American Petroleum Institute), or Internet Protocols (standards body: IETF, or Internet Engineering Task Force), and pressure equipment technology (standards body: ASME, whose *Boiler and Pressure Vessel Code* has wide international acceptance at regulatory and non-regulatory levels).

3. Other relevant definitions

163. A number of other definitions are likely to be helpful (and less controversial). The definitions below come from ISO's *General vocabulary - standardisation and related activities*³⁶

Standardisation

activity of establishing, with regard to actual or potential problems, provisions for common and repeated use, aimed at the achievement of the optimum degree of order in a given context. Note: In particular, the activity consists of the processes of formulating, issuing and implementing standards. Important benefits of standardisation are improvement of the suitability of products, processes and services for their intended purposes, prevention of barriers to trade and facilitation of technological co-operation. (Para. 1.1)

Subject of standardisation

Topic to be standardised. NOTE: The expression "product, process or service" has been adopted ... to encompass the subject of standardisation in a broad sense, and should be understood equally to cover, for example, any material, component, equipment, system, interface, protocol, procedure, function, method or activity. Standardisation may be limited to particular aspects of any subject. For example, in the case of shoes, criteria could be standardised separately for sizes and durability. (Para. 1.2)

Regulation

*Document provided binding legislative rules, that is adopted by **authority** (para. 3.6)*

³⁶ ISO Guide 2, 1996 edition. Available from ISO secretariat

Standardising body

Body that has recognised activities in standardisation (Para. 4.3)

164. The same source (ISO Guide 2) indicates the breadth of these activities. For example, a chapter headed *Types of standards* refers to the following, in Chapter 5:

Product standard

Testing standard

Basic standard

Terminology standard

Process standard

Service standard

Interface standard

And if that were not enough:

A separate Chapter 2 lists *Aims of standardisation*:

Fitness of purpose

Compatibility

Interchangeability

Variety control

Safety

Protection of the environment

Product protection

165. A separate set of chapters (13 to 17) define terms used in the process of testing, conformity evaluation, assurance of conformity (including certification), approval and recognition arrangements, and accreditation of conformity assessment bodies and persons.

APPENDIX 4: THE SEARCH FOR THE IMPORTANT VARIABLES: METHODOLOGY

166. This project used the simple checklist below as a basis of identifying the variables perceived to justify attention in any programme to optimise the contribution of standardisation to trade liberalisation. It led to the analysis in Chapter 6 of this report.

- Procedures and criteria used to set priorities for standards development, in particular any procedures relevant to trade. How is the work programme set?
- Guidelines for writing standards (e.g., codes of practice).
- Criteria for representation on standards development committees or policy councils (e.g., mandatory representation of industry, consumers, regulators)
- Number and nature of categories of standard or guide (including any procedures/ criteria to allocate a given subject to a specific category). For example, are there categories designed specifically to deal with fast-moving technologies?
- Development time for standards.
- Agreements with national or regional standards bodies which determine whether new standards should be developed nationally, regionally, or globally (e.g., Vienna/Dresden agreements for ISO/IEC).
- Procedures or ground-rules for authorising national, regional or other deviations, and statistics on such deviations.
- Number of standards by major sector, and the nature of any further breakdowns of standards by category, including current output per year of new standards.
- Statistics on adoption/transposition of international standards at national level
- Any other data on use (as opposed to adoption) of standards, including incorporation of standards into mandatory regulations.
- Procedures for automatic review of standards with a view to updating or eliminating obsolete standards.
- Statistics on number of updates/suspensions/cancellations of standards.
- Procedures, past or planned, to measure *market relevance*
- Details of any recent or current studies under any of the above headings.
- Schedule for any future reviews under the above headings.
- A sample list of standards regarded as particularly successful/relevant, or unsuccessful/irrelevant, with reasons.