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STANDARDISATION AND REGULATORY REFORM:

SELECTED CASES

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STANDARDISATION AND REGULATORY REFORM: SELECTED CASES

I. Introduction and summary

1. This project follows up an analytical review of international standardisation discussed by the Working Party in 1998.¹ Following that study, it was suggested that some sectoral case studies might be useful for providing evidence of the strengths and weaknesses of standards used, of the processes through which they are developed and of the ways in which they are used as regulatory tools. It was agreed that the sectors of electrical and machinery products should be the focus of this work. Taking account of the few resources available for this project and the primary goal of underpinning trade-policy analysis, the Secretariat selected four cases inside these sectors, all with major economic impact. For each case, research considered international standards activity; relevant provisions and discussion in the World Trade Organisation; the regulatory approach to standards in the EU, Japan, and the USA; and national or regional standards activity in those same three countries/regions. Opinions of the players were actively sought and considered as evidence was collected. The information collected in each case has been organised according to the analytical framework developed in the initial review.

2. While the cases differ sharply in detailed content and implications, there emerge some themes of potentially wider interest. The cases reveal important geographical differences in the approach to using standards in regulation. They also reveal potential financial obstacles to any reform which might lead to a restructuring of the relationship between global standards bodies and those with regional, national, or sectoral responsibilities – how will any restructured system be financed? At the same time, an attempt is made in the cases to identify seeds of consensus between the main players on possible action to help improve the efficiency of the link between standards and regulation at the global level.

3. The cases permit some clarification of issues. For example, obsolescence of international standards was not a primary problem in the cases studied; and only occasionally could problems be attributed to a lack of transposition of international standards as national standards. More important problems emerged in the way the standards themselves are produced and linked to regulatory objectives, and in the way regulators use the standards or fail to use them. In some of the cases, the principal issue was not to adapt or to optimise the use of existing international standards but rather to create a standard for the first time.

A. *Case 1: Electrical Products and Electromagnetic Compatibility*

4. This case brings to light some of the issues that arise from the provisions of the WTO TBT Agreement. The standard studied, applicable to almost the entire electrotechnical sector, was originally not developed as a mandatory instrument, but as a voluntary text which its members were free to use or not, according to their own judgement of its relevance to their needs. Now, however, under the TBT Agreement

¹ TD/TC/WP(98)36/FINAL

Members are required to use existing international standards when technical regulations are required. This provision modifies the nature of the work of standards bodies, making it necessary to consider the potential regulatory consequences of this work and raising questions about the appropriate consultation process for standards with potential to be recognised as quasi-regulatory instruments, in both the developed and the developing world.

B. Case 2: Pressure Equipment

5. This case highlights issues which arise when new efforts are made to harmonise standards in a sector characterised by different national or regional standards, all with global influence yet closely linked to their own national or regional regulatory regimes.

6. Two issues dominate the case of pressure equipment. First, practical progress can be observed in resolving a conflict between regulatory authorities. The issue is how to resolve the problem of competing standards. The approach being considered would lead to a leaner core of high-level international standards, around which clusters of “registered” lower-level standards or codes could exist, reflecting differences in design practice. That model, if adopted, may provide a practical way of harnessing the strengths of different standards bodies to develop international standards, although a number of difficult practical questions must be addressed before the model can be considered workable. Secondly, this case illustrates the difficulty of agreeing on and setting up appropriate financing for any modification of the present structure of international standards development. This issue is likely to arise when the changes imply that established standards bodies will face a loss of revenue from the sale of their copyrighted standards.

C. Case 3: Construction Machinery

7. This case highlights one of the most developed sectoral programmes for standardisation within the global bodies directly connected to the TBT Agreement. Construction machinery represents a highly international sector, with active participation by major global players and a large body of adopted international standards. It has nevertheless proven difficult to achieve and monitor the transposition of such standards to the national level. Although international standardisation in this sector seems to operate smoothly between industry and standardisers, regulators sometimes fail to reflect harmonised standards fast and efficiently in national regulations, thus leaving trade barriers in place despite the best efforts of voluntary standardisation.

D. Case 4: Machinery Safety

8. This case examines the ways in which the machinery sector has been affected by the Vienna Agreement between ISO and the main European standards organisation (CEN), which aims to ensure that regional harmonisation activity in Europe supports efforts towards global harmonisation. Notably, the Agreement imposes certain conditions of transparency, defines principles for avoiding duplication of work or conflicts between regional and global standards, and provides for smooth and almost simultaneous adoption of standards in both systems. It has helped the regional and global bodies involved to link their activities and has promoted efforts to expand the body of international standards.

II. Context and methodology

9. The potential for mandatory national technical regulations to act as non-tariff barriers or technical barriers to trade is widely understood. Use of internationally harmonised standards is recognised to be one important way to overcome barriers of this kind. For that reason, study of standardisation is an element of the Trade Committee's work programme on regulatory reform.² A policy recommendation endorsed by the 1997 OECD Ministerial meeting provides direction for the present study:

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.

10. That recommendation led to the commissioning of two studies in 1998. First, an analytical inventory was undertaken of standardisation activities that affect international trade.³ It identified the players who develop internationally accepted standards, including regulators, industry and standards bodies; and identified variables which, in the view of the players, determine the effectiveness of standards as tools in the regulation and deregulation of international trade. A second, separate study⁴ provided complementary evidence of the costs for international trade in meeting disparate technical regulatory requirements; it confirmed the economic benefits of international standards harmonisation.

11. Following review of the first study, the Working Party asked for sectoral case studies to be conducted, with the goal of deepening understanding among trade policy officials of the types of issues that arise. This goal was to be achieved by producing hard evidence of the strengths and weaknesses of the standards used, the processes through which they are developed and of the ways in which they are used as regulatory tools. It was agreed that the sectors of electrical and machinery products should be the focus of this work.

12. The case studies are concerned with two main levels of issues:

- At the level of final standards, to determine whether there is a significant problem of obsolescence in standards; whether standards have been focussed on the most important issues for regulatory harmonisation and liberalisation; and whether the standards bodies have used appropriate deliverables, or categories of documents.
- At the level of process, to determine whether the relevant standards bodies ensure transparency; how they obtain and use the views of relevant parties (including other standards bodies, industry, government and trade organisations) and how they reconcile conflicts between them; whether and how they consider international standards; how they take decisions on new standards; and what mechanisms exist, if any, to make decisions binding and subsequently to monitor implementation or compliance.

² See, for example, *Product Standards, Conformity Assessment and Regulatory Reform*, chapter 6, The OECD Report on Regulatory Reform, Vol. 1: Sectoral Studies (1997).

³ TD/TC/WP(98)36/FINAL

⁴ TD/TC/WP(99)8/FINAL

13. For practical purposes, it was decided to focus primarily on the EU, Japan, and the USA, while considering as appropriate the wider implications, including the interests of other OECD members and of developing countries. Although the four case studies raise many issues of a technical nature that are primarily of interest for standards experts, the presentation here attempts to bring out those elements that are of particular relevance for the Trade Committee's work on regulatory reform and, more broadly, for international efforts to eliminate TBTs in the WTO and elsewhere.

14. Taking account of the few resources available for this project and the primary goal of underpinning trade-policy analysis, the Secretariat selected four cases inside the two sectors, each of a different nature but representing major economic importance. For each case, information was collected on international standards activity; relevant provisions and discussion in the World Trade Organisation; the regulatory approach to standards in the EU, Japan, and the USA; and national or regional standards activity in those same three countries/regions. Comparative evidence from other sectors or geographical areas was used where appropriate to throw light on issues raised. Opinions of the various players were actively sought.

15. The report is primarily intended to be fact-finding. As far as possible, judgements about *what is important* reflect the views of the players themselves. The goal of this report is to highlight the targets aimed at by the players themselves and the action taken by them in their attempts to meet those targets. The information collected in each case has been organised according to the analytical framework developed in the 1998 report, which identified seven key variables as determinants of the effectiveness of standardisation in trade liberalisation. A summary table appears in each case highlighting the issues that emerge as most important.

III. Electrical products and electromagnetic compatibility

A. *The case and its importance to trade*

16. This case covers almost all electrotechnical products; specialists in the electrotechnical sector have estimated that this sector can account for 15% of the entire economy in developed countries.

17. The case covers a single IEC standard⁵ for EMC (electromagnetic compatibility). It includes a specification for a method to prevent damage to electricity supply networks from a type of electromagnetic emission produced by electrical products. The method limits the emission at source, in a product, at a cost. Its scope is broad, covering almost all electrotechnical products, and it has particular interest because of its importance to the IT sector, which has shown explosive global growth since an earlier version of the standard was developed in the early 1980s.

18. The standard is not a universal regulatory requirement today, and is not used in regulations in many parts of the world e.g. in the US. However, the EU and Japan have made it a quasi-regulatory requirement and, as an IEC standard, it appears to meet WTO guidelines for using international standards as the basis of regulation.

⁵ IEC = International Electrotechnical Commission in Geneva. This organisation is closely involved in the WTO's TBT process. In the WTO *Code of Good Practice for the Preparation, Adoption, and Application of Standards*, IEC appears alongside ISO as one of the central bodies co-ordinating notification of the acceptance of that code, and it has observer status on the WTO TBT Committee. The standard is IEC 61000-3-2. Its title is *Electromagnetic Compatibility. Part 3: Limits. Section 2: Limits for harmonic current emissions (equipment input current ≤ 16A per phase.)*

19. Although it is difficult to estimate the cost of regulation, one estimate by industry indicates that, if the standard were imposed as a global regulatory requirement, the cost to industry could exceed US\$50 billion per year. Many industry groups have questioned the justification for imposing it, for either of two reasons: that is not necessary at all in certain electricity network environments, or that it is not the most cost-effective method of dealing with the problem.

20. Against that background, the case study has considered how the standard was developed, and how the players judge its relevance to regulation today.

B. *The technical issues*

21. How do the technical issues of standardisation relate to the economic issues presented above: security of power supply, and costs of achieving that security? The outline below deliberately tries to present a complex technical case in essentially non-technical terms.

22. Electrical products inherently produce electromagnetic emissions, which can disturb other electrical equipment. Two examples are: a hair-dryer which can produce a fuzzy TV screen if operated in too close proximity; or instructions on passenger aircraft to avoid using electrical equipment during take-off and landing.

23. Among the “unwanted” electromagnetic emissions generated by electrical products are low-frequency harmonic emissions. Unlike many emissions, these go back up the electricity supply line. If they are too strong or numerous and the distribution system is too weak to withstand them, the quality of the electrical power itself can be degraded, or in other words the supply of reliable power can be disrupted. At a minimum, that is inconvenient, and in business environments costly. But at a maximum, for example, in electrical equipment used in hospitals, it can pose a major safety hazard. The problem is therefore not simply that networks themselves have difficulties, but that those difficulties can radiate outwards, with harmful effects.

24. It is generally agreed that there are two conceptual approaches to dealing with any danger, to be used in a compatible combination. Either the emissions can be suppressed at source by installing some kind of protective device or system inside an electrical product, or the electricity supply lines can be strengthened to make them immune to the disturbance. Ultimately, the supply lines must have a level of immunity at least equal to the level of emissions produced by the electrical products.

25. However, there is disagreement about how serious the danger is. The following questions are at the heart of the current debate:

- Is the danger of disturbance from electromagnetic emissions equivalent in all kinds of network?
- What volume of electricity usage is needed to create a danger?
- What is the most cost-effective solution to limit emissions from the products, or at the level of plants and buildings containing the products?
- Is it more efficient to increase protection in the electricity supply network?

26. The standard studied in this case – IEC 61000-3-2 and its antecedents – represents one approach, which concentrates on the suppression of emissions from the products themselves. Technically, other solutions would be possible, offering a different balance between emission and immunity requirements. This standard makes no attempt to answer the question of whether or when a different balance might be suitable; it only states how to suppress, or limit, the emissions.

27. However, the technical debate is inseparable from economic debate, since cost-effectiveness is central. It is concern about the economic implications – the costs of various alternative technical solutions for dealing with the problem – that is driving an active current debate.

C. *Global interest in the issues in the case*

28. Why has this case attracted attention? Three main factors, all external to the development of the standard itself, appear to have driven the rise in interest.

29. First, the explosive growth in use of electrical office equipment, which creates demands on electricity supply systems that simply did not exist even fifteen years ago and which creates pressure for new initiatives, regulatory or private to ensure security of supply.

30. Second, the harmonisation initiative in the European Union in the late 1980s which led to the adoption of a directive on electromagnetic compatibility, or EMC⁶. The EU was the first region of the world to adopt a harmonised regulatory approach to technical regulation of this kind, and therefore sets a potentially important precedent. The EU's EMC directive used the so-called *New Approach* to the use of standards, and made it possible to give a privileged position to recognised *harmonised standards* as a means of compliance with EU regulations. The standard studied in this case has been granted recognition in that context, thus making it, in the eyes of many producers, a *de facto* requirement in the EU,⁷ and also offering an important precedent for global harmonisation of EMC requirements. Japan has followed the EU initiative by issuing a "guideline", recommending application of the standard.⁸ Although many participants in the standardisation world agree that this standard is well-adapted for European electricity networks, some of them feel that this standard may not be suitable for universal application. What the standard does is to specify a method of limiting harmonic current emissions, leaving open the question of when such limitation may be optimal or desirable.

31. Third, the implementation of the TBT Agreement, which aims among other things to ensure that technical regulations and standards do not create unnecessary barriers to trade. It thus encourages the use of "international standards" in regulation:

*Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them....as a basis for their technical regulations.*⁹

⁶ Directive 89/336/EEC.

⁷ In fact, the requirement will only apply fully in the year 2001. It has been announced but not yet applied. Details appear in the EC Official Journal edition C57 of 1999-02-27.

⁸ This guideline was issued by the Agency of Natural Resources and Energy of MITI. The guideline has no formal regulatory force, but discussions with Japanese manufacturers during this project indicated that a guideline of this kind is in practice applied.

⁹ TBT Agreement, Article 2.4.

32. Moreover, it is clear that IEC standards could be considered to meet the definition of an *international standard* in this context. For example, ISO (International Organisation of Standardisation) 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*”.

D. The players and their relevant activity

33. Who are active in the development of international standards and relevant national/regional standards and in the application of those standards to technical regulation in this field? If any lessons are to emerge from this case, they must be related to specific players and to their methods of operation.

34. Although many organisations have shown interest in the issues covered here, a limited number emerge as playing a dominant role as international organisations, standardisers or regulators:

- **The World Trade Organisation (WTO)**, although not actively involved in the debate on this standard, must be considered. It established the basic framework for the link between technical regulation and standard. Without it, the case would lose much of its importance in the context of regulatory reform and trade.
- **The International Electrotechnical Commission (IEC)**, the main global standards body in this field, has developed the standard that is the focus of this case study: IEC 61000-3-2.
- **The European Committee for Electrotechnical Standardisation (CENELEC)**, the main European standards body in the field, has transposed the standard in question and its members participated deeply in its development.
- **The United States National Committee to the IEC** has established a working group on powerline harmonics (the issue covered in this case) to co-ordinate US input to IEC on this case. The current, most active phase of activity of this working group began in early 1999.
- **The Institute of Electrical and Electronic Engineers (IEEE)** in the USA, has produced the document which comes nearest to being a US standard in this field.¹⁰ The document is titled: IEEE519A - *Guide for applying harmonic limits on power systems*. It is not equivalent to the IEC standard.
- **The European Commission (EC)**, which developed a European directive on electromagnetic compatibility and which recognised the IEC standard studied in this case as providing a presumption of conformity to that directive.
- **The Ministry of International Trade and Industry (MITI)** in Japan, which, through the Agency of Natural Resources and Energy, issued a non-binding recommendation based on the IEC standard considered in this study, to Japanese manufacturers.

¹⁰ The document carries the reference IEEE 519. In some reports (e.g., a 19 May 1999 *Powerline Harmonics Position Paper* prepared by the US National Committee referred to above) it is called a standard. In other texts, it is referred to as a guideline or recommended practice.

35. The absence of the US government as a regulatory player is notable. Several US government agencies have an interest in EMC regulation: the FCC (Federal Communications Commission) for radio communications; FERC (Federal Energy Regulatory Commission) for security of networks; OSHA (Occupational Safety & Health Administration) for safety aspects, which itself links some of its work with UL (Underwriters Laboratories). No evidence emerged that any of these agencies is currently considering regulatory intervention on this specific point.

36. It is apparent that industry has played an active role. This has come mainly through supplying members for the *Technical Committees* in the standards bodies which developed or adopted the standards in question, or who are considering their possible wider use. "Industry" in this context includes both manufacturers of electrical products and equipment (which produce the products which generate the emissions or disturbance covered by the standard), and electricity utilities (which supply the power liable to be disrupted by the disturbance). In this context mention may be made of the:

- **The Trans-Atlantic Business Dialogue (TABD)**, which has begun to play a new role in Europe and North America, providing policy advice to governments and industry on how action in the field of standardisation can contribute to trade growth. The TABD has explicitly identified standards on electromagnetic compatibility as an issue deserving attention, but has not yet defined a detailed position.

E. The issues raised by this case

37. The core issue already identified is whether technical regulation is needed in this case (as opposed to voluntary standards) and, if so, whether the recommendation in the TBT Agreement to use international standards as the basis of the technical regulation is appropriate.

38. The latter question emerges because the standard in question has all the credentials,¹¹ within the frame announced in the TBT Agreement, to become a wider global regulatory requirement. Nevertheless:

- Some major business organisations are indicating that it would be unjustified to move in that direction.
- The experts in IEC have argued that the standard is inappropriate to certain electricity network environments and should not be imposed as a regulatory requirement without consideration of the network environment in which it will be used.
- There has been disagreement within IEC itself about the nature and/or number of standards required to deal with this issue. Notably, disagreements emerged between two separate technical committees on appropriate limit levels for this class of emission. As a result IEC gave responsibility to a high level advisory committee: ACEC (Advisory Committee on Electromagnetic Compatibility), reporting to the IEC Technical Management Board. This group has prepared a proposal aimed at reconciling the views, but at the time of this report the proposal had been rejected by the relevant National Committees, and the subject is still under discussion.

39. IEC developed the standard as a voluntary consensus document. Under IEC procedures, this means that it is available for use where appropriate but no member is obliged to apply it. The standard

¹¹ As already presented: ratification by one of the major, recognised global standards bodies (IEC); formal regulatory recognition in the EU; unofficial regulatory recommendation in Japan.

specifies a method of limiting a class of electromagnetic emission. Therefore, members are free to use the standard whenever they judge that that degree of suppression or limitation of the emissions is appropriate. It does not matter if, as in this case, the standard may only be optimal in a limited range of network conditions, since it is left to individual members when or whether to use it. In this case, European electricity utilities appear to have supported use of the standard as representing the optimum approach in European networks to balancing emissions from electrical products with the immunity of the supply network.

40. The TBT Agreement provides for a different approach to the use of this standard. This Agreement aims, *inter alia*, at ensuring that technical regulations and standards do not create unnecessary barriers to trade. As mentioned above, it requires the use of relevant international standards if technical regulation is judged to be necessary. It is thus the broader needs of the multilateral trading system which provide a new background for reviewing the strengths and weaknesses of the standardisation process itself.

41. The TBT requirement to use international standards might be interpreted in this case to mean that regulators, when considering the possible danger of electromagnetic disturbance, could adopt as mandatory an international standard directed toward limiting emissions -- even though this is in fact only one method of dealing with the problem. It is significant that the TBT Agreement includes no requirement to consider factors such as cost-effectiveness or the regulatory impact of imposing certain standards as technical requirements

42. Therefore, some industry circles have expressed concern at the possibility of adoption of the IEC standard as a basis of technical regulation without sufficient analysis of regulatory impact. However, regulators in different countries can consider other possible options different from the approach taken by the European Union within the framework of the TBT Agreement:

- When technical regulations are considered necessary, to regulate the immunity of the electricity supply rather than the level of emissions;
- To encourage voluntary, consensus agreements between suppliers of electrical products and electrical utilities;
- To take no action until adequate analysis is completed of regulatory impact of different approaches.

43. Hence the danger and the debate. Doubts are seen outside Europe:

- In the US, a working group has been established in 1999 with the aim of producing guiding principles for regulation and international harmonisation in this field. In its most recent paper,¹² it emphasises the need for further discussion between standards bodies, equipment manufacturers and suppliers of electric power.
- ACEC asked one of its members from Japan to chair a high level working group to find a solution to this disagreement: the chairman did not represent Japanese industry in this role, but acted as an impartial chairman.

44. In addition, the WTO itself recognises that international standards may sometimes not be used because they are inappropriate. The first triennial review of the operation and implementation of the agreement on technical barriers to trade states that,

¹² Dated May 19 1999. Title Powerline harmonics position paper.

The Committee noted that difficulties might be encountered in relation to the use of certain international standards and that trade problems could arise through, inter alia, the absence of international standards or their non-use due to possible out dated content. There was a need to examine these difficulties as well as the potential trade effects arising from international standard.....the committee agreed to invite Members, on a voluntary basis, to submit specific examples to the Committee addressing the difficulties and problems they encounter in relation to international standards.

45. Although the first triennial review did not intend to address the issues arising from the regulatory cost effectiveness of international standards, this electrical case could be placed in line with this effort by the WTO and highlight a new issue still not well discussed.

46. As can be seen from the table below, three of the seven key variables for effective standardisation emerge as significant considerations in the case of electromagnetic compatibility: the focus on issues relevant to regulatory harmonisation; the appropriateness of the “deliverable” or final document; and consultation with interested parties.

a) *Lack of a global focus on regulatory implications*

47. It is clear that some players in the field themselves feel that a number of issues relevant to regulation have not been dealt with appropriately. All the standard does is to define a method for limiting harmonic emissions. Against that limited goal, the technical clarity of the document may be adequate. But participants raised a number of questions of apparent importance to regulators, because in the development process they did not need to consider the possibility that the standard might be used as a basis for technical regulation, since no member of IEC was under any statutory obligation to use it. :

- Is regulatory intervention needed, and if so for what specific reasons?
- Might regulators want to allow other technological solutions, for any reason such as varying network conditions or cost minimisation? Does the TBT agreement need safeguard clauses?

48. Although there clearly was discussion of some of these questions in the technical committees of the standards, for example, discussions between electricity utilities and others in Europe, no evidence emerged of a conscious and separate focus on the regulatory implications at global level in the development of that international standard.

49. The lack of a co-ordinated *global* focus on the regulatory implications contrasts with the attention given to those implications in *regional* trade liberalisation programmes. In the EU, discussion of the link between voluntary standards and relevant regulations is an integral part of internal trade liberalisation efforts. In every sector covered by technical harmonisation, regulators and standards bodies meet to discuss which standards should be recognised in regulation, and the EU has an extensive set of core texts defining the principles which underlie their use.¹³

¹³ The publication of official lists of standards recognised as providing a presumption of compliance with the relevant EU directives is a natural consequence of this consultation process. An example of the core principles can be found in EU presentations of what it calls its *New Approach* and *Global Approach* in the area of technical regulation. The EU experience in this field has already been commented on in this OECD project. See the 1998 analytical inventory of international standardisation, TD/TC/WP(98)36/FINAL and specifically paragraphs 142 - 144.

Case 1 - Electrical products and electromagnetic compatibility: analysis according to determinants of effective standardisation

ISSUE	COMMENT
Final standards: Are the standards obsolete or obsolescent?	Obsolescence is not a factor in this case
Final standards: Are the standards focussed on the issues most important to regulatory harmonisation and liberalisation?	The standard does offer one solution to a legitimate regulatory need: guaranteeing reliable power supplies to the public. However, it is not yet verified by engineers there are not any other cost effective options in other network environments.
Final standards: Have the standards bodies used appropriate deliverables or categories of document?	The final “deliverable” in this case does not include any background cost and benefit analysis
The standards development process: Have the standards bodies ensured transparency?	There has certainly been no restriction on participation or access to data.
The standards development process: Have all interested parties been consulted, and have effective attempts been made to reconcile any conflicts between them?	The economic cost resulting from mandatory implementation of this standard was not addressed and therefore a question would be whether regulators should participate in the standard development process.
The standards development process: Is the decision-making process efficient?	No evidence emerged to suggest that it was not efficient in this case.
The standards development process: Has implementation or compliance been monitored?	Transposition and implementation of IEC standards is optional, not mandatory, and no detailed records are kept.

b) *The appropriateness of the “deliverable”*

50. This point is inseparable from the previous one. If, during the preparation of the standard, there was a lack of focus on the global regulatory implications of the standard, then the final document could not offer such focus. In this case, the basis of the standard was established well before the WTO established any mandatory frame for the use of international standards, and it is therefore perhaps not surprising that the focus on regulatory implications was limited.

51. What the final documents do *not* include may be as important, in this context, as what they do include. Notably they do not include explicit comment on economic, business and regulatory issues. The standards bodies urge business and government to participate in the standardisation process, and support those exhortations with wide-ranging attempts to integrate business planning into their own activities; specific, helpful examples are obtained and examined in this study. And yet their main output like the standard examined here contains no analysis or comment on economic, business, or regulatory issues.

52. This gap in the output contrasts with experience of regulators in the EU of *regulatory* harmonisation. That experience suggests that such conscious attempts to explain the justification for new initiatives with regulatory implications can be helpful. For every new harmonisation initiative in the EU, an *explanatory memorandum* must be published by regulators, which explains the goals, the background, the alternative approaches which have been examined, the effects on business and the economy. Informal support for this concept was also expressed by the US regulatory authorities. If such attempt to examine the regulatory impact and alternatives fails to support regulation based on international standard, further discussion and consensus building is necessary to explore the better approach rather than using that standard as a basis of technical regulation. However, a critical question remains on whether international standard bodies should attempt to examine the regulatory impact or regulators should take all the responsibility for the cost-benefit analysis of using international standard.

c) *The consultation process*

53. If IEC's own objective is considered to be the production of voluntary consensus standards for use by its members to their own advantage as they judge appropriate, then no evidence emerges to suggest that the consultation process was flawed.

54. However, if the IEC is expected to produce standards as a basis for mandatory international regulation, then it may ask whether it needs to consult with all parties who might be affected by that regulation.

55. In that context of technical regulation, it is clear that some parties likely to be affected feel that they might have been consulted more thoroughly and that opportunities might have been created for them to express their concerns. In this regard, it may be noted:

- In the USA, consultation processes have only recently been established in this specific field. The primary example is the US working group on Powerline Harmonics referred to earlier in this report, which brings together the main players.
- The advisory committee ACEC established by IEC referred to earlier appears to perform a related role at the global level.
- It seems unlikely that any similarly broad-ranging consultation process exists in Japan.

IV. Pressure equipment

A. *The case and its importance to trade*

56. This case throws light on the question of how to handle international harmonisation in sectors which are only beginning to address the issue and in which influential different standards systems presently exist. It illustrates, in particular, the practical effects of one of the features of international standardisation identified in the 1998 analytical reviews: that diverse models of standardisation exist. This case shows what can happen when different models co-exist inside a single sector: how can they be harnessed in a coherent global system within the framework of the WTO TBT agreement?

57. The case covers the entire field of pressure equipment, which is part of the mechanical engineering sector, and frequently part of the machinery sector when pressure vessels are incorporated into machines. In the EU alone, the main part of the sector has been estimated to have annual sales of over \$40 billion per year.

58. The standards and codes with the greatest global influence today are several different national standards of European countries and American standards from ASME (American Society of Mechanical Engineering), linked to technical regulations in individual US states. In the rest of the world, either code is used as a basis for local regulation. For example, in Japan, national regulation in the early 20th century leaned towards Europe, to be replaced by US-oriented regulations after the Second World War.

59. An active programme to harmonise European codes is under way, encouraged by a brand-new 1999 harmonised EU technical regulation. At the global level, no significant harmonisation has yet taken place, but a new initiative through ISO has been launched within the last two years.

B. *The technical issues*

60. Although some standards codes run to many thousands of pages, the technical frame relevant to this case is relatively straightforward. The single most important technical issue is the difference between pressure equipment standards in Europe and the USA.

61. The different national codes are generally closely linked to regulation. Therefore, the technical differences between them represent technical barriers. Many of these barriers are only indirectly related to standards in the sense of product specifications, and cover conformity assessment. For example, many pressure vessels may only be sold if they are certified and marked by a body recognised or accredited by national regulators. In some cases, the standards body is closely involved in establishing procedures for the accreditation of the certifier, which is the case in the USA.

62. The product standards¹⁴ themselves are the subject of this case study. Differences between them appear sometimes to be minor rather than scientifically fundamental. For example, one code may impose a design calculation method which leads to a specification requiring the use of thicker steel than that which results from a broadly similar design calculation in another competing standard; in addition, there may be differences in specified tolerances. In other cases, the differences between standards may be more

¹⁴ In the sense of the definition used by many standards organisations. An example can be found in the Introduction to ISO on the ISO web-site www.iso.ch: *standards are documented agreements containing technical specifications or other precise criteria to be used consistently...to ensure that materials, products, processes and services are fit for their purpose.*

fundamental. For example, one source indicated that European codes place greater emphasis on detailed materials specifications than the US codes. And a further feature mentioned by some players is a concentration on prescriptive design calculations or specifications rather than on performance issues.

63. The importance of the differences is magnified by the fact that there is not yet any global forum for reconciling them. European standards are developed within the European standards body CEN, whose work is linked to that of ISO. All CEN members are also members of ISO, and in addition CEN has a formal agreement with ISO (the Vienna Agreement¹⁵), which aims to avoid duplication of work and common adoption of standards developed by either organisation. On the other hand, US standards are developed by ASME.

64. A separate technical issue is the adequacy of standards for steel as a material in standards issued by ISO. Analysis in Japan has suggested that current ISO standards, both for chemistry and strength of steel, are inappropriate for today's technology. However, this issue emerges as less important to the players than the basic conflict between the pressure equipment standards.

C. *Global interest in issues in the case*

65. The pressure equipment sector has attracted attention at the highest global level in standardisation bodies. ISO sent a delegation from its *Council*, its highest governing body, to the USA at the end of 1998 to discuss with the major American body in the field, ASME, how American standards could be integrated into the global system represented by ISO itself. The discussion led to agreement on a pilot programme in that direction, discussed later in this report. After that meeting, in early 1999, the ISO secretariat recommended¹⁶ that the work of its main technical committee in this sector should focus on the objective of defining a global framework-- conceptually, an umbrella standard--for pressure equipment standards under which competing detailed standards could retain a role through registration as satisfying the requirements of the umbrella standard.

66. The sector has also attracted high interest at government level in which standards bodies should be integrated with regulation in the pressure equipment sector. It reveals a difference between European and American views, at government level.

67. In understanding the difference, the starting point is the nature of the standards bodies in Europe and the USA. CEN, the European standards body, operates a voting system based on national delegations. ASME, the US body, is open to individual members from anywhere in the world, and votes through its membership regardless of geographical origin, although in practice the majority of its members are based in North America.

68. Both sides – European and American – feel strongly about the value of their standardisation systems and of their respective output. It would be a problem if there would be two international standards that compete. However, it is not yet evident that they are committed to reconciling the two systems in a common, global system. Separately, the specific issue of materials standards for steel has attracted global attention. As a result of Japanese requests, ISO standards for pressure equipment material were reviewed to determine whether they were up-to-date. However, this specific issue has attracted less attention than the broader issue of conflict between the different standardisation systems today.

¹⁵ So-called because it was signed in Vienna. The title is: *Agreement on Technical Co-operation between ISO and CEN*. Signed in 1991, it has been kept up-to-date through a series of circulars and clarifications. The latest guidelines on its implementation can be found on www.iso.ch/infoe/directiv.htm

¹⁶ In an unpublished letter from the Secretary-General of ISO to the central technical committee in this field

D. The players and their relevant activity

69. Players important to the issues debated here are essentially standards and government organisations. Industry participation is achieved through the standards organisations, without separate programmes.

- **WTO** must be considered a player, because of the link between the case and the TBT Agreement. Given the conflict between the two major groups of standards used globally today, which standards can be considered legitimate, under the TBT Agreement, for use in international regulation?
- **ISO** has a technical committee (TC 11) for pressure equipment. This technical committee has only just ended a 27-year period of inactivity and it has no recent standards for the sector. But TC 11 now does meet regularly, and it is apparently the intention of its members that it should develop a body of global standards for the sector. It is currently working on an “umbrella” standard for the sector, which will define basic requirements. It is taking explicit account of the standards programme of CEN (listed below) but is deferring any decision on accepting European design codes as ISO standards until the over-arching umbrella requirements have been defined. ISO operates a voting system based on national delegations and the TC has 23 participating members, of which 8 are from the EU.
- **CEN** participates through the Vienna Agreement¹⁷ to prevent duplication of work or conflicts with ISO standards. Like ISO, CEN requires geographical balance in its voting, based on its membership, that is, one member per European country. Unlike ISO, CEN already has a body of several hundred standards for pressure equipment, and is working on several hundred more. Notably, CEN is implementing a “mandate” in this sector for the European Commission, under which it agrees to develop and submit most of the standards in its programme to the Commission for recognition under the EU’s Pressure Equipment Directive. However, at the time when information was gathered for this case study, none of CEN’s standards had been granted formal recognition under the main Pressure Equipment Directive.
- **ASME**, the main US standards body in the field, whose standards are integrated into regulations in most of the United States. It sends delegates to the Technical Committee of the ISO. Like CEN, it has several hundred standards in its programme, and its standards are offered to the world. ASME shows several significant differences from CEN and ISO. Some significant differences are:
 - **Membership.** ASME has exclusively individual members, of which there are 125 000, although only around 700 of these are reported to be active in its technical committees for pressure equipment. There is no geographical restriction, and no attempt to achieve any defined geographical balance, as in ISO.
 - **Voting structure.** Like its membership, voting on standards takes no account of geographical origin. Instead, ASME’s rules require a balance between interest groups, manufacturers, distributors, insurers, regulators and users, regardless of geographical origin.
 - **Comprehensive technical codes.** ASME tries to offer a visibly all-embracing technical package for pressure equipment, covering material and design specifications, conformity

¹⁷ The source of the Vienna Agreement is presented in paragraph 66 of this report.

assessment, marking, personnel training, accreditation, etc. The core codes are updated and re-issued annually.

- **The Japanese Standards Council (JISC)** has a Committee on Pressure Vessel Codes and Standards, which produces its own pressure-vessel code.¹⁸ The basis of this code was established after the Second World War, and was at that time aligned with ASME codes. Today, it is reported to have diverged and to show significant national differences, while still retaining relatively close links with ASME.
- **European Commission** has published a new directive that enters into force in 1999 and that will harmonise technical regulations in the sector in phases, starting later this year. This EU directive covers essential technical requirements for materials, products and personnel, conformity assessment procedures, documentation and marking. The time taken to publish the directive in this sector illustrates the extreme complexity of harmonisation in this sector. Directives of this kind allow the European Commission as a regulator to announce that identified harmonised standards provide a presumption of conformity to the essential requirements of the directive. At the time when information was gathered for this case study, no such announcements have been made under this directive, but they are expected in due course. Harmonised CEN standards will thus be bound directly into the regulatory process.
- **Individual state governments in the USA, and the National Board of Boiler & Pressure Vessel Inspectors**, through which many of these states enforce their pressure equipment regulations. The U.S. federal government is not directly involved in regulation of this field. Nearly all state governments recognise ASME codes as the basis for their regulations.
- **MITI**, as a regulator in Japan. Japanese regulations contain the full text of any technical requirements, permitting no variations. It is reported, however, that there are in practice no differences between the regulations and the Japanese standards (JIS) developed through the standardisation process above.

E. The issues raised by this case

70. In collecting information on this case, the primary focus has inevitably been on efforts to achieve harmonisation rather than on the result of harmonisation. Therefore, little attention has been paid to questions of whether international standards are up-to-date or obsolete, whether they are focussed on the right issues, or whether they are being used in practice. (International standards do exist in one relevant part of the sector: materials standards for steel. It is possible to apply the questions above to those standards, but not to others.)

71. From the following table, two variables emerge as of greatest significance: (1) the recognised desirability of having a core of international performance standards and (2) concerns about the efficiency of the standards process in the sense of its financial sustainability. A third variable emerges as of lesser importance: the possible obsolescence of materials standards for steel.

¹⁸ Unlike the USA and Europe, the Japanese code appears under a single reference number: JIS - 8270.

a) *The focus on issues relevant to regulatory harmonisation*

72. An important initiative has been decided recently in ISO, through its Technical Committee (TC11) dealing with pressure equipment. The initiative involves a search for international consensus on core principles of safety in the pressure equipment field, and the simultaneous abandonment, until those core principles are defined, of attempts to adopt any individual prescriptive solutions as detailed standards.¹⁹ The dimensions of the standard have symbolic significance in that its core principles could be defined in 10 or 20 pages, compared with many thousands of pages for the full set of prescriptive standards which make up many pressure equipment codes.

73. The initiative to define sectoral core principles is considered unusual in ISO, but not unique: other sectors where similar initiatives are currently being undertaken in ISO are medical devices and machinery; the latter is discussed in the fourth case in this study.

74. The fact that brief core principles are being developed appears more important than their precise form, although disagreements have emerged about the optimum form and about who should be involved in their development. For example, the European Commission, acting as a regional regulator, has for many years integrated the principle of *essential requirements* into many of its technical harmonisation directives. Those texts are developed as regulatory texts, not voluntary standards and they serve as the basis for developing and approving standards subsequently, in support of the regulations. The European Commission has argued strongly that the concept of *essential requirements* should be extended to the global level. While conceptually the current ISO initiative to develop high-level core principles appears to share much with the practice of defining *essential requirements*, it is too early to judge whether ISO's core principles will emerge as identical to them. For example, the view was expressed outside Europe that the ISO's core principles could be more focussed on performance than EU's "essential requirements."

¹⁹ The recommendation by the ISO secretariat to suspend such work is reported earlier in this chapter.

Case 2 - Pressure equipment: analysis according to determinants of effective standardisation

ISSUE	COMMENT
Final standards: Are the standards obsolete or obsolescent?	The question is relevant for materials standards for steel.
Final standards: Are the standards focussed on the issues most important to regulatory harmonisation and liberalisation?	A consensus emerges that the standards in use today are unsuitable for global regulatory harmonisation. The primary reason is that there are two influential different standards. The consensus extends to agreement that a simpler core of core requirements is needed.
Final standards: Have the standards bodies used appropriate deliverables or categories of document?	No evidence suggested any dissatisfaction with the basic form of today's pressure equipment codes, despite their extreme complexity.
The standards development process: Have the standards bodies ensured transparency?	Within the environment of each standards system, standards development appears open and transparent. At the global level, it is premature to judge whether the harmonisation efforts at the global level achieve adequate transparency.
The standards development process: Have all interested parties been consulted, and have effective attempts been made to reconcile any conflicts between them?	At the global level, the answer must be "not yet", since the conflicts between the different systems have not yet been reconciled. But there appears to be a common will to reconcile them.
The standards development process: Is the decision-making process efficient?	This emerges as a potentially critical variable. While there is no evidence or claim of inefficient practice as such, this study revealed significant concerns about the financial sustainability of evolving structures in international standardisation
The standards development process: Has implementation or compliance been monitored?	Not applicable for the bulk of the sector.

75. Some observers have suggested that, if high-level core principles can be developed and agreed, then they might become the basis for a new system under which lower-level, detailed standards could be registered as compliant. A “registered design code” is explicitly seen as a possibility. Such codes could be proposed by the existing standards bodies in the field. The concept offers potentially a neat solution to the integration into the ISO system of bodies presently excluded from it. However, it appears premature to judge how well this approach by ISO will work. Some of the problems that may lie ahead are listed in the following paragraphs:

76. Can essentially voluntary standards – with all that the term implies for participation in their drafting committees – succeed in defining principles that will be widely acceptable to regulatory authorities as the basis for regulation? The EU experience is relevant, in which the highest core principles have been separated from the standardisation process and incorporated directly into regulation.

77. To what extent is it possible to define technologically neutral core principles that will be acceptable to business and governments worldwide? Even inside the EU, which has the strongest track record in the world of technical harmonisation of this kind, agreement in this specific sector on the detailed core principles and their method of application took longer than in any other major sector of industry. The subject of interoperability provides an example of the potential problems ahead and two extremes can be identified in regulatory approaches to the issue.

- At one extreme, regulators may leave interoperability entirely to the market. For example, there is a trend in EU telecommunications regulation to de-emphasise interoperability as a regulatory issue, and to concentrate instead on the three issues of safety, electromagnetic compatibility, and radio spectrum management. Choices on the extent to which systems should be interoperable, how possible it is to take a telecommunications device from one country and use it in another, are being treated as voluntary decisions by network operators and equipment suppliers.
- At the other extreme, interoperability is imposed as a mandatory, safety requirement. An example is the oil exploration industry, where parts must be quickly interchangeable on drilling rigs if catastrophic spills are to be avoided. A second example is one of the classic stories showing how the need for standardisation came to be accepted in history; a massive fire in Baltimore (USA) in 1904, so big that fire engines were summoned from other states, only to discover that their hoses could not be connected to the local water. As a result, the regulation standardised the connections.

78. Will that be decided to be in the interests of trade and of the public interest? Cases very similar to this have already arisen in ISO.

79. What form of agreement, or principles of activity, will define how lower-level bodies will relate to higher international bodies? More specifically, can the existing Vienna Agreement form a model for wider use? Although some players argue that this agreement, the only one of its kind in the ISO network, is indeed applicable elsewhere, it was not evident in this project that it would be compatible with the new frame under consideration. The Vienna Agreement lays down procedures for avoiding duplication of effort, and conflicts in output, for standards of equal levels. The new concept under consideration in this case, however, implicitly leads to standards of different levels, with the higher level being reserved for the global organisation.

80. Finally, the development of a core of international standards may have profound financial implications for the bodies currently involved in standardisation in this field. That financial point is discussed below.

b) *Financial sustainability of international standardisation*

81. Important signs emerged during this case study that finances are potentially unstable in the standardisation world, and that the danger of instability increases when new international co-ordination structures – regional or global – are imposed on the existing, disparate set of standards bodies in operation today. Since no activity can operate efficiently unless it is a solid financial core, this issue is given separate treatment.

82. The first example comes from the USA. The main co-ordinating national standards body, ANSI, has run into grave financial difficulty and it has lost money heavily, and it is unclear how financial health will be restored. ANSI has a loose, “umbrella” role, representing, in various contexts, the interests of a diverse group of nearly 200 independent standards bodies: for example, ANSI represents them in ISO, adopts their standards as ANSI (or American National) standards, and sells many of their texts. As a co-ordinating body, ANSI has failed to define a sustainable financial basis for this co-ordinating role. Many of the bodies which it represents, on the other hand, are financially strong. That picture of a high-level co-ordinating body and a diverse group of specialist bodies doing much of the detailed work shares many similarities with the picture of regional or global standardisation structures.

83. The second example also comes from the USA. It illustrates the need to experiment with new financing mechanisms. During this research, one of the main US standards bodies, ASTM reportedly agreed for the first time to make available some of its standards through ISO, without copyright fees. Now, ASTM is financed to a large extent by sales of its standards. Its rationale for offering them without charge via ISO appeared to be that ASTM felt that any sales through ISO would be incremental to its core business and would not constitute any financial danger. But it is regarded as an experiment, not as a definitive procedure.

84. The EU provides the third example. The EU has invested massively in central resources for standardisation. For example, CEN has expanded its personnel more than tenfold since the EU launched its *New Approach*²⁰ to technical harmonisation in Europe. At the same time, the national standards bodies have broadly retained their older structures. Now, the European Commission has provided massive resources, estimated earlier at well over Euros 50 million, from public funds to finance regional harmonisation, although it has recently been at pains to emphasise that its funding is declining and will decline further. One of the themes they discussed in *Standardisation Summit*²¹ was how European standardisation could be financed in the long-term, given the increasing role of regional standardisation and the declining role of national standards in Europe.

85. The conclusion from this evidence is that, as efforts proceed to integrate today’s competing standards bodies into a new global structure, the financial issues are recognised as needing special attention.

²⁰ The EU experience in this field has already been commented on in this OECD project. See the 1998 analytical inventory of international standardisation, TD/TC/WP(98)36 FINAL and specifically paragraphs 142 - 144.

²¹ It was held in April 1999, bringing together many of the highest representatives of European standardisation.

c) *Obsolete standards*

86. The Japanese Steel Federation, which produces Japanese standards for steel, has concluded that it cannot use ISO standards for steel in their present form, because neither the chemistry nor the strength specifications are appropriate to modern needs. As reported above, ASME also does not use ISO material standards, although it is not clear whether this implies a disagreement about their validity.

87. It is not clear how serious a problem obsolescence may be here. It appears likely that it will receive attention as ISO develops its programme to offer a comprehensive standards harmonisation programme in the pressure equipment field.

V. Construction machinery

A. *The case and its importance to trade*

88. This case covers a programme of international standards harmonisation in the sector of construction machinery which has already produced over 100 international standards. The sector, which includes products such as excavators and bulldozers, is a lively and significant sector of international trade in machinery. Estimates of the global market size are in the US\$60 - 100 billion per year range. International trade is large and one of the main multinationals in the sector exports around 50% of total sales. A limited number of powerful multinationals, European, Japanese, and American, dominate the sector, but there are many smaller competitors in those markets and outside.

89. Broadly, technical regulations and barriers in this sector cover three main issues: safety, noise and exhaust emission. To varying extents, the standardisation programme covers all three. The standards programme in this sector is generally considered by industry to be effective. (A fourth subject, electromagnetic compatibility, has been covered above).

90. Unlike the two previous cases, this case therefore throws lights on the consequences for free trade of a successful and wide-ranging international harmonisation programme in a given sector of trade, concentrated in one of the international standardisation bodies, that is, ISO:

- What factors make it possible to launch and sustain an effective international harmonisation programme?
- When the output of such a programme, a body of high-quality international standards, is widely recognised as valuable by the industries affected, do the resulting standards lead to the elimination of technical barriers in regulation or not?

B. *The technical issues*

91. Regulations addressing the three technical issues above can lead to trade barriers.

92. Since the equipment in question is by definition used on construction sites, rather than in environments visited by the public, **safety specifications** focus on the protection of workers, including the driver, although there are some public-related issues, such as safety of pedestrians when the machines do come in proximity.

93. **Noise regulation** is partly linked to safety (dangerous noise levels can damage drivers' hearing), but is also used to achieve broader environmental objectives: excessive noise, even when not physically harmful, can disturb people close to the construction site.

94. **Exhaust emission regulation** serves primarily to protect the environment, and in this context recent international moves such as the Kyoto Agreement on climate change have added new incentives to tighten requirements.

95. In all three cases, there are technical links with regulations or standards used in other fields: exhaust emission regulation follows principles to those used for diesel-powered cars; safety specifications and noise specifications share common principles or common measurement methods with other parts of the machinery sector.

C. *Global interest in the issues in the case*

96. With one important exception outlined below, standardisation in this sector has attracted only limited policy-level interest from outside the sector and outside the standardisation world. However, that may be an indirect compliment to the quality of international standardisation. International standardisation in the sector is regarded as active and effective, and no evidence in this study suggested any disagreements about policy, such as those found in the two cases already presented in this report.

97. Industrial participants in the relevant technical committees as well as the central secretariats of the standards bodies which provide the umbrella for their activity regard the sector as a successful example of international standards harmonisation. Nevertheless, one of the most active inter-regional industrial co-operation programmes between business in this field, the Transatlantic Business Dialogue (TABD)²² between the EU and the US, the sector has been listed as one which requires further attention by regulators. An example of the concern appears in a 1998 paper submitted to a TABD meeting in Charlotte, N.C., by the main European federation of manufacturers in this field:

The Heavy Industry Sector has a good base of harmonised standards.....However, these standards are in some cases not respected [by regulatory authorities] and in others, are interpreted differently in different member states.²³

Similar concerns have been expressed in all three regions covered by this study. The lack of a consistently smooth linkage between standards and regulation can be demonstrated through examination of the issues covered in both.

D. *The players and their relevant activity*

98. As in all cases in this study, **the WTO** must be considered a player, because of the link between the case and the TBT Agreement. Here, we find regulators criticised either for failing to implement international standards in regulation or failing to apply international standards consistently. Those are both issues which can be considered relevant to the TBT Agreement.

²² The TABD is discussed more fully in the sub-chapter on "players" below.

²³ The paper was entitled as "The need for improved surveillance of the workings of the Single Market. " The federation is CECE.

99. Beyond the WTO, the relative roles of standardisers and regulators are of particular importance. A picture emerges of a standards harmonisation programme at global level which is dominated by industry, working by voluntary consensus; but of parallel standards development at national or regional level, in which closer attention is paid to local regulatory preferences or requirements.

- **ISO** has adopted standards defining safety specifications and separate standards which specify test methods for measuring noise and engine emissions.
- In March 1999, 103 or 105 separate safety standards²⁴ had been adopted by the main Technical Committee, TC127. It does not have standards which set limits, as opposed to test methods, for noise or engine emissions.
- ISO standards are influential in all three regions considered in this study. For example, one of the main US multinational manufacturers of construction equipment²⁵ calculated in 1999 that, of the 105 standards quoted above, 64 had been at least referenced²⁶ by CEN in its own standards. In Japan, 43 ISO standards were used as the basis for JISC, the Japanese member of ISO. It appears remarkable, however, that despite the perceived importance of use of the standards in trade, no central record is available of the transposition, let alone use in regulation, of ISO's standards here.
- **National or regional standard programmes** continue to play an important role. It is a striking feature that all three regions examined in this study maintain important standards outside the ISO list.
- **CEN in Europe** has programme largely based on the ISO. European standards harmonisation has been able to take account of global-level work, and vice versa. However, despite this, not all CEN standards are based on ISO standards. Perhaps the largest single example is a series of standards under the heading of *EN 474: Earth -moving machinery*, which define safety specifications in terms considered relevant to EU directives. EN 474 reports no explicit linkage to any ISO standard, although its title indicates its broad scope and its importance to the entire sector.
- **JISC in Japan** has simply tried to adapt its existing standards to ISO developments. The figures above show that it has made considerable progress, but still maintains a significant number of unique, national standards. JIS standards, of which there are 68 for this sector, are increasingly aligned with ISO, and cover both specifications and test methods. Alignment with international standards in this sector is consistent with broader Japanese progress.

²⁴ Two separate counts were obtained in this study: one from ISO's own web-site, and another from one of the multinational users of the standards.

²⁵ The figures come in an internal table prepared by Caterpillar Inc.

²⁶ Being referenced is not the same as being identical. ISO and IEC have various guidelines which specify varying degrees of association with ISO standards (including *identical* and *equivalent*). No detailed technical analysis was conducted in this study to determine the extent of the variations in Europe and Japan, or their reasons.

- **SAE (Society of Automotive Engineers) in the USA** has historically dominated this sector, and its major industrial members in this sector continue to provide appropriate finance for its secretariat. Its role in this sector, however, appears to be in practice increasingly subordinate to that of ISO, and ISO's standards are reported to be widely used.

100. In the promotion of ISO-level standardisation work here, the role of **industry** appears central, and particularly the role of the small number of multinationals which dominate the sector.

- Because of the highly international nature of the industry, the major multinationals follow developments closely on all three continents: thus, for example, both Japanese and US manufacturers either participate in European standards committees or observe their work, although participation by non-Japanese organisations in Japanese standardisation activity does not appear to be as well developed.
- Manufacturing industry has an established forum in which the manufacturers in the three regions in this study can discuss common interests. It meets annually, and brings together the Construction Equipment Manufacturers' Association (CEMA) in Japan, the Committee for European Construction Equipment (CECE) in Europe and the Equipment Manufacturers' Institute (EMI) of the USA. This annual meeting reportedly reviews strategic issues in standardisation and the progress of international standardisation specifically, even though it is in no sense a standardisation body itself. In addressing the question on *how international standardisation has been able to achieve such progress in this sector*, these established, co-operative mechanisms between a small group of powerful industrial players, combined with their high interest in eliminating barriers to international trade, therefore emerge as crucial.

101. Finally, **regulators** play a crucial role in this case. All three areas studied have more or less formal systems which encourage the use of international standards in regulation, but there is no automatic, direct and universal link between standards and regulation, in any of the three geographical areas, no global forum for discussing such linkage, and in practice there are significant regulatory requirements which are not covered by international standards.

- **In Europe**, the central authority responsible for proposing technical harmonisation legislation is the European Commission.
- The *New Approach* of the Commission applies today only to the safety issues of construction machinery by the Machinery Directive 98/37 and two other issues are today outside the scope of the *New Approach*. Engine emissions are regulated by a specific directive 97/68 and it imposes specifications directly in the regulatory text itself. And environmental noise has not yet been regulated under the *New Approach*. Instead, a disparate series of older directives still applies. Therefore, only the first of these has a current link to international standards.

- However, from ISO’s list of over 100 standards adopted for this sector of construction machinery, of which 64 have been referenced in CEN standards, the EU authorities have so far only recognised 8 under the directive.²⁷ At the same time, the EU recognises the standard EN 474, a multi-part standard without any explicit link to an ISO text. The concern expressed by industry in Europe about the lack of consistent, harmonised regulations in this sector has already been mentioned in paragraph 100.
- **In Japan**, the linkage between standards and regulation is complex, but several features emerge which demonstrate a trend towards use of voluntary standards.
 - It seems fair to say that there is no automatic or statutory linkage at all, but that regulatory authorities in practice try to take account of standards, both Japanese and international, when regulations exist. Regulations only exist for safety issues in this sector; no Japanese regulations were reported for environmental noise or engine emissions.
 - As in the EU and the USA, a multi-sectoral policy provides a frame. Encouragement to use standards in regulations is provided by a Japanese cabinet decision of 29 January 1999. Although there is no compulsion, international reviews have indicated that the encouragement does bring results in practice: a joint EU/Japan review in December 1998 between CEN and JISC identified 45 Japanese laws which referred to JIS standards. Although the Japanese cabinet decision cannot be considered identical to the *New Approach*, it does in practice appear influential in achieving broadly similar results. Since a government ministry, MITI operates the secretariat of the JISC, Japanese national standards body, and therefore influences decisions on adoption of Japanese standards, government involvement in the entire process is assured.
 - Within that frame, the *General Machinery Committee* of the JISC appears to play an important role in this sector. It recommends which texts should be adopted as Japanese standards. It has members from government, academia and manufacturing organisations. In practice, this process has led to the adoption of many ISO standards, directly or in equivalent texts.
 - However, despite the policy guideline and the work of the committee above, industry reports that Japanese regulations in the sector normally contain detailed specifications in the text of the regulations themselves, thus leaving it to the reader to work out whether the texts are identical to voluntary standards or not. Regulations may come from a number of different ministries, in which the Ministry of Labour appears dominant, since it has responsibility for safety standards of this kind. Industry sources indicated that Japan has no mandatory regulations yet covering noise or engine emissions.
 - In practice, government influences technical practice through an additional mechanism, beyond regulation. Public purchasing specifications are reported to be so widely used in construction contracts in Japan, that they play a *de facto* role as mandatory standards even if they do not in principle have regulatory force. These purchasing specifications may deviate from standards and impose unique requirements.

²⁷ They are EN 22860, EN ISO 2867:1, EN23164, EN23411, EN23449, EN ISO 3450, EN ISO3457:1, and EN ISO 6682. The list is obtained by comparing the list of standards formally recognised under the Machinery Directive (available on www.newapproach.org) against the list of standards produced by ISO TC 127, and the CEN standards which transpose them or are equivalent to them.

- **In the United States**, similar policy-level encouragement exists to use standards in regulations.
 - Notably, the *National Technology Transfer and Advancement Act* has led to the issue of a procedural guideline, called OMB A119,²⁸ which requires federal government departments or agencies to consider using consensus standards as the basis for their regulations. Although neither the base act nor the supporting circular refer explicitly to *international* standards in this context, National Institute of Science & Technology (NIST), the government agency responsible for monitoring compliance with the guideline, indicated that it intends to treat that specific aspect in its mandatory annual reviews.
 - At present, however, use of international standards in regulations in this sector in the USA is reported by industry sources to be limited, although no quantitative analysis was possible. Where voluntary industry standards are included in regulations, they are reported to be the older ones of SAE rather than the newer ISO standards. In the safety field, however, the main agency responsible Occupational Safety & Health Administration (OSHA) is reported to be beginning to take account of ISO standards. The USA has no regulations covering environmental noise of machinery of this kind since it regulates only the health aspects of noise in the driver's cab. It uses no voluntary standards in its emission regulations, but co-ordinates its actual limits with the EU.

E. The issues raised by the case

102. Three issues emerge as dominant. First, how effective is the international standards harmonisation programme? Second, if it is as effective as most industry sources believe, what has made it so in contrast to many other sectors such as pressure equipment? And third, if it is effective, what explains the apparent obstacles to its wider use in regulation?

103. As in all cases in this study, analysis has started by focussing on the seven key variables in standardisation identified in the 1998 OECD study as determinants of success in standardisation as a regulatory tool. They appear in the table on the following page.

a) The achievements of international standardisation in this sector

104. What has gone right in standardisation in this sector? Why has one of the major international standards bodies been able to launch and sustain a successful programme of standards harmonisation? Can the experience be repeated elsewhere?

105. This study does not reveal any decisive answers to those questions. For example, it reveals no unique structural features of the industry or unique conditions of the standards needed. That suggests that the experience may be broadly repeatable.

²⁸ OMB stands for Office of Management and Budget, a US federal agency.

Case 3 - Construction machinery: analysis according to determinants of effective standardisation

ISSUE	COMMENT
Final standards: Are the standards obsolete or obsolescent?	Obsolescence was nowhere raised as an issue.
Final standards: Are the standards focussed on the issues most important to regulatory harmonisation and liberalisation?	Industry feels that the answer is “yes”. Regulators, however, fail to use them comprehensively. Unless the regulators are simply incompetent, the only explanations can be that the standards do not deal adequately with regulatory issues, or that the regulators have not been adequately consulted.
Final standards: Have the standards bodies used appropriate deliverables or categories of document?	No suggestion was made that standards are in an inappropriate form.
The standards development process: Have the standards bodies ensured transparency?	No suggestion to the contrary was made, although the complexity of the process in Japan specifically makes transparency difficult.
The standards development process: Have all interested parties been consulted, and have effective attempts been made to reconcile any conflicts between them?	It is difficult to find any other explanation for the fact that industry feels that regulators do not use the standards widely enough.
The standards development process: Is the decision-making process efficient?	No evidence emerged to the contrary.
The standards development process: Has implementation or compliance been monitored?	No central mechanism exists to monitor transposition as national standards, or use in regulation in the major global markets.

106. In that context, it may be recalled that earlier OECD work has already revealed that international standardisation is highly diverse,²⁹ and that there appears to be no optimum model. The model examined in this case is therefore one of many. In that earlier OECD work, when the question was asked of key players *why the field is so diverse and why specific standardisation structures did emerge in the way they did*, the most frequent answer was that a particular need emerged at a particular time, and a particular group, government or private sector, had the resources and the will to deal with it.

107. It is difficult to avoid the conclusion that harmonisation in this sector has been the result of such fortuitous circumstances. In this case, the group that had the resources and the will to deal with it were major multinationals in the field, and ISO offered a practical vehicle for their efforts. They threw their weight behind the existing ISO structure, and it has been working as a result. It may be hoped that public recognition of the ability of the standardisation bodies to respond, as they have in this case, may increase the chances that the model will be repeated.

b) *The link with regulation*

108. This emerges as the key area for improvement in this field. Basic data on regulatory activity and the concern of industry has already been presented.

109. Two facts emerged which may be relevant. First, it is not clear that regulators accept that there is a problem. No regulatory authority interviewed in this project indicated any fear that it was acting as an unreasonable block to international trade. On the contrary, regulators appeared reasonably content that they were making progress toward the use of international standards. That makes the second fact even more important: no global forum exists in which regulators can discuss and resolve any problems that do exist, either alone or with industry.

110. Several comments collected during this study suggested that there are problems which deserve study. Three examples may be cited:

- First, references to *traffic codes* as an important source of regulatory barriers.
- Secondly, since in many parts of the world technical regulations in this field fail to make explicit reference to international standards, the process of updating regulations to take account of updated standards is likely to be cumbersome and slow. When an updated standard is adopted, the old text is left in the regulation until the regulator finds the time to update it.
- Thirdly, a recent report from the EU,³⁰ which offers a highly developed example of attempts to bind international standards in to regulation. The report acknowledges that, even in a region with highly developed regulation to eliminate technical barriers to trade, most businesses believe that barriers still remain.

²⁹ See, in particular, study TD/TC/WP(98)36/FINAL, quoted at the start of this report.

³⁰ Communication from the Commission to the European Parliament and the Council entitled *Mutual recognition in the context of the follow-up to the Action Plan for the Single Market*. Versions distributed to the public carry no date or reference, but the report was made available in the first half of 1999. Although its title refers to mutual recognition of national regulations rather than application of harmonised international regulations, much of its content is directly applicable to both issues.

111. The absence of a global forum to discuss issues such as this is striking. Few, if any, international initiatives at regional or global level to remove regulatory barriers to trade have succeeded without bringing the participants together to agree how to do it. And yet in the ISO Technical Committee which is central to this sector there is no automatic regulatory participation at all. Even in the EU, which has a long history of intergovernmental working groups to remove regulatory obstacles to trade, a special working group has been constituted in this specific sector ten years after the adoption of the relevant directive because of dissatisfaction with progress towards removing regulatory barriers. There appear to be no equivalent initiatives at global level.

VI. Machinery safety

A. *The case and its importance to trade*

112. This case examines a specific, multi-sectoral agreement intended to achieve smooth linkage between regional and global standardisation programmes, and considers its results in one field: machinery safety.

113. The interest of the case stems from the increasing importance of regional standards harmonisation programmes. Regional standards appear in the EU, APEC, ASEAN, NAFTA, MERCOSUR, SARC and many other groups. Both developed and developing countries are involved. In most cases, these regional initiatives are formally independent of each other, although many make conscious efforts either to integrate global-level standards into their programmes or to take account of moves in standardisation in other regions. Even if regional efforts to break down barriers to trade may be laudable, and even if they are consistent in principle with the global goals of the WTO, it is an important question how conflicts between any new regional standards can be avoided. In the context of the goals of the WTO, the elimination of national technical barriers to trade would be of relatively limited value if they were simply replaced by regional barriers.

114. As the first region to launch a major regional standards harmonisation programme, Europe offers experience of co-ordinating its regional efforts with the global bodies. CEN signed the Vienna Agreement with ISO in 1991 and it was designed to avoid duplication of effort and secure transparency linkage between regional and global standardisation.³¹ A similar agreement has been signed in Dresden for the electrotechnical sector specifically between CENELEC and IEC.

115. Those two agreements remain unique in global standardisation. They may therefore help answer the questions: what type of linkage between regional and global bodies will help the development of global standards and what conditions are needed to ensure regional standardisation activity, through its link with regional regulatory activity, does not hamper global trade liberalisation?

³¹ The full title of the Vienna Agreement is *Agreement on Technical Co-operation between ISO and CEN*. It was signed in 1991. Practical issues of implementation have been dealt with in a series of guidelines since then, of which the most recent set can be found on ISO's web-site at www.iso.ch/infoe/directiv.htm. This study failed to identify any web-site where the 1991 agreement itself is available, but a summary of its purpose can be found on www.cenorm.be/activities/activities.htm. The full text of the conceptually comparable Dresden Agreement between IEC and CENELEC (referred to in the box above) is available for comparison, on www.iec.ch/cenelec.htm

B. *The technical issues*

116. There is broad agreement about the importance of regulation to ensure machinery safety. Unsafe machines can injure both consumers and workers. Their construction is therefore frequently subject to regulation, covering specifications, conformity assessment, or both. In working environments, use of machinery is often subject to complementary regulation often called *Health & Safety* regulation, and covering issues such as warnings to workers, safety zones, etc. All three geographical areas considered in this study (the EU, Japan and the USA) have mandatory regulations covering machinery safety.

117. In considering issues of technical specifications for machines, this report makes a conceptual breakdown, dividing standards into three categories:

- First, generic standards defining core principles of safety, applicable to the entire sector. They are frequently referred to as *Class A* standards
- Second, standards dealing with specific, cross-sectoral issues. Examples are noise and vibration. They are referred to as *Class B* standards.
- Third, product specific standards, containing performance requirements and/or descriptive specifications for individual products or product families. An example would be a standard for power drills. They are referred to as *Class C* standards.

C. *The players*

118. The Vienna Agreement is between ISO and CEN.³² Both base their membership, control, and voting on the *one national body per country* principle, although both also make provision for some kind of formal association with multi-national sectoral professional associations. Both have some kind of formal and statutory linkage with the core regulatory or quasi-regulatory authorities at their respective levels.

119. Like other standards organisations, both bodies manage standards development through technical committees. For what might be called cross-sectoral standards across the whole sector of machinery, that is, the Class A and B standards, ISO and CEN have a broadly compatible set of technical committees, as follows:

ISO TC Number	ISO TC title	CEN TC Number
199	Safety of machinery	114
43	Acoustics	211
159	Ergonomics	122
108	Mechanical vibration and shock	231

120. Cross-sectoral issues of electrical safety are not dealt with directly by ISO or CEN, but by IEC and CENELEC, their respective sister bodies for the electrotechnical sector. IEC TC44 and CENELEC TC 44X deal with the issue.

³² Basic data on the structure, membership and activity of these organisations can be found on www.iso.ch and www.cenorm.be respectively.

121. In addition, both ISO and CEN have separate technical committees covering individual products and product families. Examples for ISO are:

- TC 29 Small tools
- TC 39 Machine tools
- TC 70 Engines
- TC 86 Air-conditioning equipment

122. Behind the work of the technical committees, the regulatory position of the European Commission, and its impact on CEN, are important. The EU has harmonised technical regulation through its Machinery Directive,³³ first adopted in 1989. That directive contains a lengthy technical annex of *essential requirements*, which were agreed between European regulators as a common core for specifications, conformity assessment and enforcement.

123. That technical annex, in its latest version, is 28 pages in length. The *essential requirements* in the annex were then used to draw up a list of several hundred standards needed to implement those requirements in practice. There are approximately 800 standards in the EU programme, of which around 130 are in the Class A and B categories. As a result of this programme, CEN has managed a massive programme of standards development through most of the 1990s. The programme is still under way and only 196 of the 800 standards in the EU programme had been formally recognised by the EU, as of June 1999, as providing a presumption of compliance with the directive. This massive programme therefore forms a major example of the potential for co-operation between CEN and ISO.

D. *The Vienna Agreement: content and context*

124. What exactly does this agreement³⁴ cover, and why was it developed? Its elements of *technical co-operation* include:

- Exchange of two-way information. Notably, both sides keep the other informed of their work programme, and their policy decisions.
- Co-operation on standards development. This provides not only for regular progress reports on the work programme, but detailed mechanisms which permit each body to send non-voting delegates to technical committees of the other.
- Adoption of existing ISO standards as European standards is encouraged. Notably, CEN retains freedom to modify ISO standards as it judges appropriate, but makes a commitment to inform ISO of the reasons, so that ISO can itself decide whether to accept the deviation, or to change its own standard.

³³ Directive 98/37/EC. That text dates from 1998, but is based on an original directive (89/392/EEC) adopted in 1989. The directive is one of a series of so-called *New Approach* directives. The *Approach* is that described here: a core list of regulatory requirements, supplemented by a larger body of standards developed by standards organisations as a preferred method of meeting those requirements. The EU approach in this context has been commented on extensively in an earlier OECD study, referred to elsewhere in this report.

³⁴ See box at start of this chapter for references.

- Parallel voting procedures for new standards, to ensure that, where co-operation on a specific standard is agreed, voting is more or less simultaneous.
- Monitoring and co-ordination.

125. The agreement places no ultimate obligation on either side to accept the results of the work of the other. Thus, for example, if CEN feels that ISO action in a particular field is too slow, or inappropriate to European needs which it judges to be different, CEN retains the freedom to run a separate work programme and adopt separate standards. In that context, the agreement explicitly acknowledges the differing obligations for implementation of ISO and CEN standards by their respective members. The agreement refers to:³⁵

the different backgrounds and significance of [votes in the two bodies]: ISO....not mandatory for national implementation. CEN: implementation as national standard mandatory for CEN members.

126. That outline of the agreement makes evident some of the reasons for its development. Notably, both sides acknowledge that they may ultimately have different needs and objectives, but wish to take advantage of the substantial opportunities for synergy: avoidance of duplicated effort, and avoidance of unnecessary technical deviations. And in support of both those objectives, a fundamental requirement for total transparency is imposed: there are no secret dealings on either side, and the work of each is available for inspection by the other. The agreement also refers to a so-called fast track procedure under which standards from CEN may be considered for direct adoption by ISO. However, this fast-track procedure is not unique to this agreement. The same procedure is available to any other body, and CEN is given no privileged position in that respect.

E. The Vienna Agreement: measuring the impact

127. Statistics exist which show how many CEN standards are derived from ISO standards in total. The latest figure as of June 1999 shows that around 1,900 out of 5,115 CEN standards, or just under 40% are identical to ISO standards and another 40% of CEN Standards refer international standards. However, that figure says virtually nothing about the impact of this agreement. Japan, for example, consciously promoting integration between its national standards and those of ISO, estimates that a similar percentage of its own standards, 3000 out of 8000 are now based on ISO standards.

128. However, three facts do suggest that the Vienna Agreement has had an impact in this sector:

- Most of the issues covered in Class A and B standards do in fact appear to be covered in both CEN and ISO programmes, and notably including a core standard defining basic principles of safety for machinery. Both CEN and ISO personnel made the statement that ISO and CEN are working on a common core of cross-sectoral standards. Superficial examination of the actual standards programme of the relevant technical committees, and particularly of the number of standards included, suggested that the statement was correct, although more detailed technical analysis of individual standards would be required to confirm it.
- A procedure adopted initially by CEN to highlight the link between standards and regulation is reported to have been accepted in ISO. Specifically, where a European standard is submitted for recognition in the context of harmonised technical regulation, it now includes

³⁵ In Article 5.1 of the Agreement.

an *Annex Z* which states which specific regulatory issues are covered. ISO accepted to produce an Annex Z in ISO with its expertise throughout the elaboration process, but it will not make available this Annex Z in its finally published standards as CEN does. The system is still at an embryonic stage. While the regulatory reference base is clear for European standards, what will it be for ISO?

- The procedures of the Vienna Agreement under which direct participation by non-members in Technical Committee work have been applied in identified cases in the machinery sector, and notably in the field of construction machinery treated in Case 3 in this study. The procedures work.

129. A separate fact, however, indicates that CEN and ISO do not share the same view of the number of machinery standards which are necessary for regulatory harmonisation in this area. In Europe, the CEN programme contains around 800 standards, of which over 600 are reported to be Class C, or product specific standards. The majority of these 600 standards do not appear to have been incorporated into ISO's own programmes, although no precise measure was possible. Some European sources have suggested that, even in Europe, many of the 600 standards are not in fact needed for regulatory purposes. If true, that would suggest that the Vienna Agreement is in fact working: ISO have been given the opportunity to consider the need for CEN standards, and have replied that they are not needed at the global level.

130. The agreement also appears to have achieved its objective of transparency. No complaint of any kind was made from any source about access to information on standards covered by the agreement. No equivalent guarantees of transparency to non-members were identified in any other regional standardisation programme, despite the fact that all players in global standardisation appear to accept the need for transparency.

131. Despite those arguments, some attacks on the impact of the Vienna Agreement have been made inside ISO, and from countries which are outside Europe. In public ISO meetings, for example, it has been suggested that the agreement does not achieve its objective of transparency, and that recognition of CEN standards as a means of compliance with EU technical regulation still emerges before those standards are subject to full and timely consultation with other countries in a wider international forum. A reading of the text of the Vienna Agreement indicates that that may happen: it allows CEN, as a European standards body, to continue to work independently for EU regulations wherever ISO members judge that they do not need similar measures. However, it does not become an issue unless the European Commission recognises as a means of compliance CEN standards that are not based on ISO standards. Therefore, the ultimate cause may lie not in the Vienna Agreement itself, but elsewhere.