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Trends in Conformity Assessment Practices and Barriers to Trade

FINAL REPORT ON SURVEY OF CABS AND EXPORTERS

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TRENDS IN CONFORMITY ASSESSMENT PRACTICES AND BARRIERS TO TRADE: FINAL REPORT ON SURVEY OF CABS AND EXPORTERS

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by Barbara Fliess and Raymond Schonfeld

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ABSTRACT

This analytical report presents findings from a survey conducted in 2005/2006 of conformity assessment bodies (CABs) and exporting companies from the OECD region. The survey was conceived to gather primary data from key players in the field on perceptions of conformity assessment (CA) barriers: what they are, where they are, and how important they are. A second goal was to identify trends in CA practices, including in the use of tools aimed at removing barriers and facilitating international trade.

Drawing on the survey, some follow-up research and expert discussions, the report identifies what appears to be major CA problems or issues and consequently where policy action might be helpful and timely. For example, it appears that a significant proportion of products still need to be assessed in the import market. Also there is no evidence that Supplier's Declaration of Conformity is reducing third-party CA. On the positive side, CABs report that the single most important factor in encouraging their cross-border CA activity is wider use of international standards. They also tend to confirm the usefulness of mutual recognition agreements. Exporting companies participating in the survey, too, raise a number of concerns, for example the complexity and delay in obtaining information on CA requirements in the destination market or inefficiencies caused by non-acceptance of home-country test reports, repetition of identical tests for different markets, or other requirements.

Keywords: conformity assessment, technical barriers to trade (TBT), accreditation, product testing, product certification, mutual recognition agreement (MRA), Supplier's Declaration of Conformity (SDoc), CASCO, ISO.

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The Working Party of the OECD Trade Committee discussed this report and agreed to make the findings more widely available through declassification on its responsibility. The study is available on the OECD website in English and French: <u>http://oecd.org/trade</u>

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EXECUTIVE SUMMARY

To gather up-to-date primary data that will deepen analysis of the nature and impact of conformity assessment (CA) procedures on trade in manufactured goods, the OECD Secretariat carried out a survey of conformity assessment bodies (CABs) and exporters in OECD member countries from October 2004 through July 2005. The survey was designed to identify, quantify and prioritise CA barriers in trade in manufactured goods today. The operational goal was to obtain evidence from key players in the field on perceptions of barriers: what they are, where they are, and how important they are.

The issues explored in the survey were investigated further, with a view to eliciting ideas for action, by drawing on discussions that took place in a wider conference co-organised by the OECD in Berlin in November 2005 on how progress could be accelerated in reducing barriers presented by both standards and CA. Furthermore, a small set of deep follow-up telephone interviews with respondents to the survey was conducted, in which both the results of the survey and the ideas from the Berlin conference were explored.

Considering that the survey is on conformity assessment, one might have expected a stronger participation from CABs, whose business is CA, than from exporters, for whom CA is only one of several trade and marketing concerns. However, the number of CABs participating is fairly small and the response rate from exporters extremely low. As a result, any conclusion can only be indicative and the study serves best as good basic information for further investigations.

The 428 CABs which responded included a disproportionate number from Europe, but enough responses from outside Europe were received to indicate that this geographical bias does not invalidate the conclusions that might be drawn at the global level. The responses suggest that:

- Where independent conformity assessment is performed on products traded internationally, a large proportion of the products concerned appear still to be assessed in the import market. Given that governments, in an effort to minimise negative impacts of CA procedures on trade, have in recent years taken steps to promote the principle of "one product, one test, accepted everywhere", this continued high use of testing in individual destination markets suggests that multiple testing should be a cause for concern. An important contributing factor appears to be the failure by authorities in destination markets to recognise home-country accreditation of CABs in the producer country, despite many attempts by governments and groups of co-operating accreditation bodies to facilitate such recognition.
- It also appears that Supplier's Declaration of Conformity (SDoC) is not having a major impact in reducing third-party CA, contrary to the objectives of many government programmes.
- On the positive side, responses from the CABs indicate that the single most important factor in encouraging their cross-border activity is wider use of international standards. The widespread exhortation by governments in international trade discussions to develop and make more use of international standards does appear to have a significant positive impact. These CABs also mention MRAs, both government-to-government and private-sector, relatively frequently.

Because the number of exporters participating in the survey is very small (110), their responses are at best illustrative of exporting companies' experiences and need to be interpreted with caution. Still, together with in-depth interviews that have been conducted with some respondents, the survey data point to remaining pockets of sectors in which CA barriers are important. Other relevant data emerged from the OECD conference in November.

Despite the issue of statistical validity, the survey of exporters seem to indicate that:

- From the low response rate, it seems that conformity assessment in general is not perceived today as a widespread, critical barrier to exports by companies headquartered in OECD member countries.
- However, there remain important pockets of concern, described normally in terms of sectors. Unsurprisingly, these predominantly concern technical products with complex specifications; examples are electrical machinery, telecommunications and IT equipment. But there are also concerns in other areas, such as food.
- In content, the problem highlighted by the greatest number of respondents (56%) as moderate, major or critical was the complexity and delay involved in obtaining information on CA requirements in the export market targeted. But inefficiencies or barriers caused by testing requirements were also mentioned repeatedly in various forms each of which was included separately in the survey and may be considered, in total, to be of even greater concern. All of the following were mentioned as moderate, major or critical problems by over 40% of respondents: 1) the refusal by governments in export markets to accept home-country test reports, 2) the repetition of identical tests for different markets (i.e. by different CABs) and 3) the imposition of different types of tests for different markets. Follow-up of these findings in interviews confirmed that exporters feel that even where the imposition of different types of test may be justified (for example, to meet different climatic conditions or user practices), home-country testing normally ought to be possible.
- The reported effects of these inefficiencies are consistent with earlier studies of the effects of TBT: survey results here confirm that they add unnecessary cost and delay time to market. An additional effect, potentially even more damaging, is noted: the use of requirements for technical documentation and manufacturing information to acquire illegally proprietary technology.

Results from the survey of CABs and exporters were subsequently explored in more depth in followup interviews and at the Berlin conference. The goal was to verify the apparent findings and elicit ideas on what might be done about barriers mentioned by survey respondents. This work revealed the following:

- There is widespread support for the goal of extending SDoC (i.e., eliminating mandatory third-party certification imposed by government) in order to eliminate these barriers, but some disagreement about the order of the steps needed to reach that goal. Some respondents favour an exclusive focus on the SDoC goal and on building the infrastructure widely recognised as necessary to make it feasible: notably, strong structures of supplier liability (product liability law) and market surveillance. Others appear to feel that even if the goal of SDoC is valid, it will in many countries take so long to reach it that intermediate solutions are needed.
- The most frequently mentioned "intermediate solution" is wider recognition of test reports and certificates issued in producer countries, and here the view of exporters supports the data from CABs outlined above. While no magic formula emerged to achieve this, helpful examples and some pointers did emerge. It appears to be accepted that the potential solutions include

alternatives to government-to-government mutual recognition agreements advocated in the past but more rarely promoted today, and cover the potential for using non-governmental schemes more effectively. Examples of non-governmental schemes include accreditation networks based on international standards and incorporating strong peer assessment processes.

- In the light of the general support for SDoC, when coupled with effective market surveillance, but differing opinions about how realistic quick progress here is, it may be helpful to survey WTO member governments to provide more hard facts on the rate of progress and product coverage of SDoC to date.
- The potential relevance of Good Regulatory Practice (GRP) to this field also emerged. Many of the specific complaints reported by business appear to result from a lack of discipline in technical regulation, affecting content, transparency, or the allowance for time to adjust. At the global level, the establishment of a more disciplined structure of technical regulation, based on harmonised principles of GRP, could help remove inefficiencies of those kinds, and also build the confidence that would allow wider recognition of single-test-location procedures for CA, replacing the imposition of separate procedures in each destination market, which are widely perceived by exporters as unjustified and inefficient.

TRENDS IN CONFORMITY ASSESSMENT PRACTICES AND BARRIERS TO TRADE: FINAL REPORT ON SURVEY OF CABS AND EXPORTERS

I. INTRODUCTION

1. Conformity assessment (CA) provides benefits for manufacturers, consumers, government regulators, and trade in general, but it can also act as a technical barrier to trade. While it is indispensable to trade and regulation, available business surveys and notifications by governments to the WTO-based Negotiating Group on Market Access indicate that CA is also an area of continuing difficulty for traders.

- Technical barriers to trade (TBT) represent the leading category of NTBs notified by WTO Members in the context of the NAMA negotiations, and 36% of those are about conformity assessment. These NTBs have been reported by OECD Member as well as non-Member countries.¹
- A recent company survey conducted by UNICE on remaining trade barriers in the EU single market found that close to half of the respondents encountered requirements for additional national testing or certification of their products.²

2. The survey presented in this paper is part of a broader investigation of how and under what circumstances CA procedures can facilitate trade or create barriers.³ By reviewing national and international experiences, this work seeks to promote understanding of what appear to be effective approaches for reducing negative trade effects. Towards that end, the OECD Secretariat collected empirical data from conformity assessment bodies and OECD exporters by way of an electronic questionnaire survey that was open for responses from October 2004 through July 2005.

3. Data on the costs and the market access effects of the different CA procedures that countries use are scarce. Hence the strategic goal of the survey was to *identify, quantify, and prioritise conformity* assessment barriers in trade in manufactured goods today. The operational goal has been to obtain evidence from key players in the field on perceptions of conformity assessment barriers: what they are, where they are, and how important they are. At a broader level of analysis, the survey data help *identify* trends in CA practices, including tools aimed at removing barriers and facilitating international trade. Such information can contribute greater specificity to the information and national experiences that countries are exchanging in various fora, including the WTO Committee on TBT.

4. This paper reports results from this survey exercise with a view to identifying areas where further policy developments and actions could contribute to the facilitation of trade. The issues explored in the survey were also explored in a wider conference organised jointly by OECD and InWent Capacity Building International in Berlin in November 2005, to discuss how progress could be accelerated in

¹ Calculated from notifications contained in Non-tariff barrier notifications (TB/MA/W/46 and 46ADDs), Negotiating Group on Market Access, WTO, Geneva.

² Union of Industrial and Employers' Confederations of Europe (UNICE), *It's the Internal Market, stupid!, A company survey on trade barriers in the European Union*, Brussels, May 2004.

³ An introductory analytical paper currently under preparation describes the policy context for studying CA procedures and reviews concerns and other observations about CA practices and their trade impact brought to the attention of the WTO TBT Committee since 1995 or documented by other research.

reducing barriers presented by both standards and CA. Where relevant, the paper draws also on the discussions that took place at the Berlin conference.⁴

II. METHODOLOGY

5. Two separate questionnaires were developed, aimed respectively at: (1) conformity assessment bodies (CABs), and (2) exporters of manufactured goods. Geographical scope included all member countries of the OECD but with a special effort to reach respondents from Canada, France, Germany, Japan, United Kingdom, and United States. Sectoral scope is broad, the aim being precisely to obtain perspective on the sectors presenting the most important barriers. In size, the survey aimed to cover the full range, from SMEs up to large multi-national companies.

6. The questionnaires aimed to elicit responses that would identify, quantify, and prioritise conformity assessment barriers in trade in manufactured goods. The questions covered: 1) perceptions of the seriousness of CA barriers to international trade today; 2) identification of sectors and countries where barriers were felt to be still significant, and the nature of those barriers; and 3) factual information on respondents (such as size, location, age of company), to determine whether perceptions of barriers vary by type of respondent.

7. Annex 1 lists the CA problems used as the basis for drafting the categorical and "open-ended" questions of these questionnaires, expressing them both in practical, business terms and in the administrative language used in the TBT Agreement. Annex 2 provides further information about the methodology and examples of the questions used.5

8. In soliciting responses to the initial questionnaires, CABs and exporting companies were not approached directly. Rather, a number of organisations representing CABs and businesses were contacted in writing with a request to alert their members to the survey. The process of contacting the target groups was initiated in late October 2004. The questionnaires were open for responses until the end of July 2005.

9. In light of the statistically low response level from exporters to the Internet questionnaire, a very limited number of personal telephone interviews were conducted, in order to strengthen and develop the evidence of barriers which appeared to emerge from the questionnaire. Six interviews were conducted with exporting companies including four major multinationals, four with major trade associations representing exporters, and – as an independent check on technical aspects of conformity assessment identified in those interviews – one further interview with a major international conformity assessment body.

⁴ The International Workshop and Policy Dialogue on Standards and Conformity Assessment in International Trade: Minimising Barriers and Maximising Benefits took place in Berlin on 21-22 November 2005.

⁵ The questionnaires were designed to optimise user-friendliness, and for administration via Internet with at time demand of no more than 20 minutes per respondent. Respondents were able to access, by using a special access link, the questionnaires and submit their answers at the non-OECD website *http://www.formsite.com/*.

III. SURVEY RESULTS

A. Target group "conformity assessment bodies"

1. Profile

10. Distribution of the questionnaires to conformity assessment bodies (CABs) focussed on highquality CABs: those accredited or recognised in major accreditation systems or associations, and notably the 5000+ conformity assessment bodies accredited by bodies which are members of the *International Accreditation Forum*, perhaps the most widely recognised international body in this field. ISO, many of whose national member bodies also control conformity assessment operations, was also used as a channel, along with major sectoral associations. **Annex 3** lists the channels used to reach conformity assessment bodies.

11. A total of 428 completed questionnaires were received. If one assumes that all CABs accredited in the IAF system were reached, approximately 8 percent of this target group responded. Because the survey was publicised more broadly and reached also other CABs (notably also those affiliated with ILAC) the response rate is lower. No figures exist for the universe of accredited CABs (the number of accredited laboratories in the ILAC network is over 20,000, but many organisations have several laboratories, and ILAC does not calculate the number of organisations covered: an informed guess would put the number of organisations conducting CA, including multi-laboratory organisations, at >10,000). There is no information available enabling us to compare qualitatively the representativeness of the set of respondents with the broader target group.



Figure 1. Respondents' country of primary activity, by geographic region

12. CABs of all sizes are represented, although the majority (355) are small and medium sized businesses (SMEs, with less than 500 employees). 11 percent employ more than 1,000 employees.

13. As shown in **Figure 1**, the geographical balance of the responses is not optimal, but nevertheless reasonably international. Of the 428 respondents in the survey, the majority are operating in OECD

member countries, but an important minority (16%) have their primary activity in OECD non-members. 64% (274) of the respondents carry out their primary activity in Europe, with Switzerland (69) Spain (31) United Kingdom (24) Czech Republic (23) Netherlands (20) Poland and Germany (18 each) leading the list of respondents from that region. Bulgaria, the Russian Federation are also represented. The other respondents operate mostly either in North America (United States 38, Canada 7) or in the Asia-Pacific region (Australia 54, Japan 12, Hong Kong 6, New Zealand 2, and China 1). Responses from countries in Latin America and the Caribbean were dominated by Brazil (10) and comparatively few, as were responses from North Africa and the Middle East (Egypt 4, Israel 7, Morocco 2, and Iran). A list of all countries represented is shown in Annex 5.

14. Survey responses are concentrated among CABs undertaking conformity assessment of products: the vast majority of respondents (323) are working in one or several of the fields of a) *product testing*, b) *product certification* and c) *technical documentation*, mandatory and/or voluntary. These are also the activities most directly associated with trade in goods. A majority furthermore report that they assess conformity of management systems, for regulatory purposes or for voluntary purposes, whereas fewer respondents are involved in calibration/metrology. **Figure 2** shows the distribution of areas in which the 428 respondents undertake conformity assessment in their home countries, both regulatory and/or voluntary. Across the range of activities, a breakdown by region shows that CABs with primary activity in Europe are represented in more or less the same proportion as in the overall set of 428 respondents.

15. CABs were asked to name the most important product area or sector in which they undertake conformity assessment of products. Most often mentioned were *electrical and telecom products, building materials and components. Food products* constituted another leading item. Other sectors of CA activity well represented in this survey are *automotive products, machinery of different kinds, chemical products, pharmaceuticals, measuring appliances and instruments, and medical devices.*





Note: 355 of 428 respondents provided information on their fields of activity. Respondents could choose one or more fields of activity.

2. **Observations**

a) Involvement in international trade and scope of activity

16. Is there significant involvement by CABs in international trade, and if so what elements appear to facilitate that cross-border activity?

17. CABs were asked how important to their activity was "import"-related conformity assessment of products (i.e. CA of a product produced outside the CAB's country but intended for sale in its country). 40 percent of the 428 respondents reported that this was either very important or important. This indicates that *a large proportion of traded products are still assessed in the import market, not the export market*. Since it is widely accepted that the TBT Agreement is in principle aiming to support the goal of "*One product, one test, accepted everywhere*", this continued high use of multiple testing in individual destination markets should be a cause for concern.

18. Similarly, 45 percent of respondents reported that "export"-related conformity assessment of products (i.e. CA of a product produced in the CAB' country but intended for sale outside the country) was either very important or important.

19. This indicates that the respondents as a group are quite heavily involved in international trade, in the sense that a significant proportion of their activity is export- and/or import-related. (It says nothing about the percentage of international trade in which CABs are involved; much trade is conducted without their involvement.)

b) Trade facilitating and other factors associated with high or moderate export-related activity

20. Respondents were asked to indicate how their trade-related CA activities were evolving. As far as *export-related CA* is concerned, **Figures 3** and **4** show that:

- 110 CABs (or 26%) reported that they have experienced *moderate or high growth* in their *export related CA* of products over the last five years. Compared to the overall set of 428, respondents here include fewer CABs with primary activity in Europe (53% for high and moderate growth combined) and more CABs from Asia and North America.
- 201 CABs (47%) reported *low or no growth;* CABs from Europe having answered to a greater extent that they reported no export related growth (73%).
- 20 CABs (3%) reported *negative growth*. CABs from North America are not represented at all in this category.

21. Considering that 18% of the 428 CABs participating in the survey are operating in Asia, this region is represented more strongly among the 110 respondents reporting *high growth of their exportrelated CA activities* (26%) as well as among those reporting *negative growth* of (also 26%). Moreover, virtually all Asian CABs that reported *negative growth* are from Australia, whereas Asian CABs reporting *high growth* are from either Australia or China. Furthermore, 63% of CABs from Australia reported that they experienced either low, no or negative growth in export-related CA activity.



Figure 3. "How have your export-related CA activities evolved in the past five years?"

Note: Of relatively many CABs (99) that reported that they did not know if they had experienced export-related growth in revenues, 75 also responded that they didn't know if they experienced increase in activities due to import-related CA. These CABs do not seem to distinguish between export-related to import-related business performance in their accounting system.



Figure 4. Reported export-related growth experiences by region of respondents' primary activity

22. Among the 110 CABs with high or moderate growth of export-related CA, 29 countries are represented; however, the CABs operate predominantly in Switzerland (17), the United States (13), Australia (10), Spain (9), and United Kingdom (8). A breakdown by region is presented in **Figure 5**. Noteworthy is that while central and eastern Europe are very well represented in the overall sample of CABs answering the questionnaire, there are comparatively fewer CABs reporting high or moderate growth here than in other regions.





23. These 110 respondents were then asked to consider a list of potential reasons given by the questionnaire for the growth in export-related activity. From the distribution of answers shown in **Table 1**, the most frequent reasons mentioned are that *international standards and CA procedures have become more widely accepted*, along with *efforts that the CABs have made themselves* (i.e. they have increased their sales efforts in export markets and/or added new areas of technical competence that are relevant to export markets).

24. Responses generally confirm that CABs perceive the *growing acceptance of international standards to be the single most important factor in their international expansion*. This perception appears to cover both product standards and standards for conformity assessment processes such as ISO 17025, which were mentioned explicitly by several respondents even though they were not directly asked to do so. ISO has allocated much effort in recent years to a comprehensive modernisation of the body of standards which assure integrity of conformity assessment processes (often referred to collectively as CASCO standards, where CASCO = Committee on Conformity Assessment), and this survey seems to confirm their value.

25. The 66 CABs attributing their growing cross-border activity *inter alia* to the growing acceptance of international standards predominantly operate in OECD countries, but 17 operate in non-OECD home countries (which represents 24 percent of all non-OECD CABs participating in the overall survey). A majority of the 66 CABs work in the fields of product testing and product certification. When asked to name specific sectors where the growing acceptance of international standards had benefited them, respondents mentioned most often *electrical machinery and apparatus, pharmaceuticals and chemicals, machinery*, and *electronic and telecom products and equipment*. For a detailed breakdown by product sector, see **Annex 6**.

Reasons for moderate and high export growth of CAB's export-related activity	Responses	%
Broader acceptance of international standards and CA procedures	66	60%
Increased sales efforts in export markets	59	54%
Technical competence in new areas that are relevant to export markets	52	47%
Higher growth of export market relative to domestic market	40	36%
Better identification of CA requirements	38	35%
Promotion of use of the MRAs and MLAs on the part of accreditation bodies	32	29%
New accreditation by foreign governments(s) to undertake CA	32	29%
Formal Mutual Recognition Arrangement (MRA) involving home country	28	25%
Non-government mutual recognition scheme (e.g., IECEE CB scheme)	25	23%
Acceptance of CA reports and certificates in foreign markets	22	20%
Removal of sub-national requirements in export markets	13	12%
Technical assistance provided by home government	9	8%
Other	8	7%

Table 1. Factors associated with moderate or high growth in export-related CA activity of CABs

Note: Sample = 110 respondents reporting "moderate" or "high" growth in their export-related CA activity. Respondents could check multiple items. " Other" responses include: increased popularity of own lab and closing down of other labs; being privately owned and independent and good, responsive and accepted; respondent is accredited for new private protocols; and introduction of non-tariff barriers by the export market which has made respondent's clients test more.

26. Among activities where governments have an opportunity to facilitate trade development for CABs, *formal (government-to-government) mutual recognition of CA comes an important second*: it appears significant that, despite the very low number of operational mutual recognition agreements, CABs reporting moderate or high growth in their export-related CA activity mention these relatively often as contributing to this growth. The role of these formal MRAs, as well as non-governmental mutual recognition schemes, is explored in more detailed in a subsequent section.

27. Not all factors appear to matter to the same degree for all regions. **Figure 6** shows that fewer CABs with primary activity in Europe and more CABs from other regions (notably North America and Latin America) than are represented in the set of 110 CABs that answered these questions identified factors such as "non-governmental mutual recognition" or "acceptance of CA reports in foreign markets". By contrast, many more CABs from Europe and fewer CABs from other regions identified "broader acceptance of international standards", "increased sales efforts" and "removal of sub-national requirements".



Figure 6. Factors associated with moderate or high growth in export-related CA by CABs, by region (CABs from Europe compared to other regions)

Note: Sample = 110 respondents reporting "moderate" or "high" growth in their export-related CA activity. Respondents could check multiple items.

How this Figure should be read: Compared to the regional distribution of respondents reporting high to moderate growth shown in Figure 5, in Figure 6 respondents from certain regions are sometimes overrepresented and sometimes underrepresented for some of the factors associated with high to moderate growth. For example, European respondents constitute around half (54%) of total respondents (see Figure 5) but provide a much higher percentage of affirmative answers for the factor "*Increased sales effort*" in Figure 6. By contrast, for the factor "*Non-government mutual recognition*", their response rate is much lower, whereas the proportion of respondents from North America having selected this factor exceeds by far the 14% share of North American respondents in the distribution of respondents shown in Figure 5.

28. Based on the survey results, the 110 CABs that report high or moderate growth in export-related CA differ from other CABs that report low or no growth along a number of dimensions. For example, high or moderate-growth CABs are:

- More likely to be mid- to large-size in headcount (> 500) and large in turnover (>\$250million), and unlikely to be very small (>\$0.5 million turnover).
- More likely to use subcontracting (i.e., commission some part of the conformity assessment process from other entities).
- More likely to have formal agreements with CABs in other countries and outside their own group, which generally consist of mutual recognition of test reports or certificates of conformity.

29. The last two points provide confirmation of the feasibility of using sub-contracting and mutual recognition as tools for growth.

30. When set against the three points, an apparently surprising result is that high/moderate growth CABs are less likely to belong to a group with facilities abroad (54% of them report having no facilities abroad). Most of the highest-turnover CABs – shown above to be in the high/moderate growth group – are known to be multinational, implying that high and moderate growth accompanies multinational presence and large size. So are the data contradictory, indicating that a multinational presence is not in fact associated with high growth? The data are probably not contradictory, and can be explained by the simple fact that larger multinationals (>\$500 million turnover) are relatively few in number and are simply outnumbered in the high/moderate growth group by mid-size, single-country CABs.

c) Sectors and markets where export-related CA activity has grown

31. Respondents reporting high or moderate export-related activity growth were asked to list up to three sector/country combinations that had been most important in the growth of their export-related activity.

32. 94 respondents answered this question.⁶ Food products, electrical and electronic products, measuring instruments and medical equipment were the most frequently mentioned sectors.

33. The markets most frequently mentioned were the European Union (leading by far), followed by the United States and China.

34. With respect to product sector/country combinations:

- Food *products exported to the European Union* was the most often mentioned source of growth in export-related CA activity. Reporting CABs are based either in developed countries (other EU trading partners, New Zealand, Australia, Switzerland) or in developing countries (e.g. Egypt, Israel, and Brazil).
- Markets associated with *measuring instruments and medical equipment* are primarily the *European Union* followed by the *United States*. Reporting CABs are mostly from the OECD region. For *electrical machinery and apparatus*, destination markets are the European Union followed by the United States und certain markets in Asia (especially China, but also Chinese Taipei and Japan); here many of the reporting CABs are based in the United States and Australia.⁷

⁶ Some respondents notified sectors but not countries, or vice versa.

⁷ The reference to measuring instruments may be misleading: a sample check with exporters who reported developments or problems under the same heading revealed that this term is sometimes confused with simple

d) Role of Supplier's Declaration of Conformity (SDoC)

35. Conclusions on the growth and importance of SDoC are less clear. The survey responses suggest that, contrary to the objectives of many government programmes, *SDoC is not having a major impact in reducing third-party conformity assessment.*

36. Respondents were asked whether within the past five years they had lost any third-party CA orders for the primary reasons that SDoC had replaced third-party CA as a requirement. The vast majority of the 428 CABs (87%) stated that this had not been the case. While these figures cannot be used to quantify the extent to which SDoC has in fact replaced third-party CA in international trade, evidence that the introduction of SDoC is often a complex, difficult, or slow process was provided by some of the national experiences presented and discussions that took place at a workshop that the WTO Committee on TBT held on the subject in March 2005.⁸

37. For the set of 428 respondents, a breakdown by region shown in **Figure 7** indicates that respondents from Europe and North America report relatively more often than their counterparts from other regions that they have lost business because of SDoC (respectively 16% and 15.5% affirmative responses). At a level of greater detail, within Europe some countries appear more affected by this trend (e.g. affirmative responses of almost 50% for Germany and the Netherlands) than other (e.g. affirmative responses of 7% for Switzerland).

38. A relatively small number of CABs — 56 — responded that they had lost orders because of SDoC, and that this has had some impact on their business. These 56 respondents were asked to identify up to three sectors/countries in which they found a wider use of SDoC.

39. A total of 62 sectors/countries were listed. The sectors most often mentioned were *electrical*, *electronic and telecommunications products* as well as *machinery*. The leading markets mentioned were the regions or individual countries of the *European Union and Europe* (leading by far), followed by the *United States* and *China*. For electrical, electronic and telecom products, many respondents reported that the impact on business as a result of lost third- party CA orders had been "major", whereas for machinery the perceived impact was reported to be less significant.

control instrumentation which falls more appropriately under the heading of electrical apparatus, and which does not have any connection with regulations or procedures associated with metrology as such (e.g., procedures under the aegis of the OIML – Organisation Internationale de Métrologie Légale). The study did not explore this aspect in any greater depth, and it is necessary to caution against deriving conclusions about metrology from the survey.

⁸ The workshop held by the WTO TBT Committee documented the benefits of SDoC, but also some of the challenges that regulators face when introducing SDoC regimes. See Annex 1: TBT Workshop on Supplier's Declaration of Conformity, in: WTO, Committee on TBT, Minutes of the Meeting of 22-23 March 2005 (G/TBT/M/35)



Figure 7. Have you lost any third party CA orders for the primary reason that SDOC has replaced third-party CA as a requirement?: Responses by region

40. What might explain this apparent evidence that, even though SDoC is spreading (the number of CABs reporting loss of business resulting from the introduction of SDoC may be only a minority of the total, but even those minority reports provide hard evidence of its growth), the vast majority of CABs see no reduction in third-party CA as a result? Two explanations are possible: 1) that even if application of SDoC is spreading, it is not spreading fast enough to have a major impact on the market; and/or 2) even if its is spreading at the regulatory level, *the market* does no consider it reliable enough to abandon third-party certification.

41. Observation of trade-related discussion suggests that the expectations originally attached to SDoC may have been too high, at the level of both the growth in its use by regulators and its impact on the market. Evidence from exporters, reviewed elsewhere in this report and including results from in-depth interviews, supports the view that in several sectors exporters want to see more progress in the direction of SDoC, and that they are concerned not only about *regulatory* requirements for third-party certification, but also about requirements imposed by customers as individual buyers or in groups. It is also widely acknowledged, in the market and in government-level discussion, that the introduction of SDoC requires strong supporting structures of product liability regulation and market surveillance, and that those supporting structures are frequently perceived to be lacking.

42. Against that background of dissatisfaction with the rate of expansion of certification-free exporting, one way of exploring the issue would be for OECD member governments or WTO member governments more broadly to report on exactly where they have introduced SDoC to replace previously mandatory third-party testing or certification, during the life of the TBT Agreement (i.e., since 1995). The analogy of internal EU activity in the decade before that (i.e., 1985-1995) may be instructive: during that decade, the EU systematically went through sectors where CA requirements varied between EU member states in order to remove inconsistencies. The result was the documented removal of third-party CA, and the introduction of SDoC, in a number of country/sector combinations. There are many other examples, for example telecom equipment in Canada, automotive products in Korea and electrical/electronic products in New Zealand. However, we are not aware of any attempt to document achieved change at the global level. An attempt could be made to prove or disprove the impression left by this survey.

Note: Sample = 428 respondents.

e) Role of cross-border recognition

43. Among the tools available to facilitate international trade are various types of recognition schemes. One way of breaking the field down is to distinguish between governmental and non-governmental agreements.

44. **Governmental agreements** are generally called "mutual recognition agreements" (MRAs) and may involve two or more parties. The essence of a governmental MRA is encapsulated in the following text describing an EU-USA MRA: the MRA *specifies the conditions by which each Party [i.e., the governments] will accept or recognise results of conformity assessment procedures, produced by the other Party's conformity assessment bodies or authorities, in assessing conformity to the importing Party's requirements.*⁹ In other words, under MRAs certification is carried out by a CAB in the country of origin/export against regulatory requirements in the country of destination/import. Such agreements improve the efficiency of testing by enabling all testing required by regulations of BOTH parties to the MRA to be conducted in the country of production, and thus reduce approval costs and allow faster and more predictable time to market. They may even reduce the total number of tests, but only where the test requirements are identical under the regulation of both parties to the agreement. These agreements may be based on parallel agreements (also sometimes called *arrangements*) between accreditation bodies, as described in para. 46 below, but the link must be established case-by-case and is not automatic.

45. This kind of MRA may be bilateral (e.g., US-EU) or multilateral (e.g. APEC's non-binding mutual recognition scheme, ASEAN) and focuses exclusively on regulatory recognition of CA results imposed by regulation. Where there is no mandatory conformity assessment, there is no need for such an MRA.

46. Governmental MRAs also have some disadvantages, for example implementation tends to be resource intensive, and although they are practical especially for countries at similar level of technological development, there have been problems even there, notably with the acceptance of home-country designation of CABs whose certificates are to be recognised. To date, MRAs have been negotiated between only a few OECD countries (mainly between the European Union and some non-EU countries and also within APEC), facilitating trade between parties to the agreements. There are some attempts, at various stages of development, to introduce MRAs outside the OECD region, including a number in ASEAN.¹⁰

47. **Non-governmental agreements** carry various names, including MRA (as in the governmental field), but the term MLA (multi-lateral [recognition] arrangement) is perhaps more widely used when accreditation is involved. The agreements may be organised under the umbrella of an accreditation network¹¹ (IAF and ILAC¹² both offer such schemes), or of another international association (such as the IECEE CB scheme of IEC in the electro-technical field, which is a multilateral agreement among signatory CABs), or simply bilaterally between CABs. They may cover test reports, measurement results, or certificates. Common features are the application of common standards of competence, and the formal recognition, in the country of a participating CAB, of results obtained by another participating member in

⁹ The full text is available from various sources including the EC Official Journal OJ L31 4.2.1999.

¹⁰ Electrical products and cosmetics are two examples of areas where ASEAN is attempting to remove barriers of this kind.

¹¹ The role of accreditation and its wider influence on the acceptance of conformity assessment results are discussed in more detail in the section of this report headed *"The role of accreditation"*, in paras 54ff. See also www.ilac.org -- arrangement section: *"Good news stories"*.

¹² The names and initials listed here have been mentioned earlier in this report, and Internet references and other details are not repeated in this chapter.

another country. Since they are by definition non-governmental there is no automatic recognition by governments, but attempts have been made to achieve government recognition. Before this survey was conducted, results of those attempts were known to have been mixed. In cases where mandatory CA certificates are required by national regulations, some governments allow their designated national CABs (i.e., those designated to issue the certificates in question) to base their certificates on test reports submitted by CABs outside their own country but which are members of a relevant non-government MRA.¹³ Even in those cases, however, the certificate itself may need to be delivered by a national CAB in the country which imposes the regulation, rather than by a CAB in the country of manufacture. Others do not even go that far. An example is the ILAC agreement, whose signing ceremony some years ago was attended by government representatives from some of the major countries involved, such as the EU and the United States; but when the question was asked "*will those governments recognise, as a basis for certification, a test report issued outside their own country under the ILAC agreement?*" the position taken by some governments was that regulatory recognition could only be granted if the CABs in question complied with the separate, regulatory procedures.¹⁴

48. What light do the survey results throw on the effectiveness of these mechanisms in practice? Does the survey data provide evidence that either or both (governmental or private) are working as expected?

49. The essential conclusion from the survey seems to be that *both mechanisms – governmental and non-governmental – are perceived by CABs to be helpful.* This derives from the following findings:

- One of the characteristics of high-growth *CABs* described above is that they are more likely to have some form of *contractual agreement* with CABs in another country.
- Second, as a perception, a significant proportion of high-growth CABs listed *inter-governmental MRAs as an important reason for their growth* (although not as important as some other factors, such as wider use of international standards, see **Table 1**).
- Third, 37% (or 159) of the 428 CABs participating in the survey (and a majority (52%) of respondents with moderate or high growth in export-related CA activity) reported that their home-country operations had *formal (nongovernmental) agreements with CABs in other countries*, outside their own group.

50. The nongovernmental agreements with CABs in other countries mostly take the form of recognition agreements covering various elements of CA: test reports, inspection results, testing methods, or certificates of conformity. **Table 2** shows the distribution of responses.

¹³ Canada is an example of a country which reportedly accepts this practice.

¹⁴ The EU, for example, requires its domestic CABs to enter into formal, direct sub-contracts with any foreign CAB (i.e., outside the EU) whose test reports it wishes to use as a basis for certification. [Evidently, in trade between EU member states within the EU itself, that requirement does not apply, and direct recognition of home-country certificates is normally assured.]

 Table 2. Factors associated with moderate or high growth in export-related CA activity of CABs

Nature of agreements	No. of responses
Mutual recognition of test reports	108 (68%)
Mutual recognition of certificates of conformity	88 (55%)
Mutual recognition of testing method	79 (50%)
Mutual recognition of inspection results	70 (44%)

Note: Sample = 159 respondents reporting that their home-country operations had formal agreements with CABs in other countries, outside their own group. Multiple responses were possible.

51. These survey data suggest a paradox: if these arrangements are so helpful, why are regulators not recognising them more widely? A general answer can be suggested, based notably on evidence from two sources used during this project: 1) the deep interviews conducted as follow-up to the surveys, and 2) the Berlin conference organised jointly by OECD and InWent in November 2005, to explore the issues in more depth.

52. The answer is in two parts. Most importantly, these agreements are not yet optimal in content, scope, or operating rules; that view is shared not only by regulators but by some operators and users of the schemes themselves. In addition, there is some suspicion at government level of non-governmental agreements which claim to be based on a form of accreditation which is not under the direct control of government.

53. The IECEE CB scheme referred to above offers an example.¹⁵ By providing for mutual acceptance of test reports in the electro-technical sector by CABs worldwide, it offers exporters the opportunity to obtain recognition of home-country test results in their international trade. Thus, for example, a member certification body (NCB) or associated testing laboratory (NCBTL) in destination country A which is asked to certify the performance of an electrical product in local conditions will recognise, in its assessment and sometimes in its certification process,¹⁶ test reports by a separate member laboratory in producer country B which has performed tests which the destination country A laboratory considers relevant; the laboratory in destination country A may use the same reports as the basis for authorising the use of its own certification mark. The exporter in producer country B therefore avoids duplication of that test. The competence of member certification bodies/testing laboratories in the scheme is assessed through a constant programme based on peer assessment (ISO 17040), and the test reports it produces are highly regarded and widely used in the marketplace by the various stakeholders.

54. However, despite this widespread recognition in the market, recognition of the IECEE CB scheme by regulators is not always assured. For example, in the relatively rare cases where the EU imposes third-party testing in this field, foreign (i.e., non-EU) test reports supplied through the IECEE CB scheme may not be used directly in the process of certifying compliance with EU requirements, unless the EU CAB formulates and signs a separate, written agreement with the foreign CAB based on conditions separate from those in the IECEE CB scheme. In some other countries (but generally not in the EU, except in the most sensitive areas such as life-or-death electrical medical devices), regulatory acceptance of a product is linked to third-party supervision of the quality management system of the supplier, and the IECEE CB scheme does not fully provide for that (although, interestingly, some separate schemes offered in related sectors by the same body – IEC – do provide for it). In this case, therefore, the solution to regulatory recognition would appear to lie in a combination of improvement in the scheme itself and an improved dialogue with regulators to win their acceptance. That latter issue – acceptance by regulators – is directly relevant to accreditation, which is addressed in the following section.

¹⁵ See paragraph #47.

¹⁶ See para. #47 for the limitations on this.

f) Role of accreditation

55. Accreditation is the formal recognition, normally based on international standards and guides,¹⁷ that a laboratory or other conformity assessment body is competent to perform specified tests or measurements or carry out other specified CA activities. It is normally specific in scope and covers a specific area of competence. Accreditation is widely recognised as a valuable tool to improve the quality and credibility of conformity assessment, and is explicitly recognised in the WTO TBT Agreement in that context. Accreditation itself is given credibility in the marketplace by the international standards and guides on which it is based.

- 56. Two aspects of accreditation deserve highlighting in the context of its role in trade:
 - its relevance to *regulatory designation* of CABs as authorised to perform mandatory conformity assessment required under regulation (for example, the use by government of a certificate from an accredited CAB to determine whether a given product complies with technical regulations). Here, the role of accreditation is sometimes misunderstood and notably, the distinction that can arise between *accreditation* and *designation*. It is possible to be accredited by a recognised non-governmental national accreditation body for a specific area of competence but not to be designated by the government of the same country as authorised to issue legally recognised certificates in the same area of competence. In practice, however, governments rely increasingly on accreditation as an integral element of the process of regulatory designation.¹⁸
 - its relevance to *market recognition* of CA certificates or reports. Examples of the use of certificates from accredited bodies in market evaluation (i.e., where there is no regulatory requirement to produce CA certificates or reports) are plentiful: the field of management systems (MS) certification is just one.¹⁹ The absence of any legal compulsion to use accreditation in these cases should be emphasised. The decisions to use accreditation are left to the judgment of the supplier and the CAB: the supplier decides freely whether to seek certification or a report from an accredited CAB, as opposed to a non-accredited CAB, and the CAB decides equally freely whether the cost of formal accreditation is justified. Both the supplier and the CAB will evidently be influenced in the recognition by the market of the accreditation process.

¹⁷ Notably, ISO produce a core series of standards and guides with the active participation of the two major accreditation networks IAF and ILAC (referred to extensively elsewhere in this report), which adopt those ISO texts as endorsed normative documents. Both IAF and ILAC normally prepare supplementary guidance for clarification of the ISO texts and application by their members.

¹⁸ The EU provides an example of this trend. Under harmonised EU technical regulations today, national governments of EU member states are not formally obliged to use national accreditation bodies in the process of designating authorised conformity assessment bodies (called *notified bodies* in one major area of EU regulation). But they are strongly encouraged to do so, and the central EU authorities strongly support the activities of European accreditation bodies through EA (European Accreditation). But the process of aligning the two activities of accreditation and designation is not complete: in practice, national governments in the EU often still apply designate procedures which complement or deviate from the standards-based accreditation processes of the accreditation bodies themselves.

¹⁹ An MS standard is applied to a site or to an organisation rather than to a product. Although rarely required by regulators, two widely used MS standards are ISO 9000 Standards for quality management system, and ISO 14000 standards for environmental management systems. In its latest survey (covering 2004), ISO reported that certificates issued by accredited bodies against those standards globally now exceeded 750 000. ISO itself welcomes the use of accreditation as a tool to improve the market acceptance of certification against ISO MS standards.

57. Under both headings, the efficiency of the accreditation process and of its use emerges as a potentially significant factor in preventing or overcoming barriers to trade presented by CA procedures.

58. Before designing this survey, we knew that many CABs felt obliged to accept the cost and complexity of multiple accreditations²⁰ in order to secure international recognition by regulators and/or by the market. While the potential attractiveness to an exporter of a "local" accreditation of his CAB in each destination market (which leads to multiple accreditation) is evident, we also knew that much effort had been devoted to improving the cross-border recognition of single-accreditation bodies also, often with active support from exporters; and we assumed that they would not have done that unless there had been a widespread consensus that duplication of systems was inefficient or undesirable. Therefore, in designing the survey, the issue of multiple accreditation was given major attention. This survey produces some evidence on how widespread the problem of multiple accreditation or multiple designation is perceived to be a widespread problem, and since multiple accreditation entails multiple layers of cost, the survey is likely to provide evidential support to efforts to improve cross-border recognition of "single-accreditation" or "single-designation" processes.

59. Survey responses confirm that *multiple accreditation is widely used*: 84 of the 428 responding CABs (or 19.6%) reported multiple accreditation in at least one area of activity.²² These CABs come from all regions but mostly from Europe (48 CABs), North America (15 CABs) and Asia Pacific (14 CABs). Leading countries are Switzerland and the United States followed by Australia, Spain, Germany and United Kingdom. Given that each act of accreditation requires the payment of substantial fees and expenses by a CAB to the accreditation body, and that those costs must ultimately be borne by the clients of the CAB, the need for such duplication is worth exploring.

60. Survey respondents were asked to provide information on the number of countries from which they hold accreditation from a national body for specific CA activities.

- In the area of *management system certification*, the majority of respondents (131) reported being accredited for 1 country. 46 CABs reported accreditation for 2 and more countries. In four cases, multiple accreditations were reported to involve between 15 and 35 countries.
- For *product testing*, again a majority of CABs (147) reported accreditation for 1 country and 45 respondents reported holding accreditation from 2 or more countries. In five cases, multiple accreditations involved between 15 and 28 countries.

²⁰ In this context, multiple accreditation is defined as accreditation by more than one accreditation body for a single specific area of competence. It does not include cases where a CAB may need several accreditation certificates for several different areas of competence (for example, one for electrical safety and another for quality management systems).

²¹ Examples are plentiful: 1) a single designation, valid throughout the EU, is one of the principles of the EU's harmonisation of technical regulation; 2) single designation is a principle in most government-to-government MRA's; 3) multilateral recognition of a single accreditation is a target of the global arrangement under ILAC (International Laboratory Accreditation Cooperation); 4) much of the activity of the IAF (International Accreditation Forum) also aims at the same goal. The activities of IAF and ILAC are described in more detail in other sections of this report, notably in paragraph 67.

²² We believe that respondents would have considered "multiple accreditation" to mean "multiple accreditation for a given scope". It is universally accepted in CABs and accreditation bodies that each act of accreditation is for a defined scope of competence, and that separate scopes require separate accreditations, owing to differences in the technical expertise required in the evaluation process. No CAB would therefore have considered the question worth asking "do you hold separate accreditations for separate scopes".

- For *product certification*, most respondents reported accreditation for 1 country (115 CABs) and 33 CABs mentioned 2 or more countries.
- For *calibration/metrology*, most respondents similarly reported accreditation for 1 country (77), with only a few cases reporting accreditation for more countries.

61. In all except the last of these four categories, the percentage reporting multiple accreditation lies between 22 percent and 26 percent.

62. Have CABs benefited from multiple accreditations in the past five years? 76 of the 84 CABs with multiple accreditations answered this question. Of these, 35 (or 45%) stated that the value to their CA business of multiple accreditations had increased in the past five years. On the other hand, 9 percent expressed the opinion that the value to their CA business of multiple accreditation had actually decreased, and 42 percent stated that there had been no change. 3 CABs did not know. The 45 – 9 percent comparison may be significant: 45 percent stating that the value of multiple accreditation had increased, and only 9 percent saying that it had decreased. The comparison tends to indicate that governmental programmes aimed at reducing the need for multiple accreditation have been less than completely successful, and it may therefore be asked whether further efforts or new approaches are justified.

Figure 8. Export growth of CABs designated by a foreign government as authorised to perform CA



63. Survey responses point to a strong link between designation by a foreign government to perform CA, and reported growth in CABs' export-related activity. While in the entire population of 428 CABs answering the questionnaire 26% reported high or moderate growth for their export-related CA activity, **Figure 8** shows that 41% of those designated by a foreign government reported either high or moderate growth. When CABs reporting low growth are added to those figures, the proportion for the entire population of CABs is 51% but reaches 71% for those CABs designated by foreign governments.

64. Elsewhere in the questionnaire, respondents were asked whether designation by a foreign government as an authorised CAB under its own regulation, would have a significant impact on their business revenues. If a CAB thinks that designation definitely would have or might have a significant effect on its revenues, this would suggest that the ability of this CAB to certify products in international trade is hampered by the lack of government recognition in the destination market. Of the 379 CABs that answered this question, 228 (60%) thought that it definitely would or might have an impact (and 22%)

felt that it definitely would have an impact), whereas 40 percent of the 379 CABs felt that it definitely would not.

65. A majority of those who felt that it would or could affect their revenues if it became possible for them to be designated by a foreign government as an authorised CAB under its own regulations:

- operate primarily within the OECD region (Australia 13%, United States 11%, Switzerland 10%, United Kingdom, Netherlands and Poland 6% each);
- use subcontracting (61%);
- do not have CA facilities in countries other than the 'home country' (66%);
- have formal agreements with CABs that are in other countries and outside of their own group (46%);
- offer CA services related to product testing and/or certification and/or management systems.

66. They were also asked to indicate up to 3 sector/country combinations where the recognition might benefit. The sectors and countries identified by respondents are presented in **Table 3**: Leading sector/country combinations include *electrical products in China*, *electronic and telecom products and equipment in China* and the *United States, food products* and *building materials and components in Europe*. If examined separately, the OECD markets most frequently mentioned are the United States, the European Union and Japan. At some distance follow Australia, Canada, Mexico and Korea. China, the Russian Federation and countries of Latin America are the non-OECD markets most frequently mentioned.

Table 3. Leading sectors and export markets where CABs indicated that designation as authorised provider would benefit them

Product sector	Most frequently mentioned export markets for sector
Electrical products, excluding domestic appliances (35)	China (12), EU (6) and United States (6)
Electronic and telecom products and equipment (29)	China (5), United States (5), countries of Latin America (4), Japan (3)
Pressure equipment (28)	EU (5), United States (4), China (3), Russian Federation (3), Ukraine (2) and Australia (2)
Food products (25)	Europe (13), Japan (4) and United States (3)
Machinery (23)	Europe (6), United States (4), China (3), Japan (2) and Russian Federation (2)
Building materials and components (21)	Europe (13), Asia (2), Middle East (2) and United States (2)

Note: Sample = 185 CABs (of 228) who answered this question. Respondents were asked to list up to 3 country-sector combinations. Some listed more and many listed less than 3 items. Numbers of sector identification or export market identification by respondents are shown in brackets.

67. This survey evidence – that multiple accreditation is still perceived frequently as a condition of business by CABs – may appear surprising when viewed against the number of programmes which aim, through mutual recognition of accreditation, at facilitating recognition of a single accreditation for a given scope, based on efficient application of international standards. Programmes of this kind exist at both global and regional levels, and all appear to aim at helping achieve the goal of the TBT Agreement to prevent and eliminate unnecessary technical barriers to trade through the wider use of international standards and conformity assessment procedures.

- At the global level, two major and complementary accreditation processes aim to achieve international recognition of home-country accreditation: those operated by the IAF (International

Accreditation Forum) and ILAC (International Laboratory Accreditation Cooperation) respectively.²³ Both develop guidance, rules and procedures for the international operation of accreditation, aiming at the highest standards of competence and probity in their own operations and in the accreditation of CABs by accreditation bodies; both aim to make a genuinely global contribution, not only in OECD economies but also in low-and medium-income economies. As already noted,²⁴ both have formal arrangements between national bodies which should assure international recognition for specific areas of accreditation.²⁵ Both report a rising trend in participation in these agreements and in their use.²⁶ The work of both is closely integrated with parallel work by ISO, which has a comprehensive set of international standards and guides (called CASCO documents) for conformity assessment intended to serve as a basis for accreditation and/or designation of CABs by governments.

At the regional level, there are also a number of examples. The EU has already been cited,²⁷ but is not alone. APEC is perhaps the most developed example outside Europe, with agreements on mutual recognition of accreditation at two levels, like the IAF/ILAC examples above.²⁸

68. Why is the influence of all these systems not greater? The fact that some of them are very new – like the APEC-PAC agreement on product certification referenced in the previous paragraph – provides part of the explanation, but almost certainly not all of it, since several arrangements have been operational for many years.²⁹

24 See in particular para. 47.

25 In 2006, ILAC (www.ilac.org) reported that 51 accreditation bodies from 42 countries had signed the ILAC [Mutual Recognition] Arrangement, whose goal is stated in these terms: The ILAC Arrangement provides technical underpinning to international trade by promoting cross-border stakeholder confidence and acceptance of accredited laboratory data. IAF (www.iaf.nu) has its MLA (Multi-lateral Arrangement), for which a section covering product certification was launched in 2004, with similar goals to those of ILAC but with a different focus, and with an initial list of 20 signatory accreditation bodies.

- 26 IAF, for example, reported most recently in September 2005 the results of a Survey on cross-frontier accreditation. While the results do not directly permit any conclusions about the trend in international recognition of home-country accreditation, they do demonstrate a sharp, recent rise in co-operation between accreditation bodies in different countries, for example by providing critical location help (assessors, auditing) to each other to improve the efficiency of the accreditation process. But in presenting the results, IAF acknowledged that reliable data could not be provided on some relevant questions: for example, on the number of foreign accreditation marks used by critical locations of CABs in their territories.
- 27 In paragraph 56 above.
- 28 PAC (Pacific Accreditation Cooperation, <u>www.apec-pac.org</u>) only added product certification in 2004 to the scope of its MLA (*Multi-Lateral Arrangement*), and reports only 3 signatories (Australia / New Zealand signing as one, Canada, and Mexico). But APLAC (*Asia-Pacific Laboratory Accreditation Cooperation*) has had a *Multilateral MRA (Mutual Recognition Arrangement*) since 1997 (details on http://www.aplac.org/aboutaplac/about mra.htm) and reports 20 signatories.
- 29 The APLAC arrangement mentioned in the previous footnote is an example. An excellent overview of the state of development of these programmes appears in a 2005 report: *International Trade and Guidelines on Equivalence and Mutual Recognition*, by Christel Elvestad and Frode Veggeland, published in Norway and available on: <u>http://www.nilf.no/Publikasjoner/Rapporter/En/2005/R200501Contents.shtml</u>. The report takes the form of a compendium and a qualitative evaluation of available tools, and makes no attempt to report on the actual impact or usage of the different systems reviewed.

²³ The names and initials listed here have been mentioned earlier in this report, and Internet references and other details are not repeated in this chapter.

69. Although the Internet surveys provided little evidence to answer that question, the deeper interviews and the November 2005 OECD conference provided helpful comments, and also revealed the elements of a potentially healthy debate. While some players feel that the task is simply to *extend the use of accreditation systems which have already proved their ability to meet regulatory and market needs* – in other words, that there is no systemic defect in the development or application of accreditation procedures, just a delay in using them universally -- others point to a combination of *imperfections in the systems themselves, and to a wilful insistence by governments on formulating and applying their own criteria for designation and acceptance of CABs*, which in turn may influence the ability of cross-border accreditation systems to win market acceptance.³⁰

70. Those who feel that only time and encouragement are necessary point to the steady growth of formal agreements between accreditation bodies, of the kinds listed above; to the increasing public recognition by governments of the relevance of international (or non-domestic) processes of recognition of conformity assessment; and to the fact that the need for accreditation is determined in part by the market, and not only by governments – it takes time for markets to develop confidence in new international systems when older national systems have a far longer track record. There are numerous examples of the progress, of which formal, bilateral government-to-government mutual recognition of conformity assessment (the "MRAs" discussed earlier in this report) is only one. Two other examples are:

- In the regulatory area, three major federal agencies in the United States responsible for product authorisations (FCC, FDA, and OSHA) were reviewed in this study, and all now include formal references to the use of international standards or guides, as well as appropriate domestic documents, in their procedures for designating CABs.
- Two surveys conducted by IAF (International Accreditation Forum, referred to extensively earlier) in 2003 and 2005 show a statistical decrease in the average number of accreditation bodies used by each CAB, although IAF itself points out limitations to the significance of the surveys: the survey size was considerably smaller than in this OECD survey, and the populations of responding CABs were different in each of the two years when a survey was conducted.³¹

71. However, the feeling that it is only a matter of time before multiple accreditation loses its significance is not universally shared, and two complementary reasons were mentioned, to support the view that some systemic changes may still be needed.

Even if there is evidence of widening recognition of the relevance of international agreements and guides, the extent of their actual, automatic acceptance has not been measured, and is perceived by many to be limited. For example, none of the US federal agencies referenced in the previous paragraph is obliged to accept foreign accreditation as the basis for its own designation, and all of them insist on the supervision of US-based staff at some stage in the process of assessing the competence of a CAB to perform operations under regulations within their sphere of competence. The EU is little different in substance on this point, although its exact processes are not the same as in the United States.

³⁰ The importance of accreditation as a factor in market recognition, as opposed to governmental recognition, has already been highlighted in the introductory paragraph to this section on accreditation (paras. 55 and 56).

³¹ The survey was reported to IAF members, but not published, in August 2005, under the title *IAF Certification/Registration Bodies – member satisfaction programme*. It reported that the average number of accreditation bodies used by reporting CABs declined from 3.36 in 2003 to 1.88 in 2005. But the difficulty of drawing general conclusions from these statistics is highlighted in the main text of this paragraph.

Insiders in the relevant international schemes themselves acknowledge imperfections or complexity in the systems. A number of examples can be quoted. The case of the IECEE CB scheme has already been discussed in this report:³² Intended to achieve widespread acceptance of home-country test reports in the electro-technical sector without the use of the ILAC or IAF processes, its own operators accept that, despite its proven strengths, wider regulatory acceptance will depend on improvements to the scheme. In IAF and ILAC, the ISO CASCO documents, while accepted as an endorsed normative reference base, are in practice not universally applied alone. Both IAF and ILAC produce supplementary guidance for clarification to their members; the guidance is developed in both cases under a Memorandum of Understanding with ISO³³, and deviations in applying those complementary texts have been reported at national level.³⁴ On top of all that, governments sometimes superimpose their own requirements for designation, dropping or adding requirements. It is difficult to escape the conclusion that the results of all these gaps or deviations are impenetrable to many of the operators who share responsibility for protecting the public, and that it is not surprising that individual authorities continue to insist on demonstrated compliance with their own rules.

g) Other experiences reported by CABs

72. The questionnaire responses provided many examples of the problems described above. A compilation of some representative comments appears in **Annex 11**.

73. A limited number of potentially significant comments were made in interviews, or at the OECD conference in November 2005 in Berlin during this project on issues which may be separated from the above:

- CABs appear to support the view of exporters that most individual, high-quality CABs are normally *technically* capable of testing and certifying products to the many different specifications and standards which exporters face today, and that there is therefore no *technical* justification for a government to refuse systematically to accept foreign CA reports. There are evident but rare exceptions to that, such as cases where a product needs to be tested over an extended period in climatic or environmental conditions which are hard to duplicate outside the country where they occur. But generally, national deviations in standards or specifications are within the field of competence of high-quality CABs.
- Occasionally but rarely, inefficiencies in conformity assessment can be traced directly back to a failure to adopt international product standards, and it is impossible in those cases to isolate conformity assessment as a separate area for regulatory action. It can happen where the form of standards or specifications in a given destination country is so different from the international norm that it makes little economic sense for a foreign CAB to set up test procedures to measure compliance against those national requirements. The example was quoted by an American CAB of electrical safety standards in the United States, where the widespread insistence on the continued use of UL standards, instead of introducing IEC standards, made it difficult for many CABs outside the United States to offer certification for the US market, even though the possibility of their doing so is permitted by US regulators. While it is important not to exaggerate the extent of problems like this especially in the electro-technical sector, where IEC standards

³² See paragraphs #53 and 54 above.

³³ The text is available on www.iaf.nu, clicking on "Joint IAF-ILAC-ISO Communiqué"

³⁴ For example, the key ILAC document describing ILAC's MRA, entitled *The ILAC Mutual Recognition Arrangement*, states explicitly on its first page that signatory bodies must maintain conformance not only with relevant ISO and ILAC texts, but also with "*a few but important supplementary requirements*."

have achieved very wide international acceptance and application - it is helpful to flag it as an occasional issue, in the interest of factual accuracy.

B. Target group "exporters"

74. Distribution of the second survey – to exporters of manufactured products – went through *two phases*. The *first phase* was deliberately broad: in countries, sectors, and in size of business. An objective announcement of the survey was made to major multi-sectoral industry federations from the OECD region, who were asked to use their standard news channels to bring it to the attention of their members. BIAC publicised the survey to its members. Other groups contacted include the *Industry Cooperation on Standards & Conformity Assessment (ICSCA)*, the *International Federation of Standards Users (IFAN)* and major industry associations like the *Bundesverband der Deutschen Industrie* (BDI) in Germany, the *Confederation of British Industry* (CBI) in the United Kingdom and the *National Association of Manufacturers* (NAM) in the United States.

75. To strengthen the chances of appropriate announcements reaching exporters, direct personal requests were made to a number of key individuals in several of the major countries targeted as top priorities (France, Germany, Britain, USA, and Canada). Annex 4 describes the channels used.

76. The first phase did not produce a quantitatively large response. The approach was therefore modified in a *second phase*. A more commercial presentation of the potential benefits of participation was used for follow-up publicity activity. In addition, direct contacts were made with sectoral industry associations in a number of sectors believed to be particularly susceptible to conformity assessment barriers.

1. General remarks

77. A total of 110 completed questionnaires were received. This is an extremely low response rate relative to the size of the population of businesses that in one way or another has been made aware of the survey. It is too low for meaningful and statistically valid analysis. Hence findings are illustrative only.

78. Since there is no evidence that the distribution channels used to bring this survey to the attention of exporters were badly selected or inefficient, the low response could mean that conformity assessment is not a widespread concern in trade to the manufacturing industry in the OECD's major member countries. This hypothesis has been explored in a series of follow-up interviews and through additional research, outlined below.

79. The survey gave large groups of exporters a chance to flag concerns, and to comment on issues which might be relevant to addressing those concerns. Significant barriers were reported. Because the set of responses received from exporters is too small to yield findings that can be considered robust and representative of the target population, a *small set of interviews* was conducted to explore in greater depth the concerns flagged in the survey, and to delineate areas where future action would be considered particularly useful for facilitating trade. These interviews involved respondents who indicated a willingness to be contacted and offered contact details for that purpose, and a few industry federations. The interviews questioned respondents critically to see if the barriers were real. Interviews were conducted with six manufacturing exporters including four major multinationals, with four major industrial federations, and – to check a number of technical aspects of CA raised – with one multinational CAB. See **Annex 4** for a description of the interview phase).

80. In most cases, there is little doubt that the barriers *are* real. There were only rare exceptions to that which have been discussed earlier in this report: notably, 1) that descriptions of product categories were misleading (major barriers were reported in areas apparently associated with metrology, but

investigation suggested that the products concerned might be more appropriately classified as electrical machinery); and 2) that occasionally, a description of what purported to be a *conformity assessment* problem should more appropriately be classified as a problem of *product standards*. But again, those exceptions were rare.

81. The conclusion from the limited evidence is therefore that there are important *pockets of concern*: limited fields – defined by sector and/or by country – where significant conformity assessment barriers remain, even for large, well-resourced multinationals. Even if conformity assessment is not *the major concern* in export trade to most companies, it is nevertheless a significant irritant and cause of inefficiency in the sectors – *mostly technical products* – which attracted most responses in the study.

2. Profile

82. The set of 110 respondents includes 88 small and medium-size enterprises (SMEs) with between 1 and 499 employees and 21 multinational enterprises employing more than 10 000 employees. The vast majority of the firms (85%) are more than 10 years old.

83. Survey respondents export across a wide range of products, with relatively more businesses exporting products belonging to the following broad categories: (1) general and special purpose machinery; (2) precision and measuring instruments and medical devices (3) electrical apparatus, including household appliances; (4) IT and electronic products; and (5) pharmaceuticals and chemicals and related products. **Annex 8** provides a more detailed breakdown of the product groups represented.

84. For the vast majority of businesses that have answered the questionnaire, the products that they make are either always identical or identical in over 50 percent of cases.

85. The leading export destinations are OECD markets. In terms of regions, particularly often mentioned is Europe, followed by North America. Non-OECD export destinations mentioned are mainly China, followed by certain other Asian economies (India, Thailand, Vietnam and Sri Lanka). Markets in the Middle East are also relatively frequently mentioned. Markets in Latin America and Africa are rarely mentioned.

3. **Observations**

a) Perceived benefits of CA

86. The primary aim of CA is to prove that products are fit and safe (or not safe) for humans, animals or the environment. They give regulators a means for preventing unsafe, unhealthy or environmentally harmful products from entering the market place. Furthermore, because they convey information on the characteristics of a product and its performance, CA procedures provide much needed data to regulators in the domestic and foreign market, thus facilitating trade and contributing to consumer/user confidence.

87. For manufacturers, CA provides a competitive advantage insofar it allows them to distinguish themselves from competitors whose products do not 'measure up' to certain levels of safety, quality or reliability. Efforts to achieve higher levels of quality or reliability may also represent protection against liability suits.

88. Respondents were asked to indicate whether they thought that, regardless of problems that they might experience, conformity assessment procedures enhanced their credibility as far as safety, reliability or quality of their products was concerned.

89. The survey results are somewhat surprising in that only a slight majority (54%) agreed whereas a significant minority (39%, or 43 respondents) expressed the opinion that CA procedures had no or not much beneficial effect.

90. The profile of the second group *(no or not much beneficial effect)* shows that the majority of them are either small (less than 250 employees) or rather large (more than 4 999 employees) firms. In 63 per cent of cases, the product models exported are either always or in over 50 per cent of cases identical to the models sold in the home market, thus making multiple CA of the identical product especially burdensome. Moreover, the 43 firms that reported CA procedures not having beneficial effects export a limited scope of products: Almost a quarter of the firms export machinery specialised for particular industries, and another 19 percent export professional and scientific controlling equipment. Another 12 percent export electrical industrial machinery and electrical appliances and housewares, respectively.

91. For the 60 firms reporting that CA procedures had beneficial effects, the product categories differ in some important respect. Many of these firms also export electrical industrial machinery, machinery specialised for particular industries, and professional and scientific equipment (combined 43%); however, a significant number of other firms export in two sectors not or seldom represented by the other group, namely pharmaceuticals and medicinal products (15% of the 60 firms) and medical devices (13%).

b) Sources of information about CA requirements

92. When asked what external source of information they use, respondents replied that they relied significantly on *private sources of information* (business associates in export markets, business associations, CABs). Among governmental sources of information, *legal publications or official Internet sites* were by far more frequently used than are WTO TBT enquiry points in export markets, as Figure 9 shows.

93. Respondents were also asked to rank the top 3 sources of information. Again, "business associates in the destination export markets" and "government legal publications or official Internet sites" were by far most often identified as the leading source.

94. It may be asked whether the reported lack of use of WTO inquiry points is due to the fact that they are not helpful or because they are not widely known. In any event, the responses seem to confirm a direction for action by governments in providing information on CA requirements, namely that the availability of clear CA information on the Internet would help.



Figure 9. External sources of information

Note: "Other" includes customers, customs brokers, direct involvement in IEC, export publications, local authorities in the importing country, forwarders and carriers, trade associations, and trade fairs.

c) Importance and impact of CA problems

95. Respondents were asked to make a **general judgment of the seriousness of problems** caused by the need to apply CA procedures for exports different or in addition to the practices in the home market. Half of them (55) described this as being a critical or major problem. 25 respondents felt it was a minor issue and 30 firms reported that the need to apply different CA procedures when exporting caused no problem at all.

96. The subset of respondents (80) who answered that differences in CA procedures posed a problem (minor, major or critical) for them were asked to specify the sectors/product lines of their export activity in which they encountered the CA problems. *Electrical products, electronic products, medical devices, household appliances* and *telecom products* were mentioned most frequently.

97. This subset of respondents was also asked to respond to questions seeking more details on how the obstacles hurt them. Results here are largely consistent with general discussion of the impact of TBT, focussing in particular on *unnecessary additional costs, delays in time-to-market*, or even the *complete abandonment of attempts to export*, although one important additional feature was mentioned, which was confirmed in later discussion: the *deliberate use of requests for technical documentation and manufacturing data to steal proprietary technology*. Unsurprisingly, there is some confusion in the responses between technical barriers and barriers that might also be classified as *administrative*, such as delays at customs, but it is clear that many responses do refer to barriers that fall directly under the heading of conformity assessment.



Figure 10. Reported negative impact of CA problems

Note: Sample = 80 respondents, who could check one or more items.

98. Details behind those general comments appear in **Figure 10**. As seen in that Figure, 33 (41%) answered that they raise their costs of exporting significantly, and another 35 percent report a moderate cost increase. More than half of the 80 respondents (56%) felt that these obstacles significantly delay time to market for new products. In addition, almost half of the respondents stated that these obstacles have forced them to abandon efforts to export at all to some countries. Another 36 percent stated that the obstacles created problems or burdens in other ways. These ranged from logistics problems to transfer of know-how. A relatively large number of respondents offered comments of different sorts under 'other', which are shown in **Annex 9**.

d) Assessment of CA problems by nature and origin

99. Given the evidence (above) that significant pockets remain in which CA barriers are important, it is important to understand what form those barriers take. Here, the data available provide a mixed picture. One general point is that *the "one-test, accepted everywhere" goal has not been achieved.* Beyond that, every type of CA problem mentioned in the survey was listed by at least some respondents: from a lack of transparency about CA requirements in export markets, to duplication of test requirements, or a need for additional test equipment to perform different tests.

100. The deep interviews which followed up the survey questionnaire added particular value, because the questionnaire responses themselves failed to identify priorities clearly enough, except by sector, where it unsurprisingly emerged that, with some reservations, *technically complex product types* were more likely to present barriers than technically simple products.

101. Responses to the section of the Internet questionnaire intended to explore the nature of CA problems show a "scatter diagram" pattern, which is illustrated in **Table 4**. Among a list of 12 items presented, the most often identified problem was *the problem of obtaining information (complexity and delay involved in obtaining information)*. Three other questions produced a pronounced high "moderate, high or critical problem" response rate: (1) *the inability to obtain recognition in export markets for test reports and certificates issued in the country of origin*; (2) *the requirement of different types of test or CA process in destination countries*, and (3) *increased number of identical tests for export markets*.

Aspect of conformity assessment	Not a problem	Minor problem	Moderate problem	Major problem	Critical problem
Complexity and delay involved in obtaining information on CA requirements in the export market	12	11	33	23	0
Refusal by government bodies in export market to accept test reports or certificates issued by home-country bodies	13	16	20	21	11
Need to meet different types of test or CA process in export market	10	21	23	20	6
Increased number of identical tests for export markets	14	21	15	26	6
Required additional fees abroad for registration or approval (independent from direct cost of testing and of customs charges)	17	14	20	24	0
Same CA procedures in export market as in home market but requirement to use different CA body acceptable to export market	24	18	15	20	0
Requirement to ship (physically) samples for assessment in export market before being able to make sales	29	16	19	15	0
Customer refusal to accept reports from home-country bodies	35	13	13	12	0
Excessive translation requirements for reports or certificates	28	16	24	0	0
Additional test equipment	30	25	12	10	0
Customer requirements for additional tests not required in home market	27	27	15	0	0
Inability to determine how and to whom to appeal if a product is rejected	34	21	14	0	0

Table 4. Nature of CA problems identified by exporters

Note: Sample = 80 firms responding that the need to apply different CA procedures for exports was a problem. However, more firms than these 80 responded and are also included here. Also, some of those who answered did not provide an answer for every item shown in the Table; hence the total number of responses per item may vary. Items are rank-ordered based on the sum of the no. of responses rating an item as either a moderate, major or critical problem.

102. However, the questionnaire also led to other pointers, through more open-ended comments on two optional questions which asked for free-form descriptions of 1) "other subjects of concern about conformity assessment for exports" and 2) case examples of problems. Some of the more interesting responses appear in **Annex 10**. These responses were used heavily in selecting targets for the later-stage personal interviews, since they frequently contained enough data to show the real "meat" in the CA problems of concern.

103. The combination of the written answers and the interviews makes it possible to narrow down the "scatter-diagram" identification of problems to a more manageable list of essential points which might form the basis for further action.

104. The most important point is the geographical dispersion of tests among several export markets, which exporters participating in this study perceive as technically unnecessary and economically inefficient, with very rare exceptions, so that there is a deep desire to make it possible for tests to be centralised at a location in or closely accessible to the manufacturing plant. (The separate evidence from the CAB survey appears to support that conclusion.) Differences in testing for different markets are accepted as frequently inevitable, but the geographical dispersion is not. For products whose technical specifications are identical everywhere, variations in testing may be justified by differences in the user environment. For products where the specifications themselves vary because of those differences in the user environment, different tests are even easier to understand. Neither of those comments diminishes the value of programmes to maximise the harmonisation of standards – they just acknowledge that there are

limits to how far that process can go. That was recognised even by exporters from the European Union, who are familiar with the EU experience of widespread harmonisation of tests. But even where tests must vary, the differences are almost always within the capability of a competent test laboratory close to the point of manufacture. Acceptance of that one point would almost inevitably lead to simplification in other areas, such as in the content and preparation of technical documentation.

105. *A second major problem is transparency, particularly of evolving requirements*. Actually identifying the requirements in time is a problem, which is compounded by the lack of adequate explanation or justification for changes. Complaints about constantly shifting requirements were relatively frequent and supported by interview data. It would seem that existing transparency procedures and information sources intended to alleviate that problem, including procedures mandated under the WTO Agreement on TBT for notification and publication of CA requirements and creation of national enquiry points, have not yet done so adequately.

106. After establishing those points, the interviews then went further, to see whether any consensus emerged on how to deal with the problems, and comments appear under "Conclusions" below.

107. Separately, responses were analysed in order to see whether a pattern emerged by sector and/or by country. Do some sectors or countries predominate in the presence of CA problems, which could provide a focus for further action? **Table 5** below shows sector, country and issue data that were examined further in the follow-up interview phase. Here, the results are reasonably clear, with some reservations.

108. Machinery and electrical/electronic equipment dominate, for almost all applications, including consumer products, heavy industrial equipment, telecommunications, IT applications and medical devices. By country, there is no identifiable "villain" in those sectors – one destination country or set of countries which presents most of the problems, leaving other destination countries free of criticism. It appears clear that problems arise in countries big and small, developed and developing. The European Union, United States, Russia, China, Brazil all appear frequently, and given the statistical weakness of the survey (low response level) it is impossible to single out one or more countries for special attention.

109. The reservation is that it would be dangerous to assume that there are no problems elsewhere. The survey responses did produce examples, but not frequently enough to justify major conclusions. A first example came from the food sector, where one of the most interesting replies in the whole survey came from a cherry farmer describing – competently and convincingly – CA problems in the fresh food sector, which in that particular case resulted largely from the failure of individual, large retail chains to apply harmonised specifications and conformity assessment, private or governmental. References to "measuring instruments and equipment" also suggested an area for attention, but produced insufficient verifiable detail to justify distinguishing them from machinery and electrical equipment above: a sample check showed that the term "measuring instruments" is used to describe products that have nothing to do with the relatively well-covered field of metrology, but which fall more appropriately into the category of electrical control equipment.

Product sector(s)	Destination country(ies)	Issue/concern
Medical devices	especially China, Chinese Taipei, and United States (as well as Brazil, Russian Federation, Japan, Thailand, Turkey, EU)	certification (e.g., mandatory local certification), registration (e.g., too many documents required) and testing (e.g., different testing requirements even in the EU)
Electrical equipment and components (such as lightning protection devices, power control products, voltage switchgears)	especially Japan and China (as well as the United States, Germany, Korea, Canada, India, Lebanon, Australia, Algeria)	certification and testing (e.g., battery rule CCC marking, time consuming test procedure)
Household appliances	especially China and Russian Federation (as well as United States, Ukraine, Argentina, South Africa, Saudi Arabia, Australia)	certification (e.g., mandatory CCC certification), testing (e.g., high testing fees and limited number of accredited labs), and documentation (e.g., additional documentation)
Precision and measurement instruments and appliances	especially United States and Canada, (as well as France, Germany and Russian Federation)	additional national requirements
Computing machinery and parts and accessories thereof	especially China (as well as Korea, Russian Federation, Saudi Arabia, Brazil)	CA (e.g., burdensome), certification (e.g., rapid change in certification requirements without transitional period, complex operation of system)

Table 5. Examples of "pockets of concern" notified

Note: Derived from a subset of survey data pertaining to 78 exporters.

110. Respondents were asked to indicate in which country(ies) they produced the products which faced the CA barriers to which their answers in the questionnaire referred. They could list up to three countries. Both developed and developing countries were mentioned frequently. Most often mentioned were China and Germany, followed at some distance by the United States, United Kingdom, Japan and European Union. Canada, Korea, Chinese Taipei, Italy and Thailand were also mentioned several times. As shown in **Figure 11**, Europe and Asia are the leading regions in which the products are produced. A comprehensive list of countries is shown in **Annex 7**.



Figure 11. Region of origin of products facing the reported CA barriers

IV. CONCLUSIONS

111. Conclusions are offered here against the range of goals set at the start of the project. In summary, they were: to identify and prioritise conformity assessment barriers to trade today, to identify relevant trends, and to identify tools relevant to removal of barriers.

112. To cover the full range of goals, this project went beyond the surveys which lie at its heart. Clearly, the question of how to deal with a problem can only be addressed comprehensively after the problem is identified and described, and since the first goal of the surveys was precisely to identify and describe the problems, they could not simultaneously explore all possible ways of dealing with them. Therefore, the surveys were complemented by two additional types of enquiry: 1) a small series of deep personal telephone interviews with respondents to the Internet surveys, and 2) the conference on technical barriers to trade held in Berlin in November 2005. Both these routes of enquiry were used to verify the nature of the problems (thus also responding to any doubts about the statistical validity of the survey responses), and to assess whether the bones of a consensus might exist on how to deal with them. A number of conclusions emerge which are supported by data from any or all of these routes of enquiry.

113. The surveys revealed that the main problems are concentrated in the *more technically complex areas*, and notably in machinery and electrical/electronic equipment, including telecommunications and IT, and electrical appliances of all kinds, although some problems also exist in other sectors.

114. By nature, the problems can be sub-divided:

Note: Multiple responses were possible: respondents could list up to 3 countries.

• The most important single problem is the *continued geographical dispersion of testing of the same product from the same producer for different markets*, which is considered to be technically unjustified and economically inefficient. This problem can be further sub-divided into two parts: repetition of identical tests by different CABs, or the requirement to use different CABs for a set of tests which, although showing some minor differences (for example, the use of different limit values for the same phenomenon or performance feature) are within the capability of a single CAB. The same problem can be expressed the other way round: the inability of suppliers to achieve international recognition in destination markets for tests and certificates prepared in a single location. The problems spill over into related areas, such as differences in technical documentation.

The same problems can be expressed in different forms, but come back to those same essential points. For example, problems caused by the failure to achieve international acceptance of home-country test reports would be alleviated if SDoC were accepted, and so the problem can be expressed as a failure to achieve the progress with SDoC which discussions in the WTO would seem to advocate.³⁵ The same failure (international acceptance) would be alleviated if there were more cross-border recognition of conformity assessment certificates, and that in turn can be expressed as a failure to achieve regulatory recognition of the large number of international mutual recognition systems established for just that purpose.

• For exporters, a second significant problem is *transparency*: shifting requirements, which are hard to identify and for which it is sometimes even harder to understand a rational explanation in terms of regulatory policy (consumer/environmental protection, etc.), and a general concern that information about CA requirements in export markets is difficult to obtain.

115. However, while there appears wide agreement on those points, there is less complete agreement on how to deal with them. The surveys produced some helpful pointers: for example, on the value of major tools such as MRAs, on which questions were incorporated in the surveys. But the survey results alone are not enough, because it was impossible to incorporate comprehensive questions on problem-solving tools into the surveys, before knowing what the problems were. The comments which follow therefore also rely on the follow-up interviews and on the discussion at the TBT Conference in Berlin in November 2005.

116. On the issue of **achieving wider acceptance of home-country test reports and certificates for exported products**, opinions were divided on how best to address that problem, and a healthy debate with two separate camps emerged.

- In one camp are exporters who believe that all efforts in global trade negotiations should focus on *the spread of SDoC* as the basis of compliance with regulations, since that will automatically reduce the negative effects of geographical dispersion of testing.
- In another camp are exporters who feel that, while the SDoC goal represents the ideal long-term solution, it will take so long to get there that intermediate solutions are needed, and that those solutions need to focus on *obtaining international regulatory recognition for test reports and certificates issued in producer countries.* In other words, they feel that SDoC can be left for later, after the critical and onerous infrastructure needed to support SDoC have been built: notably strong product liability law and market surveillance, both of which may take a very long time to achieve. In the meantime, they would like to see the inadequacies of the present voluntary mutual recognition systems outlined in this report attacked and removed,³⁶ and new dialogues established

³⁵ It is recognised that the spread of SDoC requires effective systems of product liability and market surveillance, and that SDoC therefore offers no "quick fix", except possibly in low-risk areas.

³⁶ See fore example, para. 54 above.

with regulators to ensure that the improved systems are accepted. Fora for dialogue of this kind already exist in some sectors, but rarely – medical devices is an example of a sector with an established global dialogue between industry and regulators. There are more frequent fora at the multi-sectoral level between governments; no consensus emerged in this project that they were not worthwhile, but it did emerge that a greater focus on sector-specific issues is needed.

- 117. Two lines of enquiry might be used in order to develop this debate further:
 - It might be helpful to survey WTO member governments to provide more hard facts on the rate of progress and product coverage of SDoC at the regulatory level. The survey suggests that SDoC might not be progressing as fast as the exhortations in the WTO TBT Committee should lead us to expect, but it produces no quantitative measure of progress, and enquiries suggest that there are no quantitative measures today of SDoC use and trade impact.
 - Further analysis and discussion of equivalence would seem useful so that the concept is better understood and applied. In this context, it might be helpful to explore in more depth the different processes of mutual recognition that exist today. The evidence from this project suggests that there is wide recognition of the potential and/or actual value of these, but conclusions for action are hard to draw because of the multiplicity of models of mutual recognition. Further research therefore could investigate which types of mutual recognition schemes are more or less successful.

Any further research into mutual recognition of conformity assessment results should be based on a recognition that it can be achieved in several ways and at several levels.

118. Earlier chapters of this report have presented evidence from both CABs and exporters which indicate that mutual recognition is a helpful tool, as is one-way recognition of CAB results by a foreign country government. Several questions of the CAB questionnaire covered bilateral CAB-to-CAB MRAs, non-governmental multilateral MRAs, and designation of a CAB by a foreign government under the technical regulations of that foreign government; the conclusion was that all are considered helpful. The exporter questionnaire approached the issue from the other end, asking exporters to rank barriers, one of which was "*refusal of government bodies in export market to accept test reports or certificates issued by home-country bodies*": the problem ranked second highest on the list of problems identified and a number of other responses provide support for the same point (for example, increased number of identical tests for export markets).³⁷ MRAs deal with that problem, if governments recognise them.

119. The complementary research (telephone interviews, review of TBT conference) indicated that both categories of respondents – CABs and exporters – felt that the potential of non-governmental mutual recognition agreements had not yet been fully exploited, at least at government level, and perhaps also at the market level. Respondents felt, in particular, that these non-governmental MRAs could play a role in achieving acceptance by governments of home-country CA reports or certificates, but were not in fact achieving that acceptance today.

120. Some ideas for action in this area emerged from this research, but research would need to be deepened significantly before firm recommendations could be made. The most helpful idea which emerged was an apparent consensus that even the strongest of those non-governmental schemes need significant improvement before they can hope to be more widely accepted. An example is a scheme³⁸ which is considered highly reliable for test reports on individual products, but inadequate in its reporting systems

³⁷ See Table 4 of this report.

³⁸ The IEC CB scheme.

for quality management, with the result that governments in destination countries – who insist on both – stick with their own CA schemes and refuse to recognise home-country reports at all. Some of those problems can be addressed independently of government, while others may justify strengthened fora between government, industry, and CABs. Delicate but manageable balances must be achieved between sectoral fora (for example, global harmonisation in medical devices) and multi-sectoral, bilateral or regional fora; all appear to have a role to play.

121. If research into mutual recognition were deepened, it might also explore the extent to which the refusal of recognition of home-country test reports and certificates (i.e., issued in the country of manufacture) is also a significant barrier to achieving acceptance by customers. The surveys show that it is a significant barrier to acceptance by regulators. But will action aimed at removing regulatory barriers be enough?

122. On the separate issues of transparency and justification for frequent changes in CA requirements, the survey responses from both CABs and exporters suggested that this remains a problem area: CABs considered ability to identify CA requirements as a significant factor in growth (i.e. not automatic), while exporters rated complexity and delay in obtaining information near the top of their list of problems.³⁹ While no recommendations for solutions emerged from the survey respondents themselves, either in the questionnaire survey or in the follow-up interviews, separate evidence collected during the study – discussed notably at the OECD conference in Berlin in November 2005 — suggested possible directions for action.

123. The direction would be guided by the growing efforts to strengthen the discipline of regulatory action through so-called *Good Regulatory Practice* (GRP) programmes, which address inter alia transparency issues and include tools such as Regulatory Impact Assessment. Preliminary thoughts were presented in Berlin on how that process could be started. Governments should introduce or change CA requirements only when this is necessary to meet a demonstrated need arising from a documented regulatory objective, and when the same objective cannot be met by recognising the equivalence of regulations, standards, or conformity assessment certificates already applicable elsewhere. Evidence accumulating during this project suggests that such practice would have a positive impact on trade and win support from industry. Better regulatory practice could be oriented towards achieving wider recognition of home-country test reports or certificates which would result from greater confidence in the effectiveness and in the enforcement of regulation; a limitation on the introduction of protectionist or inefficient conformity assessment; and clearer, more timely communication of changes in CA regulations which do meet the test of providing legitimate protection of the public.

³⁹ See Tables 1 and 4, respectively.

ANNEX 1. INITIAL CLASSIFICATION OF CA PROBLEMS

In broad terms, CA barriers can raise costs directly; delay market entry; or at worst, make life so complicated that potential exporters give up, thus reducing competition and retarding development. Duplicate testing is an example which can lead to all three.

In more detail, those broad problems arise from any of the following:

- Differing CA requirements in different countries, for identical specifications.40 This includes documentation as well as testing.
- The imposition of third-party testing or certification, where evidence suggests that Supplier's Declaration of Conformity (SDoC) may be a practical alternative.
- In the specific case of developing country exporters, sophisticated testing or analytical requirements for CA applied by developed countries, and which go beyond the capability of the infrastructure of developing countries.
- Difficulty or impossibility of obtaining recognition across borders for test reports or certificates issued in a given country. This covers both 1) cases where, even if the requirements imposed by separate countries for testing, analysis or documentation are identical, they must be undertaken or prepared by different bodies for the sole reason that the first body used (normally local, in the country of manufacture) is not recognised in international trade, and 2) cases where the CA requirements imposed by different countries differ, but are all within the capability of a single CA body, but where multiple CA bodies must be used for the sole reason that no single body is recognised in all intended countries of sale.

Additional CA requirements imposed by second-level or third-level authorities. Examples are states or cities in the USA.

That list can then be compared with programmes developed, notably by the WTO but also by other bodies where appropriate, to ensure that all known forms of conformity assessment barrier relevant to business can be covered. The TBT Agreement itself was the main source here, but complemented by the issue of SDoC, which is widely supported – in the WTO and elsewhere – as an important method of attacking conformity assessment barriers, but which is not in fact mentioned in the TBT Agreement itself. In addition to members of the OECD Trade Committee itself, the WTO Secretariat was directly consulted in this phase, as was ISO – the leading global body developing international conformity assessment standards and guides.

The TBT Agreement in fact focuses on the converse of barriers – the instruments needed if barriers are to be removed or their trade effect minimised – and includes the following instruments relevant here:

Art. 5.6.2. Adequate notification and information

⁴⁰ Multiple conformity assessment procedures caused by multiple specifications are excluded from this project, because multiple specifications have been dealt with in earlier OECD studies on standards.

- Art. 5.1.1. Non-discrimination against foreign suppliers: no imposition of CA procedures from which domestic suppliers are exempt.
- Art. 5.2.5 Non-discrimination in fee charges.
- Art. 5.2.6. No unnecessary inconvenience in location of facilities⁴¹
- Art. 5.2.7. Requirement that any new CA procedures must be limited to what is necessary
- Art. 5.4 Use of international guides if achieved, this can underpin the "use of internationally harmonised accreditation procedures", and "mutual recognition of national accreditation".
- Art. 5.5. Participation in preparation of international CA guides.
- Art. 6.1. Recognition of foreign CA procedures as *equivalent*, where appropriate.
- Art. 6.1.1. Recognition of foreign accreditation as a demonstration of equivalent competence, subject to use of international procedures in that accreditation. [This concept is quite close to that used in *Mutual Recognition Agreements* or MRAs.]
- Art. 6.2.1. Provision for designating foreign CA bodies whose results can be considered equivalent.
- Art. 6.4 Foreign participation in CA procedures
- Art. 7. Reduction in second-level government procedures
- Art. 9.1. Adoption of international procedures for conformity assessment
- Art. 11. Technical assistance for developing countries in this field.

That list provides an indirect link to programmes recognised under other names, such as MRAs, *equivalence* arrangements, and the wider use of accreditation as a confidence-building measure.

⁴¹ This may appear hard to understand, but the need can be illustrated by the example of France, which at one time imposed mandatory conformity assessment of certain imported electrical products in a small laboratory of limited capacity in a remote French town.

ANNEX 2. METHODOLOGY AND SAMPLE QUESTIONS FROM THE QUESTIONNAIRES

Both questionnaires were drafted in consultation with several experts in the field, including from the International Organization for Standardization (ISO).

The substance of the questionnaires was developed in three steps:

- first, to classify conformity assessment barriers in a form suitable for business discussion: CA barriers can raise costs directly; delay market entry; or at worst, make life so complicated that potential exporters give up.
- second, to ensure that all actual conformity assessment barriers identified so far by the WTO were covered (and, where appropriate, other bodies); the TBT Agreement itself, and the activity of the WTO TBT Committee over the past five years, were examined in order to produce a comprehensive list, covering programmes such as non-discrimination against foreign suppliers of CA services, and recognition of equivalence.
- finally, to write questionnaires which both used plain, intelligible business language, and at the same time led respondents to consider all conformity assessment barriers identified to date.

Examples of multiple-choice questions:

1 **Q** (for CABs): Have you ever been designated directly by a foreign government ministry or agency as authorised to perform, in your home country, mandatory CA of products destined for export to that foreign country, or of factories which require prior authorisation to export to that foreign country?

Answer possibilities: Yes / No / Don't know.

2 **Q** (for exporters): In your efforts to export, please offer a general judgment of the seriousness of problems caused by the need to apply different CA procedures for exports

Answer possibilities: Not a problem / minor problem / major problem / critical problem.

Examples of questions with simple, factual answers:

1 **Q** (for CABs): Please list up to five sectors or broad product groups (e.g., electrical products, chemicals, automotive components) in which you undertake conformity assessment of products, listing the most important first.

Answer leaves five lines open for the names of those sectors.

2 **Q** (for exporters): In which export destination countries do your most serious conformity assessment problems originate? Please list up to five countries that you were thinking of when you gave your answers and rank them in importance

Answer leaves five lines open for the names of those countries.

The one "free-text" question in each questionnaire:

- 1 **Q** (or CABs): Please comment here if you would like to identify any additional elements or programmes, beyond those that we have explored above, which you feel would improve the efficiency of conformity assessment in international trade.
- 2 **Q (for exporters):** Please describe one striking example of the problems which were in your mind when you answered the earlier questions in this questionnaire. If appropriate, identify the products and country(ies) concerned, provide data such as cost or sales volumes, etc.

ANNEX 3. CHANNELS TO CONFORMITY ASSESSMENT BODIES (CABS)

The most comprehensive channel used was the International Accreditation Forum (IAF), which has 42 national members (including all G7 countries, and most of the members of the OECD), through whom over 5000 bodies are accredited worldwide. A number of other bodies were also used, with smaller coverage of CA bodies, but often with a concentration on large bodies. A list follows of organisations which provided help:

Initials	Name and number of CABs in network	Internet
IAF	International Accreditation Forum: over 5000 bodies accredited, including Quality management systems – 971 Environmental management systems – 518 Product certification – 760; Inspection – 3650. Members are: 46 accreditation bodies; 14 associations; 4 regional groups; 2 partners and 3 observers.	www.iaf.nu
OIML	Organisation Internationale de la Metrologie Legale : 59 full members, 54 corresponding members (lower-level of scope and income). Members are one per country.	www.oiml.org
UILI	Union Internationale des Laboratoires Independants: Several hundred members (for example, the US national member has 240 company member laboratory companies.	www.uili.org
IIOC	Independent International Organisation for Certification: 8 members, all large and with multiple international locations	None
IFIA	International Federation of Inspection Agencies: 18 full members, most with multiple international locations	<u>www.ifia-</u> federation.org
ILAC	International Laboratory Accreditation Cooperation: approx. 26,000 laboratories and inspection bodies accredited by 68 ILAC full members and associates. Total membership of ILAC consists of 111 bodies covering 77 economies worldwide.	http://www.ilac.org/
ISO	International Standardisation Organisation: around 140 members, of whom up to 100 have CA operations.	www.iso.org

In addition, contacts were made with national organisations in Canada, the USA, and Japan.⁴²⁴ For Europe, European representation in the international organisations listed above was judged to be sufficient to achieve adequate coverage without further contacts at national level.

⁴² In the USA, through NCSLI (National Conference of Standards Laboratories) www.ncsli.org; in Canada through the Standards Council of Canada www.scc.ca; and in Japan through the Ministry of Economics, Trade, and Industry (METI) http://www.meti.go.jp/english/index.html

ANNEX 4. EXPORTER QUESTIONNAIRE: CHANNELS OF DISTRIBUTION

Country	Name and membership	Internet
OECD members	BIAC (Business and Industry Advisory Committee to the OECD): Members are the major industrial and employers' organisations in OECD member countries. All of these were contacted through the BIAC Trade Committee.	www.biac.org
Multi-national	ICSCA (Industry Cooperation on Standards and Conformity Assessment). It has 13 major multinational companies as direct members, as well as industry associations in telecommunications, electrical and electronic products in the USA, Germany, and Australia.	www.icsca.org.au
EU	1. The network of <i>Euro-Info Centres</i> , established by the European Commission to distribute information on business. The 269 regional centres, spread throughout the EU, have a " <i>SME-oriented mission</i> " to provide business-related data and advice.	http://europa.eu.int/com m/enterprise/networks/e ic/eic.html
	2. UNICE, the umbrella body for European (not just EU) employers' associations, generally one per country, but with exceptions, giving 32 full members in total. Distributed to around the same number of members of the <i>Free Movement of Goods</i> working group.	www.unice.org
France	MEDEF (Mouvement des Entreprises de France) Claims to represent " <i>more than 750 000 companies of all sizes and in all sectors</i> ", through 85 professional associations and 155 regional offices. 70% have less than 50 employees.	www.medef.fr
Germany	 DIHT (Deutsche Industrie- und Handelskammertag), the national umbrella organisation for 81 local and regional Chambers of Commerce (IHKs) in Germany. Reportedly has a total membership of 3.9 million enterprises. BDI (Bundesverband der deutschen Industrie eV), an association of associations, with membership limited to industrial sector associations and working groups, which together represent 100 000 businesses in Germany. 	<u>www.diht.de</u> <u>www.bdi.de</u>
United Kingdom	CBI (Confederation of British Industry): describes itself as representing "200 000 businesses based in UK [in] all sectors of business", including 60% of the FTSE 300.	www.cbi.org.uk
Canada	Canadian Ministry of Foreign Affairs and Trade, through a weekly e- newsletter to Canadian exporters from Industry Canada, with a reported readership of 30 000.	http://strategis.gc.ca
USA	NAM (National Association of Manufacturers: describes itself as <i>"the nation's larges industrial association"</i> with 14 000 members. 72% of these have <200 employees.	www.nam.org

In **Phase 2**, the OECD Secretariat contacted, either directly or through governments, trade or business associations representing specific industry sectors in Canada, the European Union (and France, Germany and the United Kingdom at the national level), Japan and the United States with a request to distribute the survey to their membership. The sectors targeted were: electrical/electronics; aerospace; motor vehicles;

machinery; medical devices; plastics; and textiles and clothing. Organisations representing SMEs and national Chambers of Commerce were also approached.

In **Phase 3**, a limited number of telephone interviews were conducted: with 1) six manufacturing exporters, all of whom had responded to the initial questionnaire and indicated their willingness to be interviewed, 2) four trade federations, including one multi-sectoral industry body from the above list (UNICE) and thee sectoral federations covering sectors frequently mentioned by the exporting interviewees. In addition, a single supporting interview was conducted with one of the top ten multinational CABs to check technical aspects of the other responses.

This interview phase used a standard checklist of questions, focusing on those which appeared most relevant in light of the specific answers given to the Internet questionnaire by the respondent being interviewed here. Notably, the interviews explored:

- The definition of sectors, whether they were accurate, and notably the apparently frequent mention of metrology-related products (metrology turned out not to be a major area of concern).
- The precise nature of what were reported as CA problems, with the goal of verifying that they were not simply standards problems (i.e., problems of different manufacturing specifications) whose effects were visible at the conformity assessment level, but which should be attacked at the level of the core specification rather than at the level of the conformity assessment process. (The verification that we were in most cases dealing with "pure" CA problems was obtained.)
- [Again] the precise nature of the reported CA problems, to confirm the accuracy of the short responses given in the Internet questionnaire: for example, the accuracy and precise meaning of statements that "duplicate testing" was the problem.
- Perceptions of the technical feasibility of increasing home-country (i.e., country of production) testing and certification of products traded internationally, and of the reasons which prevented the wider introduction of SDoC and the wider recognition of home-country (i.e., country of product) test reports and certificates of traded products.
- Perceptions of reasons why SDoC was not spreading more rapidly.
- Perceptions of the strengths and weaknesses of existing programmes to achieve cross-border recognition of test reports and certificates, and notably those operated by ISO (through its CASCO standards), IEC (through the IECEE CB scheme), IAF, and ILAC, with the goal of identifying whether any practical action could be defined which would lead to their wider use in practice.
- Opinions on how to involve governments more effectively in programmes to achieve either 1) wider use of SDoC, or 2) wider recognition of home-country testing and certification; and in particular whether sectoral or multi-sectoral programmes would be more effective.

Region	Country	Total	Region	Country	Total
Sub-Saharan Africa	South Africa	1		Russia	1
Asia -Pacific	Australia	54		Slovak Republic	19
	Japan	12		Slovenia	1
	Hong Kong	6		Spain	31
	New Zealand	2		Switzerland	69
	Thailand	1		Ukraine	2
	Singaore	1		United Kingdom	24
	India	1	Latin America & Caribbean	Argentina	1
	China	1		Brazil	10
Europe	Bulgaria	3		Costa Rica	1
	Croatia	11		Ecuador	1
	Cyprus	1		Guatemala	1
	Czech Republic	23		Mexico	1
	Denmark	9		Saint Lucia	1
	France	3		Uruguay	1
	Germany	18	Middle East & North Africa	Egypt	4
	Greece	1		Iran	1
	Ireland	6		Israel	7
	Italy	1		Morocco	2
	Netherlands	20	North America	Canada	7
	Poland	18		United States	38
	Portugal	1	Unknown	Unknown	1
	Romania	10			

ANNEX 5. COUNTRIES REPRESENTED IN SET OF 428 CAB RESPONDENTS

Note: Countries with 10 and more CABs represented in the survey are shown in **bold**.

ANNEX 6. SECTORS WHERE CAB RESPONDENTS REPORTED THAT GROWING ACCEPTANCE OF INTERNATIONAL STANDARDS CONTRIBUTED TO GROWTH OF THEIR EXPORT-RELATED CA ACTIVITIES

Product category	Number of responses
Electrical machinery and apparatus, including domestic appliances	27
Pharmaceuticals and chemicals	20
General and special purpose machinery	19
Agricultural and food products, beverages and tobacco products	18
Electronic and telecom products and equipment	17
Motor vehicles and other transport equipment	14
Building materials and components	9
Medical appliances, precision and optical instruments, watches and clocks	8
Water	3
Furniture, other transportable goods n.e.c.	3
Forestry products	2
Glass and glass products	2
Mechanical products	2
Products of wood, cork, straw and plaiting materials	2
Rubber and plastics products	1
Textiles articles	1
Electricity, town gas, steam and hot water	1
Packaging	1
Miscellaneous (unspecified)	12
Not classified/Not a product	19

Note: In this free-text question, respondents could mention up to five sectors or product groups. Responses were subsequently classified based on the CPC product classification (levels 3 and 2). In this table some divisions have been combined into one category.

ANNEX 7. EXPORTER SURVEY: REPORTED COUNTRIES OF ORIGIN OF PRODUCTS FACING REPORTED CA BARRIERS

Region	Countries
	Australia (2)
	China (27)
	Hong Kong (1)
	India (3)
	Japan (10)
Asia (65)	Korea (6)
Asia (03)	New Zealand (1)
	Philippines (1)
	Singapore (2)
	Chinese Taipei (6)
	Thailand (4)
	Vietnam (2)
	EU (9)
	France (3)
	Germany (24)
	Ireland (1)
	Italy (4)
Europe (61)	Poland (1)
	Russia (2)
	Spain (2)
	Sweden (3)
	Turkey (1)
	United Kingdom (11)
North Amorica (17)	Canada (6)
North America (17)	United States (11)
	Nigeria (3)
Sub-Saharan Africa (5)	South Africa (1)
	Tunisia (1)
Middle East and North Africa (MENA)	Iran (3)
	Saudi Arabia (2)
Latin America & Caribbean (2)	Mexico (1)
	Trinidad and Tobago (1)

Note: Figures in brackets indicate number of observations per region or country mentioned.

ANNEX 8. PROFILE OF THE EXPORTERS SAMPLE: CATEGORIES OF PRODUCTS EXPORTED

Product category	Number of responses
Electrical industrial machinery and apparatus	15
Electrical appliances and housewares	11
Radio, television and communications equipment	11
Office machines and automatic data-processing machines	8
Machinery specialised for particular industries	21
General machinery and equipment	8
Power generating machinery and equipment	4
Professional, scientific and controlling equipment	18
Medical devices	10
Photographical and optical goods	6
Pharmaceuticals and medicinal products	12
Basic industrial chemicals	7
Paint varnishes and lacquers	5
Fertilisers and pesticides	2
Soap and cleaning preparations, perfumes, cosmetics	1
Fabricated metal products	7
Iron, steel and non-ferrous metal	5
Structural metal products	2
Food products	6
Spirits, wine and soft drinks	3
Textiles goods	6
Clothing	3
Footwear	3
Plastic products	6
Glass and glass products	4
Road vehicles	3
Other transport equipment	4
Pulp paper and paperboard	2
Published printed products	2
Sporting and athletic goods	3
Watches and clocks, and jewellery and related	2
Miscellaneous (furniture and fixtures, tyres and tubes; non-metalic minerals;	4
dimensional wood)	
Not classified	2

Note: Categories based on CPC classification. Respondents could check one or more items. Related items are grouped together.

ANNEX 9. EXPORTERS' DESCRIPTION OF "OTHER PROBLEMS" (FIGURE 10) CAUSED BY THE NEED TO APPLY DIFFERENT CA PROCEDURES FOR EXPORTS

Issues	Details
Time (delay at customs)	Additional time needed to fill our documentation. Delays at customs due to approval of shipment (1 - 3 days).
Time (customs)	Customs does not have value of time of the private company.
Time (delay); and arbitrariness of administration	Because of partially "intentional" interpretation of individual national requirements significant delays occur during importation of the equipment. One has the impression that the evaluation does not depend so much on the text of the requirement than on the individual inspector.
Time; and development costs	It lengthens the time to get our product to market and increases our development costs.
Additional personnel	Additional manpower needed.
Additional personnel and facilities	Exhaustion of scarce resources (human and facilities).
Loss of know-how; time and costs	Payment of special conformity tests e.g. USA, China. Transfer of Know How by detailed drawings, documents etc. Need of time for conformity procedures
Loss of know-how; and issue of non-recognition	Chinese energy consumption mark; no acceptance of ISO 9001 certification for factory inspection; know-how loss through foreign factory inspectors.
Registration	Government registration of medical products in Asian countries. It is so difficult for us to get an approval for selling the products. Especially Korea, China, Chinese Taipei, Canada.
Registration	The process of registration in the country takes a lot of time and energy.
Repetitive testing and standards issue	For each vintage year of the same type of wine testing must be performed. The Japanese guidelines on chemical additive concentrations are more liberal than what a quality winery in Canada would use. In our case such maximum levels would never be attained as they seriously would compromise quality.
Cost and time associated with additional testing; documentation, customs clearance	Increased costs are associated with additional testing of raw materials and finished products to ensure compliance with local regulations or import requirements (testing method, materials, personnel, added time etc. There are also increased import documentation and testing requirements at the port of some countries, causing additional burden of obtaining required documents as well as added time for customs clearance.
Multiple testing and other standards/CA issues	Multiple testing, partly mandatory certification, national deviations in standards, labelling requirements.
Frequent changes of standards	Frequent changes of applicable standards.
Frequent changes of requirements; paperwork inconsistencies	Paperwork inconsistencies - continually changing requirements from shipment to shipment. Have even changed while goods are on the pier in receiving country. It is an effective non-tariff barrier.
Standards/CA problem (specifications for voluntary quality marks)	In Europe, the fire detection market has still a lot of national specifics and despite some emerging European standards some countries like France or Germany make sure that some barriers to trade remain. Furthermore the Fire Authorities enforce the use of "voluntary" quality marks which are different from country to country (this despite the fact that the EU forces them to remove such things from the regulations). Each quality mark has its own "technical" specifications which made the sale of the product impossible unless they have been modified and re-tested in the country. In fire detection just for the EU you must "retest" the same product at least 4 times and have about 10 certifications, each time with a slightly modified product.

	Request for "certificate" which can be easily passed through considering that
Standards/CA problem	country of origin (an EU country) has the strictest regulations in terms of health
	and safety for workers and environmental rules.
Standards/CA problem	I echnical difficulties in promoting common conformity design due to countries
1	unique safety/EMC standards and their implementations.
	Inclusion of various mark/symbols/logos on products (label real estate). Addition
Labelling; additional paperwork,	of specific paper work country by country. Inclusion of additional testing to meet national standards or deviations to international standards. Peneating testing
testing	already conducted _ no value added requests from customers for expertise in
	market access to additional areas
	The conformity issue is not in the product but in the related product certification
	program required by buyers. Each major food chain in the UK is requiring
	notential suppliers to become certified under their own "food safety" certification
	program Each programme differs and includes extraordinarily detailed
	procedures audits and paperwork and payment to different certification bodies to
	have auditors travel (sometimes from England) to complete the process and repeat
Multiple certification (private	it every vear – at substantial cost. For small orchard operations, the process and
sector), paperwork and costs	cost is prohibitive and many are electing to drop the market rather than pay the
	costs to qualify as a supplier (with no guarantees from the buyer that they will
	purchase, or even give preference to the "certified" product over other suppliers.
	This is a non-tariff trade barrier and also a commercial ploy to commit producers
	to buyers as producers cannot afford to comply with all buyers' certification
	programmes.
Paparwork	It is a logistics problem to re-match up documents that have to be signed at the
	Chamber of Commerce in Windsor or for shipments ex USA at the Chamber of
1 uper work	Commerce in Fort Smith Arkansas with the rest of the documents at the shipping
	site.
Paperwork	Too many documents/operation manuals etc.
Bureaucracy	Too much bureaucracy.
	No body in any of the Government agencies who are supposed to be there to help
Information problem	ever have the latest up to date information. We tell them about it when they
	should be on top telling us. So we never bother to use any of them as this is a
	complete waste of time. Also, it takes forever to get through to the right
	department to be told they do not know about that.
No big problem with CA	We actually see no big problem with CA in our industry since the European and
	other engine manufacturers (our customers) in the world are following the same
	standards regarding emission control for example and since the same or at least
	similar electronic components are used all over the world. There is not much
	ar from V group as we see it
	Different technical requirements (radio frequency allocation, newer supply
Multiple standards	voltage etc.) are required by each country
	Salas to our subsidiary in India and then resale from our subsidiary to the and
Other NTBs	customer is 20% more expensive than selling our products directly to end
	customers in India. This is because of customs duties and taxes due to be paid for
	sales within the country of India. As a consequence, our subsidiary is no longer
	competitive and we are considering closing this business

ANNEX 10. EXPORTERS' COMMENTS ON SUBJECTS OF CONCERN ABOUT CA FOR EXPORTS THAT ARE NOT COVERED BY THE ITEMS SHOWN IN TABLE 4

- If one looks at ISO 1010, which is necessary for our products, it is astonishing how many additional national amendments hereto exist, all of which require an additional test. It should be possible with an international standard to come to an agreement on setting a lower level threshold, since one cannot assume that in one country a particular item has to be classified as critical/dangerous whereas in another country this is completely irrelevant! Under NO CIRCUMSTANCES should the compromise consist of including ALL national special requirements into the standard!
- Different interpretation of the same requirements leads to discussions and loss of time.
- Every problem has to be handled with communication skills. You always find a solution!
- Excessive regulatory requirements. Changing requirements and processes. Unpredictability. Requirements available in local languages. Arbitrariness of authorities.
- Factory inspection by each country by itself.
- Get rid of commercial invoice requirements.
- HMC&E are applying restrictions on our business simply because our excise duty rates have not been harmonised with our EU partners. New proposed controls - pre-advise of all EU movements - will further restrict our business / affect our ability to meet customers' delivery requirements. We face duty assessments even after we have received AAD documents endorsed by the local customs authorities in the country of delivery, because, in HMC&E's opinion, they are forgeries.
- In many developing countries, custom authority at the time of importation conducts conformity checking either by document submission or by product testing, which causes delay in market-access. This should be treated as discriminatory measures.
- Mainly non-acceptance of existing marks of conformity when those agencies are testing to the very same standard required by the end country. National treatment of CA bodies and their marks is required going forward.
- No clear points of contact. In several countries, the requirement for customer evaluation samples is the same as actual commercial shipments.
- Our products are meant for industrial use only. This should reduce tests and documentation requests.
- Regarding prior shipment of samples to export markets: Usually only for the initial shipment of a new product do we have to send a live sample for further importing countries analysis.
- The main problems we find are the bank charges levied against us for transfer letters of credit etc. These high charges cannot always be passed on to our customers in terms of increased sales prices, as we are then less likely to make a sale. We have also encountered problems getting insurance for exports to "excluded territories" like Ukraine etc and have to pay an extra premium as these areas are not covered by our Marine Cargo Policy. Freight forwarders are no longer able to insure on our behalf either.
- Issue of uniformity of search sites: customs statistics, regulations, etc.
- We have found that we solve one problem and send back for testing and get back another problem. It would be easier if all queries were raised at the first testing.
- China has been an issue for documentation. They have requested phytosanitary certificates which the United States does not issue. Also, they have required original certificates of origin - not scanned or faxed copies. Often supplier will not issue multiple without increasing cost and original cannot be sent as it is needed for future shipments of same lot and our records. This has resulted in fines from China

- China: complete new procedures for CCC
- In China, I finished all the test and document requirements and was waiting for approval. But the law changed and I was asked to try further test and documents again.
- Our product shelf life is 3 years and we have enough back-data to support. Recently the authority of People's Republic of China informs that shelf life should be 2 years maximum according to their regulations. Accordingly, our new product registration has been pending.
- Chinese CCC mark certification: AV/ITE/Household Appliances produced outside China are subject to factory
 inspection by sending Chinese local inspection team, whereby it is impossible for the manufacturer to make a
 prior settlement of the production data since the date cannot be fixed until inspector's visa and passport
 arrangement is completed.
- In China, Latin countries and CIS (Russia, Ukraine etc), the medical regulation is a big burden for us. It requires a lot of work, it takes time and cost. Because of it, introduction of new products (endoscopes) delays always.
- Rather than an example of the issues noted [in this survey], another more encompassing problem is that for Greece, Italy and Turkey, the Certificate of Origin (&/or Certificate of Age & Origin) must be signed by the local Chamber of Commerce, but for all other countries we ship to that require a Certificate of Origin, the signature of the Government of Canada Excise officer is sufficient.
- The delay in getting approval has lost us sales in the United States and therefore slowed down our momentum. In United States, testing of a digital trigger unit to fire thyristors cost of £5 000 & on going license of £500 pa. No impact on sales volume. Also in USA, standard of power control cabinets lower than that supplied to the rest of the world so as to meet their criteria.
- Most countries we export to have Minimum Residue Levels allowed for various possible agricultural chemicals. Canada has strong standards and regulations about what is licensed and legal to apply and how this is done as well as CFIA inspections of all fruits exported, and random residue tests to ensure growers comply. These government procedures and international standards provide a good measure of food safety. In the name of food safety and consumer interest in environmentally sustainable food production practices, highly integrated food chains in the UK (in particular, but also WalMat) are developing extremely onerous and costly certification programs that suppliers must pay to get 'certified' under. The cost of this includes administrative time to fill out binders of forms, policies, and procedures, obtain independent certifications from their suppliers, etc, plus annual audits. The certification programs often duplicate the objectives of each other, but buyers will not recognise programs that are not their own. Last year we spent about \$20,000 to get Eurepgap and BCGAP certification and renewal and compliance costs will cost about \$6,000 per year. Tesco will not recognise this and insists suppliers complete and comply with their Natures' Choice program. Initial costs to meet their bells and whistles (none of which have anything to do with improving or assuring eating quality of the product to consumer) would cost us about \$40,000 the first year and another \$6,000 per year in audits and compliance costs. No premium is paid for "certified" product by buyers. There is not even any undertaking that having certified with a supplier that they will purchase your product, let alone at a competitive price. Buyers (such as Sainsburys in 2004) have stipulated that Eurepgap certification is essential, but we have learned afterwards that, in fact, they purchased products from non-certified suppliers when it suited them.
- In Nigeria, we sent 2500 samples for evaluation to the NAFDAC and after evaluation, we were informed that the documents were destroyed by fire.
- National law of Russia and Ukraine require certifications of Rostest respectively Terztest for imported goods.
- Always FDA, USA.
- For exportation to Lebanon, certification organisation Veritas had a problem to understand that the classification of customs code based only on the 4 first digits is not relevant to decide if yes or no certificate of conformity on European or U.S. standards are required or not. This especially considering passive electrical material and not active one (security test, fire improve, etc)

- The problem of CA is in our market not a problem when exporting but in our homeland market. The same rules shall apply within Europe but very unclear and unpredictable rules are applied and common rules for CA are not considered. This obviously creates obstacles for exporting companies from other countries. The product area is railway signaling equipment, sales volumes approx. 100 million euro/year.
- In France, for example, the evacuation of the building must be done by a panel called CMSI since more than 15 years not a single non-French company has been able to sell directly. This has forced the companies to acquire French companies and now that there are nearly no companies which can be acquired it is nearly impossible to enter this market.
- China's battery Law, where NiCad batteries are not allowed to be exported to China but a manufacture has to
 prove that MiHI batteries are not NiCad batteries. Japan, where a MSDS certificate is required for products
 that are painted, this certificate is required to be held on file in Japan.
- In Italy there is a new fire safety regulation according to which all textiles used in public buildings have to be suddenly washable even though these textiles will never be washed due to their size (theater curtains). Up to now such textiles were flame resistent but not absolutely flameproof. Therefore, we can no longer sell diverse qualities, because these cannot be adjusted technically and in terms of price. In all other European countries this new regulation does not exist.
- Requirements other than European standards are being imposed. Norway effort and costs.
- In the case of one of our equipments, an insulation foam was used. This insulation foam is completely covered by stainless steel sheets. In order to obtain UL certification, this foam was replaced by flame resistant foam, as requested by the relevant testing agency. This replacement has caused significant problems and costs. In this case two issues arise: 1) Shortly after the Adjustment was made we received reliable information that another company was allowed/use was not rejected for the foam for exactly the same application; and 2) the construction of the equipment makes it impossible that the foam inflames.
- Importation of electronic parts, special cable products entails generally very high investments in terms of time and costs.
- We design, develop and manufacture instruments used in highly radioactive environment. Depending on country, certain organic materials are not allowed to be used. A consensus tends to emerge in respect to the banned materials. This does not pose any practical problems unless willing to ignore the national legislations, in which case the products will be refused.

Note: Statements have at times been slightly edited and/or translated from French or German by the OECD Secretariat. A few comments by respondents addressing issues unrelated to CA procedures are not shown.

ANNEX 11. COMMENTS BY CABS ON ADDITIONAL ELEMENTS OR PROGRAMMES, BEYOND THOSE EXPLORED IN THE QUESTIONNAIRE, WHICH WOULD IMPROVE THE EFFICIENCY OF CA IN INTERNATIONAL TRADE

CAB with primary activity in:	Comments
Australia	As a company with NATA recognition and FDA accreditation for the conduct of Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) studies, we still have to spend considerable time convincing potential clients both of this fact and the subsequent inter-country endorsement it carries. In addition to the audit and inspection process imposed as a result of the NATA endorsement, we are constantly "re-audited" by clients (invariably multi-national pharmaceutical companies) resulting in duplication of effort and poor use of resources on our part. A programme targeting this sector of the industry with the aim of instilling widespread industry confidence into the NATA audit process may be helpful.
Australia	There is too much emphasis on product testing. More emphasis on services, particularly environmental, would be beneficial to some highly specialised providers. The testing for radioactivity testing is a requirement by many governments for imports and exports and international recognition of certification would be an advantage.
Australia	This Australian medical laboratory is accredited to the ISO 17025 (and shortly will be to ISO 15189) as well as by the TGA (c.f the US FDA) for medical testing and undertakes significant amounts of testing for research trials. Despite compliance with international standards we cannot practically get licensing by US authorities to perform testing on samples sourced in the United States. We can do the testing far more cost-effectively and at least the same quality (and in many cases better).
Denmark	Our primary Field is legal metrology; here a EU directive 2004/22/EC was passed that will have a major impact within the EU/EFTA countries. We urge to push the acceptance of accreditation also within the United States as e.g. UL-certification is still subject to traceability to NIST which we consider a more than virtual trade obstacle as any ISO 17025 accreditation should do!
Denmark	It would be very beneficial for all the EU countries to implement all requirements to manufacturers declaration of conformity and the accredited reports in the same manner and not, as now, have each their own version - especially in the former East European countries where requirements are very different from the "old EU". Bureaucracy is very elaborated.
India	We would like to see a stronger, firmer attitude with bodies like QCI who is covertly influencing the Government of India to offer subsidies to only those companies who are certified by NABCB. Certification bodies like ours with RvA or other accreditations will soon be wiped out in India because of this unless we have the protection of our Accreditation and other International Governing bodies.
Japan	We have no accreditation for product certification activities from any accreditation bodies as defined under ISO17000. However, we are recognised as a National Certification Body (NCB) and IECEE CB Testing Laboratories (CBTLs) under the IECEE/CB Scheme that is effective for our product certification activities which cover import and export products. Therefore we would like to recommend you to include the IECEE CB Scheme as one of the accreditation systems in your guidance.
South Africa	International Agreement/Requirement that forces Foreign CABs to be accredited in South Africa - the Cross Border Policy of IAF does not help at all. Export companies should be required to comply with quality requirements for their products and management systems before they can do business in other countries. Proof of certification should be implemented at point of export.

Switzerland	The lack of efficiency is that the conformity assessment is regarded in wide areas as formal aspect, and even some huge NBs do not differentiate between common Management-System-Certification and Conformity-Assessment and/or product testing. Thus the level of acceptance is too low and/or the moment of following incidences is too late to keep the product beyond the regulations. Typical critical fields are from my knowledge as competitor on the market: medical devices very specifically in Germany sterility. On the other hand, nearly nowhere the official governmental authorities do care if products are out of order as long as no critical incidence occurs. Thus the market aspects as low importance also forcing to low price and therefore to low service effort. Thus some NBs do follow this catching customers and cash but being unable with the level of cost yielding the sense of the regulations.
Switzerland	We are an accredited lab for testing and calibration of material-testing machines and encountered the following problems our customers have: Swiss manufacturers of airplane parts face increasing difficulties when exporting their products into the United States. The calibration of their material testing machines usually based on ISO EN standards is increasingly not recognised. They often have to calibrate their testing machines according to ASTM standards which is expensive, time consuming and is often setting lower standards than ISO. For this reason, we had very labour intensive projects. We were confronted with several incidents covering the following standards: Calibration of various hardness measurement procedures (Rockwell Brinell Vickers) Calibration of Specimen alignment under Tensile Loading (ASTM: E 1012-99). Since the ASTM standards are often very similar or even setting lower limits then ISO it appears to be a protective measure in order to protect the domestic industry from competition. [We deem this to be unfair and against the often proclaimed free trade; a barrier which is difficult to over-come. Therefore, we would suggest that the recognition and implementation of ISO standards in the United States would be an important step towards the reduction of unofficial trade barriers.
Switzerland	It is important not to mix type-examination of products and certification in quality management for process (e.g. in EC Directives), because to fulfil the essential health and safety requirements, this is not the same and has not the same result for the products with CE mark in Europe.
United Kingdom	We have started the process of obtaining recognition in another country and consider it unreasonable that their National Accreditation Service (although a member of the EAC) will not recognise (accept) that we already meet the standards and insist on undertaking a full assessment
United States	Multi-lateral agreements that encourage but do not require mutual recognition of accreditation bodies of each other s work result in commercially useless, non-value, inefficient and costly CB certification. There should be no need for duplication of accreditation audits/efforts by accreditation bodies that are accredited to the same ISO guideline or standard. These "extra" costs are passed on to organisations. The IAF seems unable to resolve this problem presumably because of the need for its members to gain/maintain revenue to feed entrenched individual interests. This detracts from the value of accreditation as organisations become aware of the valueless and wasteful duplicate costs.