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**TRADE EFFECTS OF APPROACHES INTENDED TO
FACILITATE ACCEPTANCE OF RESULTS OF CONFORMITY
ASSESSMENT: WHAT IS THE EVIDENCE?**

by

Mark Vancauteran
Hasselt University and Statistics Netherlands

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TRADE EFFECTS OF APPROACHES INTENDED TO FACILITATE ACCEPTANCE OF RESULTS OF CONFORMITY ASSESSMENT: WHAT IS THE EVIDENCE?¹

1. Introduction

1. Past and recent efforts in making the global economy more integrated by the progressive reduction and even elimination of regulatory barriers has made the subject of technical barriers to trade (TBTs) an important topic for discussion in trade policy (see e.g., Baldwin (2000), Baller (2007), Brenton and Vancauteren (2001), Maskus *et al.* (2000)). Of these regulatory issues technical barriers to trade (TBTs) arising from differences in national product or process standards and duplication of conformity assessment procedures are of primary importance. Regulatory issues such as standards and conformity assessment (CA) can foster trade by reducing transaction costs (David (1995), David and Greenstein (1990)), but they can also act to constrain trade between countries. Producers may have to adapt their products to be accepted in foreign markets with the associated costs of redesign of products to separate markets.² In addition, foreign governments may not recognize the tests performed in the exporter home country so that exporters have to undertake expensive tests in the foreign markets.

2. These issues, reflecting concern that TBTs may act as constraints upon international trade flows, have been addressed in trade agreements under the WTO and GATT, the role of which is to engage legislators and officials, at national and sub-national levels, by promoting regulatory cooperation aimed at reducing the trade distorting impact of differential standards and conformity assessment procedures. For example, the aim of the WTO Agreement on Technical Barriers to Trade (the TBT Agreement) is to prevent governments from using standards and conformity assessment procedures as protectionist measures. An important issue here is that governments are still allowed to define national standards and conformity assessment procedures according to their own legitimate objectives; however these procedures must not be applied for the purpose of restricting trade more than necessary.

3. The aim of this review is modest: to survey the empirical literature that looks at the impact on international trade flows of various approaches for the facilitation of acceptance of CA results.³ We limit

1. This survey has been prepared under contract with the OECD. The author is grateful to Barbara Fliess (OECD), Frank van Tongeren (OECD), Natalie Chen (Warwick University), Hans Ingels (European Commission), Christopher Johnson (U.S. International Trade Commission) and John Wilson (World Bank).

2. These costs are usually referred to as compliance costs. The following costs may incur under compliance (KPMG (2001)): (i) costs of monitoring the varying regulatory requirements; (ii) costs of changing product design; (iii) costs of reorganising the production system; (iv) costs of testing and certification; (v) time delay costs in market access due to the time that goes into product re-design and certification.

3. Empirical verifications related to the trade impact of standards-related TBTs are not included in this survey. For a very comprehensive survey of the recent empirical literature focusing on the impact of standards-related TBTs and efforts aimed at reducing such TBTs, we refer to the the WTO report on "Trade, standards and the WTO" (2005a). Not included in that report is most recent work by Baller (2007), Chen and Novy (2008), Disdier et al. (2008) and Sheperd (2008).

our review to those approaches or tools that have been identified by the WTO TBT Committee during the second triennial review of the TBT Agreement in 2000 under form of an indicative list (G/TBT/9 Annex 5). These include: (a) mutual recognition agreements (MRAs) for conformity assessment to specific regulations; (b) co-operative arrangements between domestic and foreign conformity assessment bodies in the voluntary sector; (c) the use of accreditation of qualify conformity assessment bodies; (d) government designation; (e) unilateral recognition of results of foreign conformity assessment; (f) manufacturer's/supplier's declaration. For the purpose of this paper, each of these tools will be briefly described in the subsequent sections. The empirical methods that have been applied in the collected literature are drawn from surveys, telephone interviews and econometric methodology.

4. The majority of the empirical studies reviewed confirm that such approaches are trade promoting. The review also shows that there is a distinct bias towards assessing the effect of mutual recognition agreements, while other forms of facilitating arrangements are less researched.

5. The paper is organized as follows. In section 2, we briefly discuss standards and conformity assessment procedures and their relationship. In section 3 we discuss various factors related to the quantification of CA procedures. Section 4 to 8 respectively examines the six types of trade facilitating conformity assessment procedures identified in (a)-(f) above. For each of the six procedures we will present some selected evidence, either empirical or survey based. Section 9 discusses the results and the final section briefly concludes.

2. Standards and conformity assessment procedures

6. While a number of trade facilitating instruments have been created that aim at removing TBTs, it is useful to distinguish “standards” from “conformity assessment procedures”.⁴ A “standard” is to be understood as a set of technical specifications adhered to by a producer that are either voluntarily (voluntarily standard) or mandated (technical regulations). These technical specifications may be related to the product itself or to related production methods and processes (WTO (1995)). A technical regulation is a compulsory standard imposed by a government at the local, regional or national level to secure health, safety, and environmental and consumer protection (Aldaz-Carroll (2006)). For instance, a technical regulation can specify the emission limits of motor vehicles. A voluntary standard is a market driven standard that “reflects the demands and tastes of consumers or the technological requirements of industrial purchases” (Brenton (2004)). One illustration of a voluntary standard is the compatibility of the “hi-fi” stereo sound system components, which are provided by interface standards that lay out the numerous components and subsystems that are provided by different suppliers.

7. Conformity assessment ensures that the product or process satisfies technical specifications that are set by standards. It includes one or more of the following procedures (Wilson (1995), Aldaz-Carroll (2006)): *testing* (declaration of conformity by own or third party testing laboratory); *inspection* (independent inspections of parts, materials, and final products); *certification* (formal certification by a third party that a product conforms to particular standards, which often includes the granting of a mark, certificate or label); *registration* (independent audit of manufacturing quality systems that results in a registration with quality systems registrar, i.e., ISO9000 or ISO14000), and *accreditation* (evaluating and attesting that testing and calibration laboratories, certification and inspection bodies are technically competent to perform a specific task).

4. See also WTO (1995), Agreement on Technical Barriers to Trade. Annex 1, Terms and Their Definitions for the Purposes of this Agreement.

8. Standards and conformity assessment requirements “stipulate what can or cannot be exchanged and define the procedures that must be followed for exchange to take place” (Brenton (2004)). The potential of standards and conformity assessment procedures to distort trade is usually related to duplicative or other unnecessary trade costs to producers as a result of complying with domestic and foreign standards and conformity assessment procedures that do not coincide. These costs are deemed to be unnecessary or even redundant if for instance, both countries set identical regulatory objectives but do not accept the standards or CA procedures used to achieve these objectives as being equivalent.

9. The *technical* compliance of standards and conformity assessment procedures always go together: if standards are accepted so are their underlying conformity assessment procedures. But whereas a country’s standards may be accepted by the other country as being equivalent; an “exporting country’s tests and certificates of conformity may not be sufficient to certify compliance in another market” (Hart (2004)).

10. In a situation where there are differences between CA procedures and standards across countries, the nature of these duplicative trade costs to producers as a result of complying with domestic and foreign standards differ from those related to the foreign acceptance of conformity assessment procedures. In order to overcome differences in standards across countries, producers incur costs related to the physical adaptation of the product or the process. On the other hand, when the product or process is subject to different conformity assessment procedures between the domestic and foreign country, the compliance may relate to unnecessary testing and certification costs, complex and lengthy product-and/or-process approval procedures, delays in time-to-market access, internal staff costs and additional transportation costs.

11. Costs related to the lack of acceptance of conformity assessment may vary from market to market, sector to sector and product to product. In the subsequent sections, we will cover a number of market structural variables (firm size, form of international trade such as trade in final versus intermediate goods, actual versus probable trade flows, type of ownership, diversification of products, etc.) that determine the rigidity of compliance costs resulting from TBTs. We return to this issue in section 9. Drawing from the literature, time-sensitive products - usually referred to as products with short product life cycles - such as innovative technologies can especially be hurt by such delays in approval (see amongst others, Aldaz-Carroll (2006), Crosby (2000), DiBiase (2008), Hart (2004), Johnson (2008), OECD (2000), USITC (1998), Wilson (1999)). For instance, US industry representatives claimed that delays in determining conformity of IT equipment in the EU reduces the product value by 5 to 10 percent (USITC (1998)). These costs do not have a regulatory justification when the domestic and the foreign country’s regulatory objectives (e.g. consumer safety, health) are identical.

12. While regulatory diversity can be justified by historical, political, economic and demographic traditions, efforts by governments, private and public standardization bodies, private industry associations and international organizations to reduce regulatory cost burdens related to duplication has become an increasingly important issue in trade policy.⁵ Trade facilitating instruments related to the removal of standard-related TBTs and conformity assessment related TBTs are also mutually inclusive (Park (2001)). However, initiatives to reduce barriers related to standards and to reduce CA procedures do not necessarily occur simultaneously. For example, for some of the sectors in the EU Single Market and in ANDEAN countries, the removal of TBTs related to conformity assessment has been taking place even when

5. At a recent EU-U.S. Summit (April, 2007), the German Chancellor Angela Merkel (who was presiding the EU at that time) affirmed that “efforts to reduce or harmonize regulatory barriers to international trade” are at the forefront of deepening the transatlantic economic integration (Congressional Research Service, 2008).

standard-related TBTs still exist (Aldaz-Caroll, 2006). Under the “cooperative approach”, which involves governmental cooperation, (Aldaz-Caroll, 2006), standards and the acceptance of conformity assessment procedures can be harmonised or mutually recognized bilaterally by members of a regional trade agreement (EU, APEC, NAFTA, etc.) or multilaterally (e.g. OECD or WTO).

3. Quantifying the economic and trade impacts of approaches facilitating the acceptance of conformity assessment results

13. Transaction costs are at the heart of the assessment of the trade impact of approaches or tools for facilitating acceptance of CA results. An important issue is that facilitation is the result of “cooperation” between conformity assessment bodies (accreditation, certification, inspection) with the aim of realizing efficiency gains. To overcome TBTs, the CA bodies ensure that the CA procedures will be accepted internationally. However, disparities between these conformity assessment bodies may also affect the efficiency of such cooperation. Aldaz-Caroll (2006) notes that the institutional disparity among EU member countries affects the speed with which methods for easier acceptance of CA results can be agreed. The author further notes that in those member countries with weaker institutions, CA procedures need to be upgraded first as a priority.

14. The review of the literature highlights that quantifying the trade impact of approaches intended to facilitate the acceptance of results of conformity assessment procedures has to address a number of complicating factors.⁶ First, unlike the elimination of tariffs, which is viewed as a static process, the facilitation of CA procedures (and also standards) occurs in a dynamic setting (David and Greenstein (1990)). Standards evolve and change over time due to changing consumer, health, safety and technology requirements and in parallel also their CA procedures. As a result, product specificity such as the diversification of products, and market specificity such as technological innovativeness, competition, and consumer awareness matter.

15. Secondly, the form of trade also matters. Trade can be distinguished by either the actual level or probability of imports or exports or exchange of intermediate goods and services within a production chain. Each of these forms of international trade has its own distinct characteristics, which also renders distinct interpretations on its relationship with the facilitation of CA procedures.

16. Thirdly, the distinction of the CA of government mandated versus industry voluntary standardization is also an important issue. The CA procedures of mandated standardization, usually through government intervention, emphasize the “public good” aspect and facilitation is aimed at removing any trade-distorting effects. It is important to note that the facilitation of CA procedures may still involve differences in procedures across countries. However, related TBTs can be eliminated when similar, or equivalent, regulatory objectives are attained by countries. In an ideal situation the objective of “one standard, one test, accepted everywhere” has become an increasingly attractive feature: firms can enjoy the economies of scale and regulators gain the confidence that products or processes have been “adequately tested and meet exacting requirements” (Hart (2004)).

17. On the other hand, the facilitation tools of complying with voluntarily standardization and related CA procedures across countries usually occur in a setting where one single international standard is issued by an international (usually designated by the WTO) standardization organization that also acts as a CA

6. It is noted that in the context of reducing barriers to trade arising from CA procedures, regulatory cooperation is only one possibility to reduce transaction costs, and hence facilitate trade. It will become obvious in the paper that other procedures such as supplier’s declaration of conformity assessment and unilateral recognition of equivalence does not depend at all on regulatory cooperation among countries.

assessment body. While an international or even global adoption of a particular standard and its CA can be trade cost-reducing for the firm, Werle (2001) notes that in dynamic industries such as telecommunication, the “co-existence of a variety of standards induces innovation and boost competition”. One implication of the author’s broad approach to this question is that the use of international standards and its CA procedures may hamper some profit related characteristics of a market which at the end may result in a worse-off situation compared to a situation where international transaction costs are reduced.

18. The literature that we selected for studying the trade impact of the tools for facilitating acceptance of CA results includes two types of approaches: econometric analysis and the survey approach.⁷ There are some interesting insights in the quantification methods for each of these approaches. The most relevant approach is to compare the trade impact situation of facilitation versus no facilitation by quantifying their respective compliance costs. However, as we will see, for many studies these comparative costs are very difficult to observe. This is because compliance costs themselves are a function of many other market characteristics for which monetary values are difficult to collect: for instance, time delay costs in market access, retraining of personnel, surveillance and monitoring, etc.

19. Popper *et al.* (2004) note that the data on compliance costs may be hard to obtain because firms may be reluctant to provide proprietary information. Alternatively, surveys and case studies may be able to gain very interesting insights on the costs of compliance by looking at various aspects on how firms, industries or even countries adjust to changes in CA procedures. For instance, it may well be so that the facilitation of CA has a positive impact on trade by reducing unnecessary certification costs; however, these cost reductions may be offset by higher expenses related to surveillance and monitoring such that the net effect on trade may be left unchanged or at least becomes conditional through the implied consequences of the facilitation efforts.

20. The dominant econometric approach to measuring the effect of the facilitation of the acceptance of results of CA has been based on the gravity model of international trade, which has become the standard tool to study bilateral trade. (Anderson and van Wincoop, 2003). Typically in a log-linear form, the model assumes that the volume of trade between two countries is promoted by their economic size (income) and constrained by their trading costs. Trading costs are considered as a set of characteristics that include, amongst others, the geographical distance, transportation costs, tariffs and non-tariff related barriers and other various factors that may constrain trade. In order to gauge the impact of CA procedures (and standards), typically these are quantified with frequency measures (e.g. number of regulations and CA procedures in an industry, trade-weighted coverage ratios, number of industries in which countries seek regulatory cooperation, etc.). It is assumed that facilitation of CA procedures reduces these trading costs and hence has a positive effect on trade. The usefulness of the econometric approach is that signs and coefficients can easily be interpreted, precise impacts are measured, and while most model use panel techniques a wide range of further questions can be analysed. For instance, the trade effect of CA facilitation is allowed to vary by sector, country or time.

21. In the following sections (section 4-8), we discuss the six methods for facilitating the acceptance of CA outcomes.

4. Mutual recognition agreements (MRAs) for conformity assessment to specific regulations

22. MRAs are agreements on the mutual recognition of conformity assessment of regulated products. Through an MRA, each party recognizes the tests, certificates and approvals issued by agreed CA bodies

7. Maskus and Wilson (2001), Maskus, Otsuki and Wilson (2001) and Beghin and Bureau (2001) provide comprehensive overviews of key economic issues relating to TBT modeling and measurement.

of the other party without additional requirements. In other words, country A trusts country B that the CA procedures applied by country B assures that the product conforms to country A's standards (Wilson (2007)). If this is the case, the products of country B can be exported to country A without any further cooperative efforts for aligning the countries' respective standards.

23. MRA agreements can be based on a bilateral or multilateral level. For example, for a number of sectors the European Union has concluded bilateral MRAs with Australia, New Zealand, Canada, Israel, Japan and the United States. Under the Asia Economic Cooperation (APEC), a multilateral MRA covers CA for regulated fixed and radio telecommunication equipment. Overall, about 40 government-to-governments MRAs have been notified to the WTO (Shortall (2007)).

24. In many cases, the MRA includes rules of origin, defined as "the criteria used to define where a product was made". For example, the MRA between the EU and Canada specifies that third country products continue to meet the CA procedures of each country in the agreement region. While this arrangement appears to facilitate trade, an MRA can also potentially be used as an exclusionary instrument so to leave out the rest-of-world members (Baldwin (2001)).

25. MRAs can provide many benefits. Perhaps the most immediate benefit is that product evaluated in the exporting country by the local designated CA body may reduce unnecessary shipping costs and time delays for market access. These benefits can be particularly important when markets are distant. Shortall (2007) lists a number of factors that are necessary for effective MRAs. These include amongst others: a sound regulatory infrastructure, underlying regulatory compatibility, a sufficient volume of trade, step-by-step approach "particularly where the technical competence of the parties is not equivalent".

26. A number of analyses focus on the trade impact of MRAs. These empirical studies comprise econometric tools, and surveys. A relatively high number of studies use survey techniques covering a wide range of countries and sectors. We categorize these studies according to their geographical coverage. Results are reported accordingly.

4.1. Empirical studies

27. A number of recent econometric studies analyse the impact of MRAs on trade. Baller (2007) studies the trade effects of efforts of harmonisation of technical regulations and MRAs. The author employs a gravity-based empirical model that consists of a two-stage estimation: the first stage estimation looks at the probability of exporting while the second stage estimates the actual level of exports. Two sectors are covered: telecommunications and medical devices. A MRA's impact on exports (probability and actual exports) is tested *only* for members of a Regional Trade Agreement (RTA) while the effect of harmonisation is tested *both* for members and countries excluded from the RTA. The sample contains eight MRAs on medical devices (sample 1986-2003) and fourteen MRAs on telecommunication equipment (sample 1991-2003) between OECD countries.

28. The interpretation of these results of MRA impacts goes as follows: in stage 1 (the probability equation) the effect of MRAs is linked to the probability that a certain firm will export (extensive margin) while the second stage, the MRA effect is linked to trade volumes for firms already exporting before the liberalization took place (intensive margin). This interpretation is derived from the Melitz (2003) model. It is assumed that fixed costs are overcome when firms engage in export decisions. When these firms then actually export, it is assumed that only variable costs related to CA procedures remain.

29. The results for the first stage estimation show that MRAs have a significant impact on export probability in both sectors. These results imply that MRAs are well functioning in both sectors and in addition, costs related to the facilitation of CA procedures are important because there is a high

probabilities for exporting if a MRA has been concluded. The results related to actual exporters (stage 2 estimation) suggest that MRAs have no effect on the volume of bilateral exports in the telecom sector while their effect is statistically significant for the medical devices' sectors. This implies that CA procedures impose "significant variable costs" on producers of medical devices.

30. Another study by Chen and Mattoo (2008) addresses two empirical questions: Do regional agreements on standards lead to significant increases in trade between participating countries? And what happens to those that are left out? The regional agreement on standards includes harmonisation of regulations and MRAs between members. The authors employ data covering trade between 42 countries at the SITC 2-3 digit level of manufacturing industries from 1986-2001. The harmonisation and MRA measures are quantified from directives covering *entire* sectors. Two types of MRAs are quantified: those with and without the rules of origin criteria. MRAs with *restrictive rules of origin* criteria require that third-country products have to continue to meet the CA requirements of each country in the region.⁸

31. On the basis of a gravity model, imports are regressed on a number of categorical variables and fixed effects (exporter, importer, year, pair-industry and pair-year), the following results can be summarized: (i) the impact of MRA turns out to be sensitive whether or not it includes rules of origin; (ii) MRAs with rules of origin have a much stronger impact promoting intra-regional trade compared to MRAs without rules of origin; (iii) MRAs with rules of origin reduce imports from third countries and especially developing countries; (iv) when MRAs do not include rules of origin, imports from both member states and third countries increase, especially from developing countries.

32. The Hogan and Hartson study (2003) analyses the trade effects of the implementation of MRAs between the EU Australia and New Zealand. The study offers interesting insights into the cost interpretation of MRAs. In line with Baller (2007), the authors anticipate that MRAs are more beneficial for new entrants to export markets because a MRA induces a "reduction in *fixed* costs". On the other hand, the effect of the MRAs on existing exporters is "likely to be small". One reason is that it may well be that in the regime prior to the MRA an informal MRA was already in operation. A second reason may be that the home country's CA (as a result of a MRA) might or might not lower the costs of obtaining approval through services offered by now more global CA bodies at lower cost. In addition, the cost-related effect of a MRA on trade is due to lower *variable* costs (per unit costs) because products that need assessment are differentiated products due to variable design (development costs) and product dimensions (production costs).

33. The study also notes that the size of firms also matters. Large firms usually have already explored all possible export opportunities along with the knowledge acquired in meeting requirements, through for instance in-house capabilities. In addition, possible cost savings from removing duplication of testing may only be a small fraction of total costs.

34. In order to gauge these effects econometrically, the effect of a MRA is quantified by a dummy that takes the value of one for the "trading partner and years for which the MRA is in effect" in addition to a set of dummies for years, partner countries and time. The coefficients of these latter dummies estimate a benchmark of the predicted exports while the coefficient on the MRA dummy captures the difference between actual and predicted values of exports. Trade data is collected at the 4-digit level of HS classification for telecommunication terminal equipment, pharmaceuticals, and medical devices and motor vehicles for each the EU member countries, Australia and New Zealand. Four models are applied on the dependent variable of Australian exports (logs and dollar values) and imports (logs and dollar values). The striking result is that the coefficient is insignificant for each of these four models and for each of the

8. The list of MRA with Rules of Origin is provided in the appendix of the cited study.

sectors for the period 1999-2001. The authors suggest that the time period may have been too short for capturing the MRA effect (for instance, the effects may appear at a later stage). We return to the survey results of this study in the next subsection.

4.2. Surveys

4.2.1. Evidence on the EU-New Zealand/Australian MRA

35. The study by Peacock *et al.* (2001) investigates CA procedures for certain medical devices that require third party assessment⁹, and its implications for the EU-Australian MRA. In other words, the study not only looks at a direct impact of a MRA but also at implications of the regulatory infrastructure by which CA procedures are implemented.

36. In Australia, CA procedures are evaluated under the the Therapeutic Goods Act (TGA), with a public, regulatory authority in charge of CA. This is the sole provider of CA; there are no competing bodies. An inquiry of moving towards the adoption of an EU model for CA procedures is sought. In contrast to the TGA, the EU approach lets manufacturers choose freely from a range of public (notified) CA bodies.¹⁰ Under the TGA many medical devices have to be evaluated on a case-by-case basis. Under the EU approach, conformity does not require evaluation of each and every device but takes the form of having to meet “essential requirements”. The EU’s and Australia’s regulatory stringency in the medical equipment industry are aligned and only their CA procedures differ.

37. A survey was sent to about 60 industry representatives. While most of the questions focused on the evaluation of CA procedures under the TGA or the EU approach, an empirical but crude consent is that the MRA between the EU and Australia of medical devices “will reduce the cost of CA for importers and exporters and increase the speed with which products are approved”. We return to this study in section 5.

4.2.2. Evidence on Latin-American countries

38. The paper by Aldaz-Carroll (2006) examines different approaches for upgrading standards and CA procedures. The paper draws on information from interviews conducted with representatives of firms, business associations, laboratories, accreditation and standardization bodies, and national and regional bodies for TBT and SPS standards in Latin America (Argentina, Brazil, Chile, Peru, and Uruguay) and in Washington DC. The paper focuses on common features of RTA standards and CA upgrading and harmonisation processes where it identifies some of its main challenges and suggests principles which developing countries could follow in such a process.

39. The ANDEAN countries are following a different approach to that of other RTAs. Rather than investing all efforts into harmonising standards in a context where there is little involvement of the private sector, they are simultaneously harmonising CA procedures and establishing MRAs. The idea is that the creation of MRAs will increase the private sector’s involvement leading to greater economies of scale (higher competition of CA bodies) and better alignment of the CA infrastructure among member countries.

9. According to the EU Device Classification, it concerns medical devices for class I (low risk), class II and class III (medium-high risks), active implantables (AIMD) and high risk IVDs.

10. Notified Bodies are conformity assessment bodies that have been designated by the “competent authority” of that member state to carry out certification in accordance with the requirements of specified EU Directives.

40. An important point is that the central authority of the ANDEAN Community imposes MRAs in *sectors with high intra-regional trade*. In other words, the MRAs not only act as instrument to facilitate trade but trade also facilitates the regulatory infrastructure of the MRAs. As a final remark, the study suggests it would be more cost-reducing to have inspectors from the extra-regional partner at the origin - this is the case with Japanese inspectors in Ecuador – because it is cheaper to have product found non-compliant at origin rather than at destination.

41. The case study by Hufbauer *et al.* (2001) looks at the standards and trade debate in Central American Common Market. One of the more important challenges in the region is upgrading legal metrology systems, accreditation and certification activities. The authors note that setting up MRAs is a matter of “slow and labored implementation” where duplicate testing is still common in trade relations between industrial countries such as between the EU and United States. The authors argue that small developing countries therefore should not negotiate an MRA within regional groupings but rather adhere to the regulatory infrastructure of the EU. Under the EU-US MRA, developing countries may enter the US market as a bonus.

42. The second part of the paper reports on TBT and SPS measures in Central America for 1999, from a US perspective. The data come from the WTO (2001) and the Office of the US Trade Representative (2000). The evidence suggests that there are significant differences among Central American countries. For example, in Guatemala product registration and testing processes are time-consuming, while the standards and certification regime of Panama conforms to WTO standards. While most of these countries have also negotiated comprehensive TBT provisions as part of their sub-regional trade agreements, the performance of prospective MRAs will much depend on upgrading the regulatory structure so as to facilitate trade with other countries.

4.2.3. Evidence on an enlarged Europe

43. An example of the MRA approach in the EU is the intra-EU mutual recognition system of CA for harmonised but also non-harmonised (technical) regulated sectors. Experiences of some of the new member states from Central and Eastern Europe (CEEC) during the EU accession period provide some useful empirical examples. The so-called Europe Agreements between the EU and each of the CEEC candidate countries provide for approximation of relevant laws in the CEEC with the EU’s internal legislation. The EU mutual recognition system for CA is governed by a MRA and is referred to as the Protocols on European Conformity Assessment (PECAs). Following satisfactory regulatory alignment, individual CEEC countries can negotiate sectoral access to the Single Market subject to the technical competence of CA bodies being of a level equivalent to that in the EU and subject to the acceptance by both parties of the results from notified CA bodies (Brenton and Manzcchi (2002)).

44. The studies by Dezséri *et al.* (2002) and Gorzelak and Żołąkiewski (2002) provide some interesting insights into the impact of the PECA on respectively Hungarian and Polish exports. Findings are drawn from surveys involving manufacturing firms. At the beginning of 2001, Hungary fulfilled the implementation of the EU standardization process and conditions of the PECA agreement, while in Poland the PECA went into force in 2002.

45. In each of the countries an identical questionnaire survey was sent out in early 2000. In reference to the MRA for CA procedures, it is reported that 46% of the Hungarian firms expected a positive impact whereas 38% expected no impact. A very high proportion (90%) of the firms expected benefits as a result of the elimination of customs documentation in trade and the elimination of delays at frontiers with the EU. The authors note that this latter result may be attributed to full harmonisation of regulations as well as the MRA. On the other hand, almost 60% of the firms in Poland expected PECA to have a positive effect. In

Hungary, the firms that anticipated additional benefits were those with foreign capital (foreign investment), while in Poland foreign capital was not an issue.

46. The case study conducted by Brenton (2004) describes the standard and conformity assessment in Moldova. Moldova is considerably behind with an alignment to international standards. The TBT Agreement obliges Moldova not to discriminate against imports or between different suppliers of imports in the application of CA procedures and encourages these procedures to follow international norms. However, little progress has been made in the system of CA and accreditation and in upgrading these. Moreover scarce information is provided to producers regarding EU requirements. Under the current system the overall costs of obtaining necessary certificates are very high. As a result, companies seeking to export to the EU are severely constrained by these higher costs, which in turn lead to difficulties in competing on international markets.

47. We noted earlier that studies have shown that the adoption of the PECA agreement has been an important factor determining EU exports. Brenton further notes that the adoption of EU standards and CA throughout Eastern Europe is an important factor affecting the access of Moldovan exporters to these markets.

4.2.4. Evidence on selected countries

48. A questionnaire-based case study conducted by Japan in 2006 (WTO (2007A) investigates the effectiveness of MRAs for a number of countries. Responses were received from twelve economies (Asian countries including Canada, Australia and New Zealand) and eight enterprises, as of 1 September 2006. The study confirms the existence of 28 governmental and non-governmental MRAs.¹¹ The general consent was that MRAs required a large amount of government resources and/or had a relative small impact on trade.¹² The Australian response concerning the Australian-EU MRA was that while most trade under the MRA is in the pharmaceutical and medical devices area, it represents a relatively small share of total trade. The response by New Zealand concerning the APEC governmental MRA for the toy industry was that the agreement facilitates the exchange of information and confidence between countries. We return to this study in the next sections.

49. An OECD (2005) study using telephone interviews and a survey, investigates the extent to which technical standards and conformity assessment procedures impede trade. The survey covered 55 firms, associated with three industries (terminal telecommunication equipment, automotive components and dairy products) in four countries (USA, UK, Germany and Spain).

50. The findings in reference to CA procedures are: (i) MRAs for CA have had a distinct and beneficial effect on costs of compliance; one major effect is the increased number of approval agencies that are accepted, leading to increased competition and as such cost reductions of obtaining approval; (ii) CA costs varied significantly among companies and across countries; often significant internal staff costs were incurred; time delays were an important indirect cost of CA; the extent to which additional time taken for CA affects costs is determined by the potential lifespan of products.

51. The study by Wilson and Otsuki (2004) reports findings from a World Bank TBT survey with data for 689 firms in over twenty industries from seventeen developing countries. The survey covers

11. These 28 MRAs are classified into the following categories: Governmental/non-governmental, multilateral and bilateral MRAs.

12. Specific results for the other CA facilitation approaches that coincide with those identified by the TBT agreement will be covered in the subsequent sections.

characteristics of firms, their export orientation and provides also data of mandatory technical regulations and conformity assessments under MRAs. First, the survey attempted to shed some light on the importance of the following export-restraining factors: low demand, cost of designing, testing/certification costs, inability to meet shipping schedule, cost of transportation, tariffs quotas, marketing and distribution costs, lack of information from the home country's export promotion offices. Several export destination markets are considered: EU, Japan, US, Australia, Canada. Overall the survey indicates that among the selected factors, testing/certification costs are important: 66% to 73% of the firms that do not export to the destination markets attribute this to certification/testing costs. Other restraining factors are low demand and marketing & other distribution costs.

52. Second, key results with respect to MRAs are the following: a majority of the firms (69%) do not make use of MRAs whereas only 23% do; firms in Eastern Europe and Latin America and Caribbean participate in MRAs most actively; overall, more firms (especially in Eastern Europe) consider MRA recognition to be cost saving: a majority of the firms (60%) say that it will be somewhat easier for them to export to destination markets with an MRA agreement.

5. Co-operative arrangements between domestic and foreign conformity assessment bodies in the voluntary sector

53. Private (non-governmental) CA bodies play an essential role in facilitating trade through cost reduction for manufacturers. The approach addressed in this section involves arrangements agreed among individual laboratories, certification bodies and inspection bodies as well as accreditation bodies directly, not through Members and central government bodies (WTO (2005b)). Consistent with the sequence of items on the TBT Committee's indicative list of distinct approaches to the facilitation of acceptance of CA results, the role of governmental and non-governmental arrangements that deal with accreditation bodies will be covered in section 6.

54. An important aspect of the mutual recognition arrangements that have been reached among individual laboratories, certification and inspection bodies is that they are more and more involved with international standard-setting organizations such as the International Standards Organization (ISO) and the International Electro-technical Commission (IEC). ISO members are national standard institutes while IEC members are national committees representing the regulatory structure of all electro-technical equipment (WTO (2005a)). The objective of these organizations is to establish networks of conformity assessment bodies whose competence can be relied upon by all members (WTO (2005b)). For example, in the area of *certification*, the scheme for the acceptance of test reports dealing with the safety of electrical and electronic products (IECEE-CB Scheme) is a multilateral arrangement among participating IEC members: once a CB test report is issued, the manufacturer can obtain national certification in all other member countries of the CB Scheme.

55. Some of these arrangements are, on occasion, recognized by governments (e.g., ISO/IEC) as a basis for the acceptance of test results and certification activities in relation to specific regulations while others very much rely on self-coordination. Examples of self-coordinated arrangements are the Engineering Task Force (IETF), an open standardization forum dealing with internet standards. In the area of certification an example is the International Certification Network (IQNet)¹³, which is composed of more than 35 certification bodies.

56. In the EU, the Council Decision on a Global Approach to Testing and Certification lists a number of ways (modules A through H) in which compliance to New Approach Directives can be shown. One of the underlying principles of this approach is that MRAs for testing and certification are promoted in the

13. See <http://www.iqnet-certification.com/>.

non-regulatory sphere. Under this approach, Notified Bodies that issue the EU CE mark may subcontract product testing, where required, to foreign-based laboratories in the exporting country (Shortall (2007)).

57. In the literature that we identified, the effect of this type of facilitation tool is assessed only through survey analysis.

5.1. Evidence

58. The study by Fliess and Schonfeld (2006) presents findings from a survey conducted in 2005/2006 of 428 conformity assessment bodies (CABs) and 110 exporting companies from OECD countries. The goal of the study was to identify, quantify, and prioritize CA barriers. As an extension, the report also explored how progress and policy-related measures can be achieved in facilitating CA procedures, following discussions during an OECD conference held in Berlin in 2005. Around 160 of the CA bodies participating in the survey reported that their home country operations had “nongovernmental agreements with CA bodies in other countries”.

59. The survey responses confirmed that the voluntary mutual recognition of test reports is the most important factor in encouraging exports (68% of respondents). Additional evidence both from the survey and additional telephone interviews suggest that exporters and CA bodies themselves would like to see wider acceptance of voluntary agreements through improvements and better sharing of information with regulators, as an alternative to MRAs at government level.

60. From the questionnaire-based case study conducted by Japan in 2006 (WTO (2007A), cited in the previous section, it appears that non-governmental multilateral mechanisms such as the IECEE/CB scheme are very effective in reducing administrative costs resulting from divergent standards and CA procedures. According to an official of the American National Standards Institute (ANSI)¹⁴, the IECEE/CB scheme works very well in an environment where industry is very much confronted with the importance of product safety.

61. One of the possible disadvantages of government-to-government MRAs is that it may lead to unnecessarily introduction of more stringent regulations and CA procedures by a partner country. A voluntary agreement between CA bodies avoids this situation. A recent survey of the U.S. International Trade Commission (Johnson (2008)), based on relevant literature and own telephone surveys with US industrial and government officials, notes this is the case especially in the electrical product industry. For instance, major electrical products trade associations in the United States have opposed MRAs with respect to electrical equipment because manufacturers voluntarily seek certification from CA bodies such as the Underwriters Laboratories (UL), not government designated CA bodies. In order to facilitate better global market access, the UL has gained full recognition by the IECEE as a national certification body for many of the voluntarily standards of the IEC.¹⁵ It is also noted that in this market, high consumer awareness of the need for self-assurance in respect to potential risky products is typical. It is believed that this system performs better than a regulatory infrastructure that is imposed by the government.

14. Contribution of the ANSI for an OECD Workshop on “standards and conformity assessment in trade: minimizing barriers and maximizing benefits”, held in November 2005 in Berlin.

15. UL has gained full acceptance by the IECEE as a National Certification Body for the following Standards: IEC 65 for Household Audio/Video Equipment, IEC 601 for Medical Electrical Equipment, IEC 730 for Automatic Electrical Controls, IEC 745 for Hand-Held Electric Tools, IEC 950 for information Technology and Business Equipment, IEC 1010 for Electrical Equipment for Measurement, Control and Laboratory Use (www.ul.com, accessed March 3, 2009)

62. The study by Peacock *et al.* (2001), which we described in section 4.2.1., provides some interesting results in an alternative hypothetical situation of an EU-Australian MRA, where in Australia the conformity assessment process for medical devices is aligned with the EU approach. Under this approach, the conformity of testing and certification of medical devices is carried out by notified bodies in the private sector (Global Approach). Currently, CA procedures in Australia are evaluated under the Therapeutic Goods Act (TGA). The TGA administers the CA. As a result, the MRA between Australia and the EU would also entail an MRA of CA by designated Notified Bodies from the private and public sector.

63. The study includes a survey that was sent to about 60 industry representatives. It recommends that Australia maintains the current TGA approach for CA procedures. Under the EU approach to CA, the (potential) costs differentials are very small (a 9% estimate of reduction in costs is approximated based on a meta-analysis) while the health risks may potentially be larger.

64. One of the survey findings is that about two thirds of the respondents would expect some benefits if a switch to the EU model of conformity assessment occurred, especially for the CE marking of devices sold in the EU. Through more involvement of EU Notified Bodies in Australia, economies of scale would increase, the price of CA would be determined by competition in the CA market and the wide choice of CA bodies would result in less costly CA for Australian producers that export to the EU. The cost reduction can be interpreted as a reduction of transaction costs.

65. We return to the Central American case study by Hufbauer *et al.* (2001). This World Bank study notes that one of the more important challenges in the region is the upgrading of legal metrology systems, accreditation and certification activities. The underlying hypothesis is that participation in international standardization organization can serve to facilitate trade through influencing the development of standards: only Costa Rica and Panama are ISO members, the other countries are correspondent members (which is similar to observer status). In a study of infrastructure in Latin America, ISO quotes an official from Columbia's National Standards Body as saying that the participation in international standardization bodies (ISO and IEC) increase technology transfer to these countries. Furthermore, participation in regional bodies (COPANT, SIM, and IAAC) can serve to facilitate trade "by expediting information exchange and by coordinating activities, where appropriate".

6. The use of accreditation to qualify conformity assessment bodies

66. Accreditation of CA bodies means third-party attestation that a CA body fulfills specified requirements and is competent to carry out specific CA tasks (Unger (2003)). Voluntary arrangements at the *accreditation* level have proven particularly important for reducing the number of bilateral coordination efforts: if an arrangement between accreditation organizations is reached, certificates from all certification bodies or test results from all laboratories accredited in one country are accepted by the other signatories without the need for further contacts at the level of certification or testing bodies (WTO (2005b)).

67. For instance, the International Laboratory Accreditation Cooperation (ILAC) operates as a forum for accreditors of laboratories and inspection bodies, and the International Accreditation Forum (IAF) fulfills this function for accreditors of certification bodies. The IAF has succeeded in establishing a "multilateral" mutual recognition arrangement among some of its members with the help of regional groupings, such as the European Cooperation for Accreditation (EA) and the Pacific Accreditation Cooperation (PAC), and ILAC has developed a "global" mutual recognition arrangement among all its 46 full members (WTO (2005b)).¹⁶

16. Usually the accreditation of CA bodies on a more global scale is subject to specific ISO/IEC guides that are prepared by working groups of the ISO Committee on CA (CASCO). CASCO established

6.1. Evidence

68. A report issued by KPMG (2002), analyses the economic impact of the MRA amongst individual national metrology institute (NMIs), signed on 14 October 1999, under the auspices of the Comité International des Poids et Mesures (CIPM). The broader acceptance of CA and testing (“promotion of international systems of CA” is coordinated by the Bureau International des Poids et Mesures (BIPM). The mutual recognition system occurs at two levels. First, there is a MRA at the NMI level (government related MRA of standards¹⁷), and second, a MRA at the level of accreditation bodies that is mediated by the ILAC. In addition, a Memorandum of Understanding between CIPM and ILAC was signed in 2002. For firms wishing to export measurement instruments abroad, the acceptance of measurement results that are ensured by an accredited calibration laboratory, in turn, determines the costs of trade.

69. Two methodological approaches are employed: a survey of NMIs and detailed interviews with Directors of leading signature NMIs. According to KPMG, from the survey findings it is “reasonable to conclude that the MRA does confer direct benefits of trade facilitation in terms of avoided costs to the NMIs.” The assertion that signatories are willing to invest in a MRA is borne out by the results of question eight of the NMI survey: 63% of respondents have a positive or very positive impression of benefits due to lower costs of conformity assessment. More striking is that the average amount of trade among MRA nations is 89% of total trade. Currently each of the NMIs enjoys mutual recognition with forty-seven other NMIs, while in the pre-MRA period the number of bilateral MRA was relatively small. The results of the survey also indicate that for each of the signatories of the MRA the cost of establishing and maintaining mutual recognition with each partner NMI is lower than it would be without the MRA.

70. From the interviews with NMI directors, the benefits of the MRA can be interpreted as recognition of calibration and testing activities related to ILAC activities. The accreditation activities of ILAC are viewed as the fundamental success of the MRA. In addition, the majority of the NMI directors (76%) has a positive and very positive impression that the NMI and ILAC MRA will benefit government regulators. In this way, the MRA stands to facilitate in part the international cooperation necessary to promote the development and application of metrology.

a working group to align with a draft amendment issued by the ISO/IEC. Below we list some important additions, related to trade, that have been included as new text or requirements under a draft amendment (Unger (2003)):

- A system to accredit CABs CA procedures should provide confidence to purchasers and regulators, “such a system should facilitate cross-border trade as pursued by trade authorities and organizations.”
- Accreditation bodies can facilitate trade by promoting global acceptance of CA results issued by accredited CABs. This is strengthened if Accreditation bodies are peer-evaluated and are member of MRA among the accreditation bodies.
- The ultimate goal is to achieve one-stop accreditation and one-stop CA. It is still a long way to go but there was still no better tool than mutual recognition which to a certain extent favors the convergence of the systems.
- A “cross-border” trade facilitating system can work well if accreditation bodies and CABs operate to globally accepted requirements in an equivalent manner
- MRA members facilitate the one-stop process through recognition, promotion and acceptance of each other’s accredited CA

17. The empirical results that relate to a government MRA of standards, under form of calibration and measurement, are for convenience added in this section. However, under the CIPM MRA the acceptance of CA certificates very much depend on reliable measurement results that are accredited. As a result, the MRA at the NMI level and the MRA at the level of accreditation bodies, under the guidance of ILAC, are very much interrelated.

71. The Moldovan case study by Brenton (2004) highlights the importance of establishing international recognition of independence for the accreditation of testing, inspection and certification bodies. “Independence” means that the Moldovan accreditation body is still under government control.¹⁸ Of particular importance is that without access to an adequate Moldovan conformity assessment infrastructure, domestic companies find it difficult to export to foreign markets. Accreditation bodies’ greater participation in ILAC should be facilitated.

72. Kakada (2006) analyses the standards and CA infrastructure in Cambodia with implications for Cambodian exports. In general, the Cambodian standards infrastructure is poor. One of the underlying reasons is that underdeveloped standard legislation (52 standards) can limit the range of products to be tested and internationally accepted. There are only a few certification bodies operating in the country, which mainly focus on garments exports, which represent about 90% of total exports. The second reason has to do with the recognition of CA system by international bodies. Because of a lack of technical competence and facilities, the testing laboratories are finding it difficult to gain international accreditation. The recommended option is that exporters, especially SMEs, use the standard certification system in the ASEAN region with international accreditation. Alternatively, the country could upgrade its standards unilaterally or by the one go approach applied in ASEAN.¹⁹ However, these alternatives appear to be too costly given the small size of the local market.

73. In the questionnaire-based case study conducted by Japan in 2006 (WTO (2007A)), according to a Hong Kong delegate, the use of the ILAC/APLAC MRA²⁰ appears to be a very promising instrument for international trade facilitation: 95% of telecommunication equipment went through the ILAC/APLAC MRA and less than 5% went through the APEC MRA. According to the survey, non-governmental MRAs appear to be more attractive because driven by industry requirements of attaining a single set of global standards.

7. Unilateral recognition of results of foreign conformity assessment as equivalent, including the possibility of government designation

74. Government-designated unilateral recognition of conformity assessment bodies is less documented than any of the other facilitation tools that have been identified by the WTO TBT Committee. Following to Article. 6 of the WTO TBT Agreement, governments can limit acceptance of testing and certification (Shortall (2007)). Under the government designation approach, governments designate specific CA bodies for assessment purposes, including bodies located in foreign countries. Japan, for instance, applies government designation for the regulation of products such as electrical equipment, gas equipment, consumer products and telecommunication equipment. Under this approach, assessment

18. Other examples of such independence include the case of Denmark and Poland. In these countries the independence of accreditation bodies was achieved by switching from government controlled agency to an independent foundation with separate management and reporting structures. In Denmark this organizational change was induced by peer evaluations of accreditation bodies in other countries. Poland was initially rejected to join the MRA of European accreditation.

19. Under the *one go* approach, member countries (e.g., ASEAN) harmonize and upgrade their standards to the international standard at once. The second approach is the *gradual upgrading approach*: member countries (e.g., ANDEAN, Mercosur) upgrade their standards gradually towards the international standard rather than immediately. This approach tends to be followed by RTAs with members that have a health, security and environment objectives that are not aligned with international standards. See Aldaz-Carroll (2006) for a more elaborated discussion on the application of these two approaches by Latin-American countries.

20. These are non-governmental MRAs of accredited laboratories. ILAC = International Laboratory Accreditation Cooperation and APLAC = Asian-Pacific Laboratory Accreditation Cooperation.

conducted by designated foreign CA bodies has the same legal effect as assessment conducted by domestic CA bodies (WTO (2005b)).

75. Under unilateral recognition, the outcome of CA is recognized unilaterally. The WTO notes that “unilateral recognition opens up domestic markets, promotes the establishment of fair competition and as a result gives consumers a greater choice of products. Recognition helps safeguard the interests of consumers by ensuring that imported products do not cost more because of reassessment.”

7.1. Evidence

76. Japan has concluded a number of MRAs in the shape of a “cross border designation type MRA” in which Japan as the importing country directly designates and supervises CA bodies in foreign countries. According to a note by Japan describing its experience, the most beneficial effect is “the more practical and effective method of ensuring CA across borders” (WTO (2007b))²¹. These CA activities are not only related to testing and certifying but also to accreditation. From the point of view of the exporter, such a mechanism reduces the burden of dealing with CA in an international setting by overcoming the distance between countries and by reducing language barriers.

77. Under various regulatory and voluntarily schemes, 7 foreign CA bodies are designated under the cross border designation system of the electrical appliances and materials safety law²². The conformity with 115 technical regulatory items is required for these electrical products. The number of certificates that have been issued by these foreign CA bodies (especially in the USA.) has increased moderately. For example, the number of certificates issued by US CA bodies rose from 26 to 75 during the period 2001-2006. Japan plans to keep utilizing this particular system so as to facilitate trade.

78. The aim of the APEC Telecommunications Mutual Recognition Arrangement (TEL MRA) is to reduce technical barriers to trade in telecommunications equipment by allowing equipment to be tested in the exporting economy and to be accepted in the importing economy with minimal further regulatory action. Under the TEL MRA, Hong Kong has unilaterally recognized the testing laboratories accredited by other APEC economies. According to a discussion note by OFTEC (TSAC (2001))²³, the major benefit of unilateral recognition is that it eliminates double testing of the equipment before placing it on the market.

79. A report issued by the USITC (USITC (1998)) looks at the computer hardware, software, and telecommunication equipment sectors. The findings are drawn from telephone interviews with industry representatives, government officials and literature reviews. While a MRA (such as the EU-US and the APEC MRA) is found helpful in overcoming trade barriers, the study also examines other potential regulatory approaches, such as the unilateral recognition of CA results.²⁴

80. According to some US trade officials, the unilateral recognition of CA results may be a less costly alternative to MRAs in a situation of identical or similar regulations in the IT industry. The reason is

21. See WTO (2007B), “Japan’s Experience of concerning cross-border designation systems” Submission by Japan, G/TBT/W/277, July 10, Geneva.

22. These include (WTO (2007b)): (i) one CAB in the U.S. (491), (ii) two in the EU (56); (iii) two in Hong Kong, China (145), (iv) one in Chinese Taipei (88) and (v) one in China (27). The average certifications for the period 2001-2006 that have been issued are put between parentheses.

23. TSAC refers to the telecommunications standards advisory committee

24. We return to this study in section where we discuss empirical findings from various CA facilitation instruments (MRAs, and SDoCs) collected in single studies.

that when, regardless where, products are assessed according to harmonised international guidelines, this should provide a good basis for a presumption of conformity. In addition, unilateral recognition of CA can easily be extended to other countries on a non-discriminatory basis. This solves one of the main shortcomings of MRAs which include rules of origin shown to discriminate and hampering market access especially for developing countries.

8. Supplier's/manufacturer's declaration of conformity assessment procedures

81. Conformity assessment remains a key element when Supplier's Declaration of Conformity (SDoC)²⁵ is used, but with this approach a third party for determining conformity is not necessary. Instead, the supplier himself declares conformity of his product based on the testing performed by himself or any other party. SDoC is similar to third-party CA procedures, but the method of ensuring compliance differs. Third-party CA involves pre-market procedures whereas an SDoC regime requires market surveillance (Shortall (2007)). Market surveillance is usually carried out by government authorities in order to check conformity but also to access the supplier's declaration or compliance records.

82. SDoC is used mostly for products that carry minimal risk for public safety (Shortall (2007)). The SDoC approach allows producers to use testing and certification facilities in which they have confidence and which are most conveniently located in relation to production facilities, reducing the cost of and time associated with testing (USITC (1998)). For example, suppliers of global product platforms with multiple imports and exporters are especially sensitive to market delays..

83. SDoC is now in use for certain kinds of products in a number of developed and developing countries. For instance, conformity assessment in the automotive market often takes the form of SDoC (Popper *et al.* (2004)). New Zealand and Australia have been working on a common mandatory SDoC regime for some products. The EU's experience in the harmonised use of SDoC has its origin in the framework of the New Approach Directives. These Directives introduced harmonised regulations in the field of technical safety (applicable for electrical equipment, machinery, toys, medical devices, protective equipment, recreational crafts, radio and telecommunication equipment and equipment for explosive sectors).

84. Some of the empirical papers compare the replacement of third-party CA by SDoC. It is anticipated that the use of SDoC has greater impact on reducing or eliminating market access delays compared to MRAs. The trade advantages of a switch from third-party CA to SDoC result from greater flexibility and time-cost savings. However, a viable SDOC regime must be underpinned by an effective system for market surveillance. We now turn to the empirical evidence.

8.1. Econometric Evidence for Europe

85. The econometric study by Fliess *et al.* (2008) investigates the impact of SDoC on trade flows. The following questions are analysed: first, does a change from mandatory third-party assessment to SDoC promote EU imports; and second, do the trade effects of SDoC corroborate with differences in EU member markets' previous CA regimes. A two-stage gravity model similar to the one by Baller (2007) is employed.

86. The data to quantify SDoC is specific to products belonging to three sectors (radio equipment and telecommunications terminal equipment (RTTE), machinery and medical devices) with a focus on the time

25. The supplier's declaration of conformity assessment sometimes is called "manufacturer's declaration of conformity" or "self-declaration of conformity". According to the definition of the ISO/IEC, a supplier is a party that supplies the product, process, service and may be the manufacturer, distributor, importer, assembler, etc.

period when SDoC was introduced for these products under the *harmonised* New Approach. Data on intra-EU imports and EU imports from selected extra EU OECD and non-OECD countries were collected at the disaggregated product level (HS6).

87. The main conclusion is that the switch to SDoC has had a positive impact on EU imports in all three sectors. However, the results vary across EU member markets. The first key finding is a striking and consistent increase in exports to EU markets from non-OECD countries, in all three sectors. Second, intra-EU trade and imports from OECD countries also increase, although more moderately and only for telecommunications equipment and medical devices. Third, SDoC has had a larger import effect for EU countries that switched from third-party certification to SDoC while, in line with expectations, it has had no influence on imports for countries such as the UK, which already used SDoC prior to of its EU wide adoption under the New Approach.

88. We now turn to two papers that look at the effects of EU harmonisation under the New Approach on trade. These papers do not focus on SDoCs explicitly but instead deal with the New Approach in general, which includes adoption of EU-wide SDoC regimes. In general, it can also be assumed that non-governmental arrangements are also captured in these aggregated data (see also the study of Peacock et al. (2001)). The paper of Vancauteren and Weiserbs (2005) looks at the impact of EU harmonisation (Old Approach (OA), new Approach (NA)) and the Mutual Recognition Principle (MRP) on intra-EU trade flows during the period 1990-1998. It seeks to empirically verify the question whether those sectors where the EU has sought to remove technical barriers to trade by harmonising technical regulations or by applying the principle of mutual recognition present a lower than average home bias. In this framework, the term “home bias” determines “the extent to which domestic consumers prefer domestically produced goods rather than imported goods.” The hypothesis is that the removal of TBTs removes trade distortions and therefore reduces the home bias.

89. Based on the gravity model, the results imply that the home bias effect between new approach products and other EU approaches yield a similar bias. However, the results show an important decrease in the evolution of the home bias effect for all NA sectors aggregated in one group. This indicates that NA approach directives have increased intra-EU trade with little downward impact of the home bias over time.

90. The paper of Hagermejer and Michalak (2006) analyses the pattern of new EU members’ exports of manufacturing products to the former EU15. The estimating equation explains the EU15 imports as a function of dummy variables for each of the three EU harmonisation approaches including the new approach, old approach and MRP for two periods 1995 and 1999. With specific reference to the new approach dummy, it is shown that CEECs exports were 12.5% higher than the average exports in 1995. In 1999, exports of new approach products increased by 10.8%. These results are based on the assumption that all products within a particular sector are subject to the new approach.

8.2. U.S. Studies

91. Popper *et al.* (2004) determine the economic costs to US exporters of TBTs including technical regulations, standards and conformity assessment procedures. An empirical assessment of TBTs, based on industry-expert interviews, is evaluated for two US export industries: pharmaceuticals and automotive products. According to an index of how US exporters view the regulatory difficulties (stringency, transparency, regulatory framework and assessment), three country groups were identified. In addition, the study crudely measures the upper bound costs to US exporters resulting from TBTs.

92. The study points out that the most problematic issue for the harmonisation process of CA procedures is the scientific interpretation of what constitutes safety, quality and efficacy of pharmaceutical products. The EU-US MRA requires that testing be conducted by independent testing bodies. However, US

exporters of pharmaceutical products prefer that the MRA also recognizes SDoC. They claim that the independent testing process is more costly and time demanding, and that redundant testing procedures raise effective barriers to exporters. In addition, as a direct contravention of the TBT Agreement, some importing countries may change testing specification without any prior notice.

93. In the automotive industry, countries such as the EU, Japan, Mexico and most other Asian and Latin American countries rely on type approval by an accredited organization while in the United States CA takes the form of SDoC. While this latter approach is less costly than third-party approval, it is noted that SDoC create legal liabilities for manufacturers making them vulnerable to civil law suits from customers..

94. The USITC (1998) study focusing on the IT industry, which we already discussed in the previous paragraph, found that SDoC is the least trade-restrictive approach to CA. One of its main advantages are “cost convenience, availability, perceived market place needs, and other business considerations. However, SDoC requires an effective post-market surveillance with “spot checks” and an opportunity to sanction manufacturers for non-compliance.

8.3. EU-Australia and New Zealand

95. As an alternative method to gauge the impact of the EU-New Zealand/Australia MRA on trade, the project described in Hogan and Hartson (2003) also conducted a comprehensive study. A survey included a questionnaire list sent to CA bodies notified under the MRA and to EC-wide producer organizations representing manufacturers of products covered by the MRA (medical devices, motor vehicles, electronics, electrical equipment, machinery and pressure equipment). The main results are in line with the econometric results described in section 4, namely, that the MRA had little or no trade impact.

96. The CA bodies’ responses suggest that the use of alternative tools for facilitating the acceptance of results of CA, such as (SDoC, promote trade, which in turn can help explain the observed reduced effect of MRAs on trade. The main results from the producers’ responses confirm that the effects of MRAs are limited because producers use instead SDoCs where available.

9. Conclusions

97. Table 1 below summarizes the research that deals with instruments aimed at facilitating the acceptance of CA results. Since countries and sectors studied and methods vary across studies, there are obvious limits to comparability. Three approaches subdivide these studies: the first approach employs panel data techniques using the gravity model of international trade, the second approach collects empirical evidence from survey questionnaires and the third approach consists of in-depth case studies. The findings underline the trade-promoting function of tools intended to make CA procedures easier. Situations in which no or negative effects have been found are under the following (study specific) scenarios: (i) where measures to make CA easier are not yet implemented – this is the case especially for developing countries; (ii) where MRAs have restrictive rules of origin – this influences imports from excluded countries negatively; and (iii) where the regulatory infrastructure is inadequate and alignment differs among RTA members – causing slow implementation.

98. At present, there seems to be empirical support that various approaches intended to make acceptance of CA results easier indeed promote trade. The empirical support is based on the quantification of such approaches using data at various levels of detail and surveys emphasizing sector and (or) country specificities. The methodological aspect has been addressed in the paper; however, the limitation of data is also a constraint in the construction of measures. Notwithstanding, these approaches seem to have contributed to deeper market integration in various countries in the world.

99. A broad conclusion from such findings is that wider use of these tools might contribute to further economic integration. However, the real question is which type of facilitation method should be considered? For example, SDoC constitutes a particularly flexible approach to CA that seeks to be very attractive for exporters. Its positive trade effect is confirmed by various studies. However, does this mean that we should consider reliance on SDoC for every product or sector? Alternative tools to facilitate CA s have particular properties that also seem very desirable. This leads to a more precise formulation of the question: under which conditions of (international) market, institutional characteristics of countries, bilateral trade relationships and degree of regulatory equivalence between trading partners will a particular approach be most appropriate?

100. The empirical research on the effects of each CA facilitation instrument leads to interesting points for consideration: first, MRAs that include rules of origin provisions have some shortcomings that could be overcome by the unilateral recognition of CA procedures. Second, the switch from third-party CA that usually occurs under a MRA, to SDoC would bring along a transformation of the regulatory infrastructure, with CA activities focused on post-market surveillance. Third, the reputation of high-quality CA procedures matters and perhaps could serve as an additional tool for facilitating acceptance of the results: documenting the results of CA procedures publicly, participation in international standardization bodies and the international accreditation of CA bodies can work effectively in cases where regulatory infrastructures between countries diverge.

Table 1. Overview of the literature

Study	Country coverage	Industry/product coverage	Methodology	CA facilitation approach	Results on trade effects	Comments
Aldaz-Caroll (2006)	ANDEAN	Total trade	Survey	Government MRA	Positive	High intra-regional trade facilitates the regulatory infrastructure.
Baller (2007)	OECD countries	Telecommunication and medical devices (products)	Panel data, two-stage gravity model (year)	Government MRAs	Positive	Distinction of a MRA effect on the intensive versus the extensive margin.
Brenton (2004)	Moldova	Total trade	Survey/Case study	Government MRA	Minor impact	Severe upgrading of the CA infrastructure is need.
Chen and Mattoo (2008)	Worldwide 42 countries	Manufacturing (SITC 2-3 digits)	Panel data, gravity model	Government MRA	Positive	MRA with restrictive rules of origin impede trade of excluded countries of RTAs.
Décszéri et al. (2002)	EU-Hungary	Manufacturing industries	Survey (2000)	Government MRA	Positive	MRA under PECA Agreement – additional benefits from firms under foreign control
Fliess and Schonfeld (2006)	OECD	Total trade	Survey (2005-2006)	Private arrangement	Positive	Better sharing of information under voluntary agreements.
Fliess et al. (2008)	OECD and non-OECD	RTEE, machinery and medical devices (HS 6 digits)	Gravity Panel data, two-stage gravity model	SDoC	Positive	More beneficial for countries that switched from 3rd party certification to SDoC; specific to products subject to SDoC under the EU New Approach; effect is larger for new exporters than for current exporters.
Gorzalak, M. and Z. Żółkiewski (2002)	EU-Poland	Manufacturing industries	Survey (2000)	Government MRA	Positive	MRA under PECA Agreement –

Study	Country coverage	Industry/product coverage	Methodology	CA facilitation approach	Results on trade effects	Comments
Hagermejer and Michalak (2005)	EU15-CEE candidate countries	Manufacturing industries	Gravity Panel data	SDoC/Private arrangement	Positive	SDoCs is not explicitly captured by the data but instead deal with the New Approach in general, which includes the SDoC (and thus also the private arrangement between CA bodies)
Hufbauer et al. (2001)	Central American Common Market	Total trade	Survey from U.S Perspectives	Government MRA Private arrangement	No direct effect reported Positive	Slow implementation process of MRAs – Latin American exporters gain access to US market through EU (EU-US MRA) Through participation in the ISO
Hogan and Hartson (2003)	EU-Australia/New Zealand	Telecommunication, pharmaceuticals, medical devices, motor vehicles (4 digit HS)	Panel data	MRA	No effect	Short time span to fully cover the formal MRA.
Johnson (2008)	USA	Electrical products	Survey	Private arrangement	Positive	IECEE acceptance of the Underwriters Laboratory; the regulatory structure under a governmental MRAs may be too stringent.
Kakada (2006)	Cambodia	Total trade (90% textiles and clothing)	Case study	Accreditation of CA bodies	No effect	Adopt ASEAN CA with international accreditation.
KPMG (2002)	48 countries	Measurement instruments	Survey	Accreditation of CA bodies	Positive	ILAC
OECD (2005)	US, UK, Germany, Spain	Telecommunication, automotive and dairy	Survey	MRAs	Positive	Cost reduction in obtaining approvals due to higher competition among CA bodies.
TSAC (2001)	Hong Kong	Telecommuni-cations	Case study	Unilateral recognition with APEC countries	Positive	Hong Kong has an unilaterally accepted the CA of other APEC countries

Study	Country coverage	Industry/product coverage	Methodology	CA facilitation approach	Results on trade effects	Comments
Peacock et al. (2001)	EU-Australia/New Zealand	Medical devices	(1) Survey 2) Own calculations	(a) Government MRA; (b) Private arrangement	(1)-(a): Positive (1)-(b): Positive (2)-(b): Minor	(2)-(b) The CA in Australia operating on an infrastructure identical to the EU New Approach (agreement with private CA bodies) would result in a minor cost reduction of the CA.
Popper et al. (2004)	USA	Pharmaceutical and automotive products	Survey	SDoC	Positive	The SDoC is the least cost alternative for CA however it requires surveillance in order to overcome liability costs for non-compliance.
USITC (1998)	USA	IT and telecommunications	Case study	Unilateral recognition	Positive	More beneficial than a MRA of products that are regulatory aligned across countries
Vancauteren and Weiserbs (2005)	EU	Manufacturing industries	Gravity Panel data	SDoC/ Private arrangement	Positive	SDoCs is not explicitly captured by the data but instead deal with the New Approach in general, which includes the SDoC (and thus the Private arrangement)
Wilson and Otsuki (2004)	17 countries	Manufacturing industries	Survey	MRAs	Positive	Especially CEECs reported high trade benefits.
WTO (2007a)	Asian including some OECD countries	Total trade	Survey	(a) Government MRA; (b) non-government MRA (c) Accreditation of CA bodies	(a) Minor impact (b) Positive (c) Positive	(b) IECEE/CB Scheme (c) ILAC/APLAC
WTO (2007b)	Japan	Mainly electrical appliances	Case study	Unilateral recognition	Positive	Multilateral governmental MRAs still generate high transaction costs related to administrative procedures.

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