

Please cite this paper as:

Fliess, B., F. Gonzales and R. Schonfeld (2008-09-26),  
“Technical Barriers to Trade: Evaluating the Trade Effects of  
Supplier's Declaration of Conformity”, *OECD Trade Policy  
Papers*, No. 78, OECD Publishing, Paris.  
<http://dx.doi.org/10.1787/235814036326>



OECD Trade Policy Papers No. 78

## Technical Barriers to Trade

**EVALUATING THE TRADE EFFECTS OF  
SUPPLIER'S DECLARATION OF CONFORMITY**

Barbara Fliess

Frédéric Gonzales

Raymond Schonfeld

**Unclassified**

**TAD/TC/WP(2008)3/FINAL**



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

**26-Sep-2008**

**English - Or. English**

**TRADE AND AGRICULTURE DIRECTORATE  
TRADE COMMITTEE**

**TAD/TC/WP(2008)3/FINAL  
Unclassified**

**Working Party of the Trade Committee**

**TECHNICAL BARRIERS TO TRADE: EVALUATING THE TRADE EFFECTS OF SUPPLIER'S  
DECLARATION OF CONFORMITY**

**OECD Trade Policy Working Paper No. 78**

**by Barbara Fliess, Frédéric Gonzales and Raymond Schonfeld**

Barbara Fliess: Tel: + 33-1-45248264: [barbara.fliess@oecd.org](mailto:barbara.fliess@oecd.org)

**JT03251370**

Document complet disponible sur OLIS dans son format d'origine  
Complete document available on OLIS in its original format

**English - Or. English**

## ABSTRACT

Since the WTO Agreement on Technical Barriers to Trade (TBT) came into force, Members have invested considerable efforts in adopting and promoting the use of measures intended to reduce conformity assessment (CA) related barriers to trade. Our knowledge of the impact of specific trade facilitating programmes in the CA field is limited so far, making empirical studies of their trade impact desirable. This study investigates the impact of Supplier's Declaration of Conformity (SDOC) on trade flows. As under SDOC regimes suppliers themselves provide written assurance of conformity to applicable technical regulations of a market, the costs of compliance are assumed to be smaller than for CA regimes requiring certification by third parties.

The study focuses on three cases of SDOC introduction in the European Union covering eligible products from the medical devices, telecommunications equipment and machinery sectors. The paper explains the rationale for using SDOC, expected benefits and design characteristics of SDOC regimes. The quantitative analysis uses a gravity model and finds compelling evidence that the introduction of SDOC in the EU was a factor that influenced the evolution of import flows into EU markets positively. Intra-EU trade flows and imports from extra-EU OECD countries increased for SDOC-eligible radio and telecommunications equipment and low-risk medical devices, whereas the results for machinery are ambiguous. The most striking increases, visible in all three sectors, are found for exports to EU markets from non-OECD (developing) countries included in the sample. Analysis of the effect of SDOC for selected individual EU members furthermore suggest that the magnitude of effect depends on the nature of the CA regime that SDOC replaced.

*Keywords:* technical barriers to trade non-tariff barriers NTB NTM certification telecommunications equipment medical devices machinery supplier's declaration of conformity SDOC conformity assessment conformity assessment procedures European Union France Germany Italy United Kingdom developing countries OECD.

## ACKNOWLEDGEMENTS

This study was carried out jointly by Barbara Fliess of the OECD Trade and Agriculture Directorate (TAD) and Frédéric Gonzales and Raymond Schonfeld, Consultants. We would like to acknowledge inputs, comments and practical assistance that we received from colleagues in-house and external TBT and statistical experts. In TAD special thanks are extended to Sébastien Miroudot, Frank van Tongeren, Linda Fulponi, Monika Tothova, Anthony Kleitz as well as Andreas Lindner and Grégory Legoff of the Statistics Directorate. Outside OECD, the authors would like to express their gratitude to Silja Baller, Christopher Johnson, Dr. Gert Schorn as well as staff of the European Commission DG Enterprise and DG Trade as well as Eurostat. The final report also benefited from discussion in the OECD Trade Committee Working Party, which has agreed to make the study more widely available through declassification on its responsibility.

**Copyright OECD, 2008**

**Application for permission to reproduce or to translate all or part of this material should be made to: OECD Publications, 2 rue André Pascal, 75775, Paris Cedex 16, France**

## TABLE OF CONTENTS

EXECUTIVE SUMMARY .....	5
I. Introduction.....	9
1. The existing empirical literature on CA .....	10
II. How SDOC influences suppliers' regulatory compliance costs and trade opportunities .....	12
1. What are the specific advantages of SDOC for suppliers?.....	12
2. Types of SDOC .....	16
III. Three EU cases of CA regime change.....	18
IV. The empirical study .....	20
1. Hypotheses and model specification .....	21
V. Data .....	23
1. Trade data .....	23
2. Data on SDOC.....	24
3. Other data .....	24
VI. Results .....	25
2. Class I medical devices .....	26
VII. Conclusions.....	32
BIBLIOGRAPHY.....	36
ANNEX 1: SDOC - WIDER PUBLIC POLICY ISSUES .....	39
ANNEX 2. EXAMPLES OF USE OF SDOC .....	41
ANNEX 3. CONCEPTUAL MODEL OF SDOC ECONOMIC BENEFITS .....	42
ANNEX 4: PARTIAL LIST OF POSSIBLE VARIANTS OF SDOC.....	43
ANNEX 5. THE EC'S REGULATORY REGIME FOR THE PRODUCTS STUDIED .....	44
ANNEX 6. GRAVITY EQUATIONS.....	49
1. The gravity equation.....	49
2. The Two-Stage Heckman Selection Model.....	50
3. Interpretation of coefficient.....	51
4. Robustness.....	51
ANNEX 7. COUNTRIES INCLUDED IN THE DATA SET.....	53
ANNEX 8. PRODUCTS INCLUDED IN THE STUDY (HS 6-DIGIT LEVEL) .....	54
ANNEX 9: EVOLUTION OF INTRA- AND EXTRA-EU IMPORTS FOR RTTE, MACHINERY AND MEDICAL DEVICES .....	56
ANNEX 10. DATA AND SOURCES.....	60
ANNEXE 11A : SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU AND NON-EU SUPPLIERS OF RTTE SECTOR .....	61
ANNEXE 11B : SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU, NON-EU OECD AND NON-EU NON-OECD SUPPLIERS OF RTTE SECTOR .....	62

ANNEXE 12A: SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU AND NON-EU SUPPLIERS OF MEDICAL DEVICES SECTOR .....	63
ANNEXE 12B: SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU, NON-EU OECD AND NON-EU NON-OECD SUPPLIERS OF MEDICAL DEVICES SECTOR .....	64
ANNEX 12C: MEDICAL DEVICES - POISSON REGRESSION ESTIMATIONS WITHOUT CONTROL GROUP COUNTRIES AND COUNTRY-, YEAR-, AND PRODUCT FIXED EFFECTS SPECIFICATION.....	65
ANNEXE 13A: SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU AND NON-EU SUPPLIERS OF MACHINERY SECTOR [WITH CONTROL GROUP OF COUNTRIES].....	66
ANNEXE 13B : SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU, NON-EU OECD AND NON-EU NON-OECD SUPPLIERS OF MACHINERY SECTOR [WITH CONTROL GROUP OF COUNTRIES] .....	67
ANNEX 13C: HECKMAN MODEL ESTIMATIONS WITH COUNTRY-, YEAR- AND PRODUCT FIXED EFFECTS [WITHOUT CONTROL GROUP OF COUNTRIES (AUSTRALIA, JAPAN, USA)], FOR MACHINERY .....	68
ANNEX 14: MACHINERY - POISSON REGRESSION ESTIMATIONS WITH CONTROL GROUP COUNTRIES (AUSTRALIA, JAPAN AND USA) AND COUNTRY-, YEAR-, AND PRODUCT FIXED EFFECTS SPECIFICATION .....	69

## EXECUTIVE SUMMARY

Product requirements can vary greatly from market to market, and it is the responsibility of suppliers to prove that applicable requirements are met. For some products, there must be an assessment of a manufacturer's conformity by a regulatory agency or a recognised certification body. For other products, a written declaration of conformity by the supplier himself is sufficient. The endpoint is issuance of a certificate or declaration of conformity.

The WTO Agreement on TBT provides that "...conformity assessment procedures shall not be applied more strictly than necessary to give adequate confidence that products conform with the applicable product requirements ..." (Article 5.1.2). The rationale is to minimise the regulatory burden that conformity assessment (CA) requirements pose for firms that wish to sell abroad. While WTO Members have invested considerable efforts in adopting and promoting the use of various CA approaches to lowering exporters' compliance costs, our knowledge of the extent to which these programmes actually facilitate trade is limited. Available empirical investigations of this question have focused on one particular approach to CA - Mutual Recognition Agreements (MRAs). The aim of this study is to respond to the lack of empirical knowledge of the trade effects of Supplier's Declaration of Conformity (SDOC), another tool available for simplifying the conformity assessment process.

The case for extending the use of SDOC is based largely on the belief that it makes international trade easier, by avoiding or eliminating burdens which would otherwise exist in the form of requirements for third-party conformity assessment. The heart of this study is an attempt to determine whether empirical evidence can be found in trade flows to support that belief: by examining a set of cases where SDOC was introduced, and determining whether there is statistical evidence of increased trade following its introduction.

The cases studied consist of the harmonised introduction of SDOC throughout the European Union resulting from the "New Approach" to technical harmonisation and standardisation put into effect between 1985 and the early 2000s. The products investigated belong to three sectors – radio and telecommunications terminal equipment (RTTE), medical devices and machinery – for which the New Approach Directives established a uniform SDOC system throughout the EU market. One of these cases – RTTE – can be considered to be "purer" than the others, in the sense that the change to SDOC can be traced to a particular point in time at which no other major changes were introduced. The two other cases involve changes to SDOC that occurred simultaneously with other harmonised measures, notably the introduction of harmonised standards across the EU region.

Estimation of the impact of the transition to SDOC shows a positive effect on imports into EU markets. Results vary somewhat across groups of source countries but support the view that SDOC can lead to efficiency gains for suppliers and render exporting to a market easier – hence facilitate trade.

As background to the empirical analysis, the paper explains the rationale for using SDOC, expected benefits and other characteristics defining SDOC regimes, acknowledging also preconditions applicable to its effective use as a regulatory tool in the public interest.

Anecdotal evidence and the discussions taking place in the WTO Committee on Technical Barriers to Trade (TBT) indicate that there is widespread interest in SDOC, and strong theoretical arguments for its use, but occasional doubts about the real extent of SDOC's economic impact.

Manufacturers expect a change of CA regime from mandatory third-party conformity assessment to SDOC, as proof of compliance with technical regulations, to result in reduced costs for approval, reduced time to market, and potentially lower product prices. Indeed, it appears that the theoretical benefits of SDOC can be sizeable.

Nevertheless, actual cost savings may be much less than anticipated for a number of reasons.

Factors that can limit the benefits accruing to manufacturers from SDOC include the growing role of customer-driven private certification schemes and suppliers' decisions, for various reasons, to voluntarily continue to rely on external services for some aspects of conformity attestation.

Equally important, the ways in which compliance costs can be reduced, and hence the effect that introduction of SDOC can be expected to have on trade, have also to do with (a) the specific characteristics of the CA regime that SDOC replaces and (b) the specific features of SDOC. Both can vary.

SDOC requirements frequently differ in their complexity, which can vary the benefits for producers. The trade and broader economic impact of SDOC also depends on the CA regime previously in place: Where SDOC replaces a regime which includes mandatory conformity assessment, then the more onerous the previous regime, the greater should be the "liberalising" effect of SDOC. For the three sectors investigated here, the national CA regimes which the EU's harmonised SDOC system replaced were, on average, more restrictive. There are however instances where EU members' previous CA requirements were not more onerous. SDOC's trade effects for different types of prior regimes are also examined empirically in this study.

Turning to the analysis of SDOC's trade effects, SDOC discriminates neither between countries in which potential suppliers are located nor on the basis of the geographical location of a testing laboratory or certification body. Hence all suppliers, local and foreign, should benefit. However, there are "additional" benefits for the part of the SDOC regime's advantages that apply only to the actual or potential suppliers residing outside the SDOC market, and this should cause them to export more to the SDOC market. In the case of EU introduction of SDOC there is furthermore a harmonisation effect that transforms formerly segmented EU member markets, each having different regulatory requirements, into a single integrated market subject to the new common SDOC regime. The effect of harmonisation is to promote economies of scale, which should reinforce the SDOC effect in the same direction, i.e., increase the flow of imports. But where a regime equivalent to SDOC was already in place in a specific EU market prior to the EC's SDOC initiative, cost savings can be expected to be less and consequently imports to rise by less.

The focus of the empirical investigation is on two questions: 1) whether transition to SDOC has promoted EU imports and 2) whether any observable differences in SDOC's influence on individual EU members' imports can be attributed to the nature of those countries' previous CA regimes.

The quantitative analysis is performed using a gravity model. To answer the first question, the two-stage Heckman estimation procedure is applied to bilateral import flows into individual EU markets. The Heckman procedure first models a selection process estimating the *probability that a country-pair will trade*, and then uses this information in a second estimation of *impact on existing positive trade flows*. In this study, partner countries are other EU members as well as a set of non-EU countries, divided further into OECD and 12 non-OECD (developing) countries. Imports consist of products belonging to the

telecom and radio equipment, machinery and medical devices sectors for which we know the EC's SDOC regime became applicable. Certain products not covered by SDOC are also included, as control group products. Use of control group products, plus the inclusion of three control group countries (Australia, Japan and the United States) who did not implement SDOC at the time the policy change occurred in the EU, ensures that determinants unrelated to SDOC – notably harmonisation across EU of SDOC introduction and other regulatory changes embodied in the EC directives introducing SDOC – are adequately controlled for in the model and any significant changes in import flows into EU markets can be attributed to the regime switch to SDOC.

There is compelling evidence that the transition to SDOC in the EU has facilitated trade:

- The most striking and consistent increases statistically attributable to the introduction of SDOC are seen in exports from non-OECD countries to the EU: they are visible in all three sectors, and for both existing suppliers (i.e., those with exports to the EU even before the change) and new suppliers breaking into EU markets for the first time. Of the three sectors, low-risk medical devices show the most striking growth in exports, at 79% for existing suppliers. In the other two sectors, the increases are lower but still visible.
- In two of the three cases – telecommunications equipment and low-risk medical devices – the study also confirms some increases in intra-EU trade and in imports from OECD countries, though less striking or wide-ranging than those from non-OECD countries.
- In the third case – machinery – the results are positive for imports from non-OECD (developing) countries but ambiguous or negative for intra-EU trade and for imports from OECD countries. One possible explanation for the latter results is that in this case the complexity of the other changes to EU technical regulation introduced simultaneously by the same technical regulation which introduced SDOC in this sector required a process of adaptation that might have been more disruptive for producers in developed countries than for new suppliers in the developing world. Although the gravity model has been specified so that the SDOC effect can be separated from other changes, because of the observed peculiar behaviour of the EU machinery market we have less confidence in the estimates resulting from variants of model specifications tried out for this sector.

Despite machinery being a weak case, the results for all three sectors confirm that SDOC has made trade easier. They also show that although SDOC applies without discrimination to all producers, regardless of their location, the actual impact has varied across the different groups of export countries. These variations can be explained as follows.

- In developing countries, the poor quality of technical infrastructure makes complex processes of conformity assessment harder to master for local producers than for producers in more developed markets. The problem is compounded when mandatory third-party CA is coupled with the requirement to use a conformity assessment body (CAB) in the destination market. The removal of third-party CAB in a destination market will therefore be an even greater benefit to a developing-country supplier who did not have the capacity to master it in the first place.
- Exporters located in OECD countries have benefited less from SDOC than their counterparts in EU countries because EU suppliers can be assumed to be generally keener to take advantage of significant new benefits offered *in their home market*, which in many cases will count for a higher proportion of total revenues than for suppliers outside.



A further notable result of the econometric analysis is that the introduction of SDOC attracts *new* supplier countries, but *already supplying* countries benefit even more. That conclusion contrasts with the diametrically opposite conclusion which has emerged from empirical work documenting the trade effect of MRAs – Mutual Recognition Agreements for conformity assessment – which concluded that the biggest beneficiaries are new market entrants rather than already established players.

To answer the second question – whether any observable differences in SDOC influence on individual EU members' imports can be attributed to the nature of those countries' previous CA regimes – Poisson regressions were applied to import flows of medical devices and for machinery, respectively, into the major EU economies.

The prediction is that SDOC should have had a positive effect where it replaced a more restrictive CA regime, notably one requiring products to undergo third-party certification in the market of sale. Transition to SDOC in countries with already liberal regimes should have changed import flows much less.

For Class I medical devices, imports are found to have increased in all three countries investigated – Germany, the UK and France. Factual information about national pre-SDOC CA regimes was available only for two economies – Germany and the UK. For the UK, results are consistent with the expected modest change in imports; however, SDOC's marginal effect in the case of Germany is substantially higher than predicted given that its previous CA regime was similar to that of the UK. While information about France's pre-SDOC regime was not available, the strong increase observed in French imports suggests that SDOC replaced in that market CA requirements that were burdensome for suppliers located outside France.

The same Poisson regression analysis is applied to the investigation of machinery imports into four major markets – Germany, the UK, France and Italy. Consistent with what the respective pre-SDOC regimes of Germany and the UK would lead us to expect, imports into Germany show a significant increase whereas SDOC is found to have no effect on UK imports. Information underpinning predictions for France and Italy was unavailable, but the strongly positive marginal effects of SDOC observed for machinery imports into either market would be consistent with more burdensome pre-SDOC regimes of the third-party certification type.

## TECHNICAL BARRIERS TO TRADE: EVALUATING THE TRADE EFFECTS OF SUPPLIER'S DECLARATION OF CONFORMITY

### I. Introduction

1. Product requirements can vary greatly from market to market, and it is the responsibility of suppliers to prove that applicable requirements are met. For some products, there must be an assessment by a regulatory agency or a recognised certification body of a manufacturer's conformity. For other products, a written declaration of conformity by the supplier himself is sufficient. The endpoint is issuance of a certificate or declaration of conformity.

2. In order to minimise the regulatory burden that conformity assessment (CA) requirements pose for firms that wish to sell abroad, the WTO Agreement on TBT provides that "...conformity assessment procedures shall not be applied more strictly than necessary to give adequate confidence that products conform with the applicable product requirements ..." (Article 5.1.2). An indicative list of approaches or tools aimed at facilitating the acceptance of conformity assessment results, which can lower compliance costs for exporters and thereby increase export flows, was developed by the TBT Committee in 2000<sup>1</sup>. Members have invested considerable efforts in adopting and promoting the use of these approaches. While they have regularly engaged in the exchange of national experiences, our knowledge of *the extent to which these programmes actually facilitate trade* is limited.

3. The few available empirical investigations of this question have focused on one particular approach to CA - Mutual Recognition Agreements (MRAs). No comparable studies exist for Supplier's Declaration of Conformity (SDOC), another tool available for simplifying the conformity assessment process and which also features prominently in TBT Committee discussions.<sup>2</sup>

4. By definition, under SDOC the supplier himself (this can be the manufacturer, distributor, importer, assembler, etc) provides written assurance of conformity to all applicable technical regulations of a market.<sup>3</sup> Allowing the supplier himself to declare compliance of a product removes the regulatory need for obtaining certification from a recognised third party, usually located in the export market. For suppliers located abroad, third-party certification causes *additional costs and delay in time to market*, which can be a

---

<sup>1</sup> Tools in the WTO TBT toolbox include 1) harmonisation of mandatory technical specifications between two or more countries, 2) recognition by an importing country of the equivalence of foreign regulations, 3) MRAs (Mutual Recognition Agreements), which provide for bilateral or intra-regional recognition by a group of importing countries of conformity assessment certificates delivered in source countries, and which may be based on government-to-government agreement or on government-recognised agreements among independent bodies, such as accreditation bodies, and 4) Supplier's Declaration of Conformity (SDOC).

<sup>2</sup> See for example the report on a 2005 WTO workshop which documented the benefits of SDOC (WTO document G/TBT/M/35)

<sup>3</sup> As stated in ISO/IEC 17050:2004 (General Criteria for Supplier's Declaration of Conformity), "the declaration normally has the form of a separate document. It may alternatively be given in, for example, a statement, catalogue, invoice, or user's instructions relevant to the product, process of service."

significant barrier for exporting to the market.<sup>4</sup> If, by eliminating fees and other costs associated with third-party certification and giving manufacturers more control over when they can place their product on the export market, SDOC results in TBT liberalisation, one would expect to see exports increase.

5. The aim of this study is to respond to the interest expressed in the WTO in SDOC and to the lack of empirical knowledge about the actual effects of SDOC by investigating the relationship between SDOC and trade. We test the hypothesis that exporting to a market will be easier when a more onerous conformity assessment system – mandatory third-party certification – is replaced by SDOC in this market. Our inquiry focuses on the harmonised introduction of SDOC throughout the European Union resulting from the “New Approach” to technical harmonisation and standardisation put into effect between 1985 and the early 2000s. More specifically, we are interested in the introduction of SDOC for products belonging to three product sectors – radio and telecom terminal equipment, medical devices and machinery. For parts or for all of the products in these three sectors, New Approach Directives established a uniform SDOC system throughout the EU market. For the empirical analysis a gravity model will be applied to data on EC-12 imports of products in these sectors from a set of OECD and selected other trading partners. Our review of the relevant literature concludes that this model is the most practical approach available for quantifying the trade impact of regulations in the CA field.

6. The paper is organised as follows. The limited empirical work on CA approaches is summarised in the following section. Section II explains in more detail what advantages, from the manufacturer’s perspective, SDOC offers in terms of compliance costs and market access. Section III describes the three cases of EU regime change analysed. Sections IV and V explain model specification and data used in the assessment of the trade impact of this regime change. Section VI presents the results and Section VII offers concluding interpretations.

### 1. *The existing empirical literature on CA*

7. Assessing the trade and other economic effects of TBT is inherently difficult because of the nature of domestic regulation. Recent years have seen some empirical analysis in this field, mostly seeking to identify the effects of national technical regulations, standards and changes therein as well as standards harmonisation on international trade performance (e.g. Shepherd et al (2006?), Vancauteren (2004), Otskuki et al (2000), Swann and Temple (1996), Moenius (1999), Chen and Mattoo, (2004)). ISO (International Organization for Standardization) maintains a comprehensive inventory of economic studies that deal with standards as the key element.<sup>5</sup>

8. When it comes to conformity assessment procedures, there are scant economic data either on the costs of meeting conformity assessment requirements or on the savings arising from reforms. The existing research base assessing the economic effects of *programmes aimed at streamlining conformity assessment*

---

<sup>4</sup> Not all products require such an assurance – or declaration – of conformity. Such declarations are generally limited to cases where some sector-specific technical regulation exists (for example, an electrical product), as opposed to general, multi-sector product safety regulations; examples of products not subject to any specific regulation might be a paper note-pad or a wooden chair. In a submission to the Committee on TBT, one WTO Member described the benefits of SDOC in terms of reducing costs of trade transactions as follows: “...[SDOC] allows flexibility in the choice of location to have a product tested, reduces the uncertainty associated with mandatory testing by designated laboratories based in foreign countries as well as associated costs... [SDOC] is also beneficial in that there is no discrimination on the basis of the geographic location of a testing or other conformity assessment body – conformity is, in short, the responsibility of the supplier. Under such a system, the question of “portability” of conformity assessment, or the need to negotiate political agreements on mutual recognition, becomes moot.”(WTO G/TBT/W/63. Committee on Technical Barriers to Trade, *Conformity assessment procedures: Supplier’s Declaration of Conformity*. Contribution from the United States. 1998.)

<sup>5</sup> <http://www.standardsinfo.net:80/info/livelihood/fetch/2000/148478/6301438/benefits/benefits.html>

*procedures* is thin and narrowly focused. Mutual recognition agreements (MRAs) have attracted the most attention in the empirical literature (see Box 1), whereas the introduction of SDOC has not been studied at all.

### Box 1: Studies of the impact of CA procedures

A study commissioned in 2003 by the European Commission attempted to assess the *economic impact of MRAs* (i.e. where two countries agree that specified conformity assessment bodies in one country can certify that products meet the technical specifications of the other country). The authors were unable to obtain the specific data required to measure firms' costs and benefits, and hence net benefits, resulting from the MRA. Using panel data regressions, they nevertheless were able to provide estimates of the effects of the MRAs on bilateral exports of products covered by the MRA for the countries that are party to the MRA, which were found not to be large.

Source: Hogan & Hartson LLP (2003), *The Economic Impact of Mutual Recognition Agreements on Conformity Assessment: a review of the costs, benefits, and trade effects resulting from the European Community's MRAs negotiated with Australia and New Zealand* “.

A recent study by the World Bank estimates the trade impact, for both partner countries and excluded countries, of two policy changes - (1) *MRAs on testing procedures* (22 cases) and (2) initiatives to *harmonise technical regulations* (EU, ASEAN) - in the telecoms and medical devices industries. For MRAs, the study finds a strong positive effect on export probabilities and trade volumes of the countries that are parties to the MRAs, suggesting that MRAs remove some significant fixed as well as variable costs for producers. Third party effects were not investigated for the study's component dealing with MRAs. The method used to quantify the effects of the regime changes was a two-stage gravity estimation, and the author explicitly recommends similar research of the impact of SDOC.

Source: Silja Baller (2007), *Trade effects of regional standards liberalization: A heterogeneous firms approach*, World Bank Policy Research Working Paper 4124, Washington, February.

A questionnaire-based case study conducted by Japan in 2006 aimed to clarify the *effectiveness of MRAs* in the APEC region. It confirmed the existence of a total of 28 governmental and non-governmental MRAs but could not evaluate them in quantitative terms because few countries participating in MRAs have analysed the result of an MRA or even tracked the number of certificates/testing reports issued under such mechanisms. Still, many respondents to the survey indicated that MRAs required a large amount of government resources and/or had a relatively small impact on trade.

Source: *Report on the case study to clarify effectiveness of MRAs*. Submission by Japan. WTO Committee on Technical Barriers to Trade, G/TBT/W/276, 19 March 2007. See also *Report on case study to clarify effectiveness of Mutual Recognition Agreements (MRAs)*. Submitted by Japan. Asia-Pacific Economic Cooperation, Sub-Committee on Standards and Conformance Meeting in Da Nang, Viet Nam, 8-9 September 2006. 2000/SOM3/SCSC/006.

9. Manufacturers expect a change of CA regime from mandatory third-party conformity assessment to SDOC, as proof of compliance with technical regulations, to result in lower compliance costs. Whether these cost savings translate into an increase of trade has however not been investigated empirically. Unclear is also the extent to which *all firms*, foreign and domestic, large and small, benefit equally when a country or region adopts SDOC. By removing de facto discrimination against foreign producers on the basis of the geographic location where a product has to undergo testing and certification, SDOC should help level the playing field between domestic and foreign suppliers. Mandating that products have to be certified in the export market increases foreign suppliers' marginal costs of exporting to this market and may discourage some foreign suppliers from entering that market at all. Empirical data can help inform

regulators when weighing alternative trade-friendly approaches to CA.<sup>6</sup> Moreover, data on the trade effects of countries' adoption of SDOC (and other trade facilitating tools in the TBT area) can provide an indirect measure or proxy of the extent to which testing and certification requirements in fact hinder trade.

10. As with any CA regime, SDOC raises questions from the perspective of not only suppliers' compliance costs but also consumer welfare and regulatory effectiveness.<sup>7</sup> Our study acknowledges the complexity of the picture in Annex 1, but its main contribution is intended to come not from a fresh comparison of arguments for and against SDOC but from its attempt to develop analysis of the relationship between SDOC and international trade.

## **II. How SDOC influences suppliers' regulatory compliance costs and trade opportunities**

11. The goal of this study is to determine whether the introduction of SDOC has a discernible impact on trade, when it replaces regulatory regimes based on mandatory conformity assessment by third parties. The present chapter provides background on the perceptions and practice of SDOC, which will be helpful when we come to examine the trade impact in Chapter IV of this report.

12. The TBT Committee of WTO has been engaged for several years in an exchange of information on the use of SDOC and alternative approaches to CA. These discussions have identified a number of sector/country combinations where products are placed in the market using SDOC, although it is believed that no body – the TBT Committee, the wider WTO, or anybody else – has ever attempted to prepare an exhaustive global list. Annex 2 lists a few known major cases. In the EU, conformity assessment using SDOC was introduced by various New Approach Directives adopted between 1985 and the early 2000s. Regulatory agencies in other countries, including Australia, Brazil, Japan, New Zealand and the United States, are also using SDOC.<sup>8</sup> This approach is mostly used for products where risk is considered low, and its appropriate use depends on the regulatory context.

### **1. What are the specific advantages of SDOC for suppliers?**

#### *a) How SDOC benefits manufacturers*

13. The essence of the background here is that there is widespread interest in SDOC, and strong theoretical arguments for its use, but occasional doubts about the real extent of its economic impact. It is the absence of hard data clarifying the situation that leads to the research in this project.

14. Manufacturers have described SDOC as saving costs, since third-party approval is not necessary and this saves suppliers money (e.g., certification fees) as well as valuable time. Annex 3 schematically

---

<sup>6</sup> Results of a recent OECD survey of conformity assessment bodies and exporters suggest that, despite concrete examples and despite support from business, the drive to spread the use of SDOC in regulation of international trade is not achieving the results expected. Third-party conformity assessment in the country of destination and use remains a barrier to trade. See B. Fliess and R. Schonfeld, *Trends in Conformity Assessment Practices and Barriers to Trade*. OECD Trade Policy Working Paper No. 37, 2006.

<sup>7</sup> Among the other effects not investigated here are potential benefits of SDOC for regulatory authorities in the sales market, including: reduced regulatory costs while meeting objectives such as safety of consumers and protection of the environment; reduced up-front government involvement and shift of resources from pre-market to post-market regulatory system (post-market surveillance), which can result in budget savings. Budget savings are however not automatic because SDOC does require well functioning market surveillance that may require substantial investment on the part of the authorities.

<sup>8</sup> See David Shortall, *Regulatory reform and market openness: Processes to assess effectively the trade and investment impact of regulation*. OECD Trade Policy Working Paper, No. 48, 2007, p.23-24.

breaks down and compares what costs a manufacturer faces under a third-party type-approval and SDOC regime, respectively. Time-to-market is an important cost factor in many industries, and third-party testing and certification is time consuming and may require even queuing.<sup>9</sup> Impeding market entry in the first few months of a product's life cycle is particularly damaging because high sales often occur when the product is first put on the market. Such delays are especially detrimental to sales of telecom products, medical equipment and other products having short lifecycles. With SDOC, the manufacturer has more control over time and access to market.<sup>10</sup> For consumers, this means fast access to new products, in addition to other potential consumer benefits (i.e. greater product choice and lower prices).

15. Anecdotal evidence of the efficiency gains that SDOC can bring for suppliers, including firms that export, comes from business representatives participating in various Workshops which the TBT Committee has organised over the years on CA approaches. For example, a major manufacturer in the IT sector (Hewlett Packard) has called SDOC the *lowest-cost model* for bringing safe, legal products to market. Similarly, a major European manufacturer of telecom equipment (Ericsson) described adaptation to SDOC without mandatory third-party intervention as potentially reducing costs for approval, reducing time to market, and lowering prices of products.<sup>11</sup>

16. Against those perceived benefits, some evidence suggests caution before concluding that they are universally applicable:

- Abandonment by regulators of a mandatory requirement for third-party certification may simply be replaced by a demand *by the market* for third-party certification. Evidence, including business views documented in the EC's Single Market review, points to the important and possibly growing role of private certification schemes. Manufacturers often face standards and testing requirements defined by user groups or large individual customers and recognisable e.g. by sector-specific quality marks. For example, the German GS (Geprüfte Sicherheit) mark remains widely used on electrical consumer products.<sup>12</sup>
- Apart from third-party certification, there is anecdotal evidence that the introduction of SDOC does not in fact lead to any reduction in *testing*. Two separate reasons are given for that. First, a supplier may feel ill-advised to reduce the testing needed to prove that his product meets basic requirements of product safety, or other public policy objectives such as environmental protection.

---

<sup>9</sup> For example, in a survey carried out in 1989-1990 across OECD, suppliers of telecom terminal equipment provided estimates of delays before gaining type approval for this equipment. For several EU countries the average delay reported exceeded 130 days. See OECD, *Telecommunications Type Approval: Policies and Procedures for Market Access*, Paris 1992, p.52.

<sup>10</sup> This has been described as being the most significant benefit of self-declaration approaches. See comments of 19 June 2001 submitted by the Communications Industry Association of Japan (CIAJ) to Gazette Notice No. SMSE-016-01 Public Discussion on simplifications to the conformity assessment process for telecommunications terminal equipment, April 24, 2001, Canada.

<sup>11</sup> See *A manufacturer's experiences: Transition to SDoC in the IT/Telecom sector in the European Communities*, Presentation by Per Döfnäs, Telefonaktiebolaget LM Ericsson to the WTO TBT Workshop on SDoC, 21 March 2005 ([http://www.wto.org/english/tratop\\_e/tbt\\_e/sdocdofnas\\_e.ppt](http://www.wto.org/english/tratop_e/tbt_e/sdocdofnas_e.ppt)), and *Supplier's Declaration of Conformity for ICT regulations*, Presentation by David Ling of Hewlett Packard to the WTO TBT Workshop on SDoC, 21 March 2005 ([http://www.wto.org/english/tratop\\_e/tbt\\_e/sdocling\\_e.ppt](http://www.wto.org/english/tratop_e/tbt_e/sdocling_e.ppt)).

<sup>12</sup> See for example, European Commission, *The Single Market Review: Dismantling of barriers to trade*, Subseries III: Vol. 1, 1998, p. 116, and a recent study by Consumer Research Associates Ltd for EFTA of voluntary certification in Europe: <http://www.efta.int/content/publications/EFTA-CERTIFICATION%20AND%20MARKS>

Second, test reports – even if internal – may be a *de facto* requirement of technical files needed to meet a range of needs: to anticipate requests from market surveillance inspectors, or to underpin quality assurance systems.

A declaration of conformity by the supplier therefore could still involve a third party - for example a test laboratory - if the supplier chooses to use external services.<sup>13</sup> This approach may be preferred especially by SMEs, who may find it more difficult to implement SDOC systems than large firms, for example if in-house assessment requires investment in specific equipment and/or internal technical expertise to perform the necessary product inspections and testing. In this case monetary and time savings accruing from SDOC would be *smaller* than for large firms. Nonetheless, if any savings materialise, SDOC may effectively remove a barrier that previously prevented an SME from entering a market.

17. A number of reasons could explain these phenomena. Market competition and rising customer expectations are one kind. But the phenomena may also be explained by concern about product liability and about the impact of official market surveillance: in both cases, third-party conformity assessment may be presented as evidence of efforts to comply with the standards the public expects.<sup>14</sup>

18. Although the two lines of argument may appear to contradict each other – for and against the conclusion that SDOC brings universal benefits to business where public policy makes it possible for regulators to introduce it – some evidence suggests ways of reconciling them. The most notable argument is that, even where the introduction of SDOC does not lead to a reduction in the number or frequency of tests, the market adjusts to the removal of mandatory certification systems by developing more efficient mechanisms which maintain the same level of protection at lower cost. For example:

- Anecdotal evidence from Asia suggests that the spread of SDOC has been followed by the emergence of new, narrow-range expert test bodies in Asia itself concentrating on critical issues (such as chemical testing, or electrical safety testing), and offering services at lower prices than either full-range multinational test bodies or far-distant specialised test bodies in destination markets. There is no hard evidence that the juxtaposition of timing – introduction of SDOC followed by growth of narrow-range test bodies – proves that the first caused the second, but the sequence deserves notice.
- This trend is reinforced by the steady progress of voluntary accreditation mechanisms such as those offered by ILAC, or IAF, and which was the subject of separate, earlier studies by the OECD,<sup>15</sup> increasing the availability of reliable, recognised testing and certification.
- Almost universally positive reactions have emerged in various studies to what is probably the most highly developed mechanism today of voluntary, cross-border testing cooperation which can be

---

<sup>13</sup> John Sullivan Wilson, Information Technology Industry Council, Washington, D.C., *Facilitating access to information technology through supplier's declaration of conformity*. Submission to Symposium on Conformity Assessment Procedures, WTO TBT Committee, June 8-9, 1999.

<sup>14</sup> A specific case in point is the EU's directive on low-voltage electrical safety (outside the three directives directly covered in this study): here, a third-party conformity assessment report, by a recognised body, while not mandatory for the supplier, must be taken into account by market surveillance inspectors if they wish to claim that a product is unsafe.

<sup>15</sup> See for example Fliess and Schonfeld, *Trends in Conformity Assessment Practices and Barriers to Trade*, opt. cit. Both ILAC (International Laboratory Accreditation Cooperation) and IAF (International Accreditation Forum) featured prominently in that report.

used to underpin SDOC: the CB scheme operated by IEC<sup>16</sup> in electro-technical products, which like the multi-sector processes of ILAC and IAF, offers processes designed to achieve the highest level of integrity and reliability in testing. Some informal studies outside Europe (for example, in Thailand) have suggested that the savings to be achieved by local exporters from the universal recognition of the CB scheme in that sector as the basis for acceptance of test reports would offer substantial – although, unfortunately, not precisely quantified -- benefits to the Thai economy.

b) *Local versus foreign suppliers*

19. SDOC is inherently non-discriminatory. SDOC discriminates neither between countries in which potential suppliers are located nor on the basis of the geographical location of a testing laboratory or certification body. Regardless of whether they are local or foreign, suppliers no longer have to submit their products to *mandatory certification by designated bodies located in the export market*.<sup>17</sup> Even where a manufacturer uses an outside laboratory for testing purposes, the choice of where to test is up to him, and he likely will choose a laboratory conveniently located in relation to where the product is produced so that he saves at least time, i.e. in his home market. These then are “additional” benefits or the part of the SDOC’s regime’s advantages that apply only to the actual or potential suppliers residing outside the SDOC market, and this should enhance their export performance.

20. Applied to the markets of Europe, this means that for example a German and Japanese manufacturer producing for customers in France no longer has to submit his products to mandatory certification carried out by recognised (i.e. designated) bodies located in France. Under SDOC, approval can take place at the home location of each firm. Moreover, with *SDOC harmonised across the EU market*, the German and Japanese products, once declared by the manufacturers to be in compliance and carrying the CE (whose origin is sometimes related to the term *Conformité Européenne*) mark, can circulate freely throughout the European market with one approval instead of up to 27. These harmonisation benefits of SDOC apply equally to all suppliers, regardless of location.

21. These conclusions follow from a simple analytical model which Chen and Mattoo (2004)<sup>18</sup> apply to study empirically the impact on bilateral trade of a policy initiative involving standards – and which can be applied also to the policy switch from a mandatory third-party certification policy to SDOC analysed in this paper. The model distinguishes between the effect of a change in regulatory regime (i.e., whether the

---

<sup>16</sup> See study in previous footnote. The CB scheme also figured prominently there.

<sup>17</sup> According to one firm’s account of what mandatory approval procedures in the IT& TE sector may mean for foreign manufacturers, “...many countries have their own in-country testing and certification procedures and requirements. Suppliers obtain permission to bring product models into the country of importation, along with technical support personnel, and place the product in queue for testing to local technical requirements. Where the product is subject to certification requirements, once the product has passed the testing phase, the test results are then placed into yet another queue to be analyzed for product certification. The delays associated with testing and certification queues and procedures have long been subject to scrutiny; questions of priority and national treatment are often raised with respect to equipment authorization for domestic versus imported equipment. In any given country, the average total delay associated with conformity assessment and equipment authorization might range from one to six months for IT&TE products. Since most suppliers are incapable of performing approval activities in hundreds of countries of importation simultaneously, the average delay for marketing product platforms is actually much greater on a global level than the per country estimate stated above.” Steve Crosby, Lucent Technologies, *Improving speed-to-market and accelerating technology access through memorandums of understanding, mutual recognition agreements and arrangements and supplier’s declarations of conformity*, GSC6/RAST9, Sapporo, Japan, 29August-1September 2000, 4 ([http://www.ttc.or.jp/e/external\\_relations/gsc/gsc6/contents/pd38.pdf](http://www.ttc.or.jp/e/external_relations/gsc/gsc6/contents/pd38.pdf))

<sup>18</sup> See Maggie Xiaoyang Chen and Aaditya Mattoo, *Regionalism in standards: good or bad for trade?* Working Paper 3458, The World Bank, October 2004.



new regime is more or less stringent than the regime which it replaces) and the harmonisation effect that transforms formerly segmented export markets, each having different regulatory requirements, into a single integrated market subject to a common (new) regime. Applied to our example, the impact on imports into France from Germany or Japan is made up by two distinct elements: the effect of SDOC replacing a more stringent CA procedure, and the effect of harmonisation of SDOC across the EU region.

22. Concerning the effect of harmonisation, since any supplier of the product to any EU market can now sell in all other EU markets by incurring a single (fixed) cost, this promotes economies of scale which in turn facilitate sales. The effect of the transition to SDOC on the other hand reflects the direct and indirect results from SDOC introduction on the number of firms and firm output. Both types of effects will operate to reinforce each other and result in an increase in imports into the EU regional market. The assumption here is that SDOC is less stringent than the individual EU members' CA regimes that it replaces. Where, on the other hand, a regime equivalent to SDOC was already in place in a specific EU market and the only effect on firms' costs, following introduction of the single, harmonised procedure by the EC's New Approach, consists of the scale economies resulting from now being able to freely sell across the EU region, imports into that specific market should still rise, but less.

23. The empirical analysis of the trade impact of the EU's SDOC regime will test these propositions: this report offers – in Chapter IV – evidence on whether EU imports have increased and whether trade flows show uneven results depending on the extent of CA regime change represented by the transition to SDOC.

24. Customs procedures may also affect the benefits of SDOC to suppliers located outside the SDOC market: do foreign products face customs procedures when entering the export market that are different under an SDOC regime? Regulatory authorities of course take measures to ensure that the integrity of a foreign supplier's declaration of conformity is maintained. Where SDOC is introduced, they set requirements for who signs the declaration of conformity, require access to the compliance records, and if deemed necessary undertake customs inspections to verify the presence of the SDOC documents. The procedure at customs point normally should however be the same whether SDOC or another CA procedure applies, so that transition to SDOC should not change customs-related transaction costs for the foreign manufacturer or importer.

## 2. *Types of SDOC*

25. The ways in which compliance costs can be reduced have to do with (a) the specific characteristics of the CA regime that SDOC replaces and (b) the specific features of SDOC. Both can vary.

26. We first look at the different possible *forms of SDOC*.

27. Despite the existence of an ISO standard for SDOC<sup>19</sup>, SDOC regimes are not necessarily identical across countries or product sectors. In its simplest form, SDOC requires no test reports or certificates, no specified form of documentation beyond the *declaration of conformity* itself, no registration with a competent authority in the importing country, and imposes no explicit liability on the importer for

---

<sup>19</sup> ISO 17050, *Conformity Assessment – Supplier's declaration of conformity*, which is divided into two parts: Part I – *General Requirements*, and Part 2 – *Supporting documentation*. It offers considerable flexibility in its specification of detail. For example, in para. 5.1 of Part 2 it specifies that supporting documentation should include *information to demonstrate conformity with the declared requirements*, but gives an illustrative list (“*such as...*”) of possibilities, without actually specifying any particular one or combination. It also leaves open the possibility of supplying – on a voluntary basis – conformity assessment data provided by a third party. Liability is not addressed by the standard. The ISO standard is broad enough to permit all the variants described in this paper.

compliance with the technical regulation in question when the manufacturer is clearly identified in the declaration. The manufacturer is left completely free to design and implement a system which ensures compliance with the regulation in question.

28. However, SDOC requirements are frequently more complex. For example, suppliers may be required to use test reports prepared by competent third parties rather than conducting such tests in-house, or to register their products via an organisation in the territory of the importing country, or to maintain a technical file. The liability of the importer may also vary under an SDOC regime: from zero to total.<sup>20</sup> The application of different variants can vary the benefits for producers resulting from SDOC.

29. Against that background of complexity, an attempt has been made to classify SDOC. For example, Guidelines developed by the WTO Committee of Participants on the Expansion of Trade in Information Technology Products for EMC/EMI Conformity Assessment Procedures encourage ITA participants presently relying on government or third-party certification to switch to one of four types of SDOC regimes described in Box 2.

**Box 2. Some variants of SDOC regimes (in descending order of complexity)**

**Type 1 SDOC:** Supplier or manufacturer declares the product meets the technical and administrative requirement on the basis of test reports by a testing laboratory recognised by the regulator. The supplier furthermore registers the product with the regulator.

**Type 2 SDOC:** Supplier or manufacturer declares the product meets the technical and administrative requirements on the basis of test reports by a testing laboratory recognised by the regulator. No registration of the product with the regulator is required.

**Type 3 SDOC:** Supplier or manufacturer declares the product meets the technical and administrative requirement. Supplier registers the product with the regulator. Testing of the product by recognised testing laboratory is not mandatory. If testing is undertaken, the choice of the testing laboratory rests with the supplier or manufacturer.

**Type 4 SDOC:** Supplier or manufacturer declares the product meets the technical and administrative requirement. Registration of the product with the regulator is not required and testing of the product by recognised testing laboratories is not mandatory. If testing is undertaken, the choice of the testing laboratory rests with supplier or manufacturer.

Source: WTO, Committee of Participants on the Expansion of Trade in Information Technology Products, *Guidelines for EMC/EMI Conformity Assessment Procedures*, G/IT/25 17 February 2005.

30. This four-part typology developed in the context of the Information Technologies Agreement (ITA) is, in fact, a simplification. Annex 4 provides a more complex picture showing 18 possible variants, indicates where the ITA classification fits, and how the ITA classification fails to cover the whole field, and gives examples from the EU of cases which fall outside the ITA's classification. Even the 18 variants

<sup>20</sup> Liability for non-compliance with a technical regulation must be distinguished from liability under what is called *product liability legislation* per se. In the simplest terms, technical regulations of the kind studied here aim to prevent damage before it happens, while product liability legislation aims to compensate for damage when it has happened. In the EU, importers can never escape responsibility under the latter.

shown here do not constitute an exhaustive list: they ignore, for example, the issue of the formal liability of the importer under the law.

31. The trade and broader economic impact of SDOC also depends on *the regime previously in place*.

32. Where SDOC replaced a regime which included mandatory conformity assessment, then the more onerous the previous regime, the greater should be the “liberalising” effect of SDOC. Moreover, cost savings should be higher still if SDOC replaces national regimes in multiple markets that previously obliged suppliers to fulfil testing and certification requirements specific to each market.<sup>21</sup> But SDOC does not always replace a more onerous regime, as the machinery and the medical devices sectors included in this study illustrate. For example, there was no formal technical regulation of medical devices at all in some EU countries before the EU introduced its main harmonised regulation in 1993. Britain is an example of that: there was indeed a Medical Devices Agency before 1993, whose responsibilities included oversight of a voluntary system and examination of incidents in the sense of patient harm, but there was no universal *ex ante* technical regulation.<sup>22</sup>

### III. Three EU cases of CA regime change

33. The form of SDOC used varies between the three sectors in this study, variations which reflect the wide range of SDOC possibilities outlined in Chapter II above. Their essential characteristics are summarised in Annex 4.

34. While a lack of further data prevents us from documenting in greater detail the specific CA requirements in force in different Member States prior to the transition to SDOC, we conclude that these regulations, on average, were more restrictive as far as the specific product groups of the three sectors studied here are concerned.

35. The EC’s current Radio Equipment and Telecommunications Terminal Equipment (RTTE) Directive (1999/5/EC) entered into effect in April 2000. For most RTTE, the manufacturer can declare conformity by testing equipment in-house or using other evidence to demonstrate compliance. The services of a notified body (a third-party agency appointed by the regulatory authorities to ensure that regulatory requirements are met) are only prescribed for radio communications products which are not purely receivers and which are not covered by a recognised, harmonised standard(s) including test suites.

36. When SDOC was introduced for RTTE, it replaced mandatory third-party CA in all Member States.<sup>23</sup> This case may be considered the “purest” case in this study. Unlike the two other directives in this study, this RTTE directive was not the first harmonised EU technical regulation for the sector.

---

<sup>21</sup>John Sullivan Wilson, Information Technology Industry Council, Washington, D.C. *Facilitating access to information technology through Supplier’s Declaration of Conformity*, paper presented to The World Trade Organization Technical Barriers to Trade Committee: Symposium on Conformity Assessment Procedures, June 8-9 1999, p. 5.

<sup>22</sup> Source: MHRA (Medicines and Healthcare Products Regulatory Agency), London.

<sup>23</sup>The United Kingdom is reported to have had a more liberal but closely supervised regime, whereby a supplier could carry out the testing and UK type approval authorities accepted the test results as the basis for approval. Also, in this product sector by the late 1980s certain EU countries recognised type approvals carried out by foreign countries under MRA arrangements. See OECD, *Telecommunications Type Approval: Policies and Procedures for Market Access*, Paris 1992, p. 31.

Harmonised technical regulation, involving mandatory conformity assessment, had existed since 1991.<sup>24</sup> In 2000, the requirement for that mandatory third-party involvement was swept away and SDOC introduced.

37. The other two cases differ from the RTTE case: while the change introduced for telecommunications in 2000 was limited essentially to the introduction of SDOC, in the other two sectors SDOC was introduced simultaneously with wider changes. In each of those two other cases, a new EU directive came into force which provided a basis for harmonising standards, documentation and marking at the same time as SDOC was introduced for defined classes of products.

38. In the machinery sector some Member States already applied SDOC before the EU introduced its pan-European regulation (Directive 89/392/EEC). A primary example is the United Kingdom, where SDOC largely applied before the date of EU harmonisation. By contrast, in Germany mandatory third-party CA was widespread until the EU introduced harmonised SDOC. This difference in pre-SDOC situations makes these two countries useful candidates for investigating the relationship between the extent of CA regime change and trade. The Machinery Directive entered into force in January 1993.

39. The General Medical Devices Directive (93/42/EEC) entered into force in January 1995. Under the Directive, SDOC applies only to a subgroup of Class 1 low-risk medical devices, which are the simplest devices with the lowest overall risk to the user and patient. The regulatory system in place prior to the harmonised introduction of SDOC is documented particularly poorly. What is known from the literature is that there was some need for multiple national testing and registration.<sup>25</sup> We can illustrate the situation with two countries studied:

- In Germany, medical devices, depending on the type, were previously subject to any or all of four separate regulatory regimes,<sup>26</sup> but a German industry expert confirmed that the specific Class I medical devices constituting the study's sample of SDOC products did not require pre-market approval – in other words, they were eligible for SDOC in Germany even before the introduction of the EU directive. German manufacturers of these Class I devices felt it necessary to lobby the German government heavily to ensure that the German SDOC regime was extended to the rest of the EU – as it indeed ultimately was – and to avoid the introduction of a more onerous regime. The adoption of a pan-European SDOC regime was considered critical to export success.
- In the case of the United Kingdom, there also was no mandatory *ex ante* (i.e., prior to placing products on the market) technical regulation at all in this sector.

40. Besides assessing the effect of the harmonised pan-European introduction of SDOC on imports into the EU regional market, the study will look at country-specific effects. More specifically, it will measure SDOC's trade effects for individual Member States in the machinery as well as the medical devices sector.

---

<sup>24</sup> Through Directive 91/263/EEC, subsequently consolidated into Directive 93/13/EC, which was replaced by Directive 1999/5/EC, the subject of the current study. Harmonised marking, standards and documentation had been introduced in the 1991 directive, which was therefore in force well before the start year of the time series import data used in this study.

<sup>25</sup> Without further elaboration, this is confirmed by respondents in a survey of the EU medical device industry. See Horst Steg and Nikolaus Thumm, Single-market regulation and innovation in Europe's medical devices industry, *International Journal of Technology Assessment in Health Care*, 17:3 (2001), p. 421-432.

<sup>26</sup> The four separate regimes were machinery, measuring instruments, radioactive emissions, and pharmaceuticals. Medical devices themselves were also the subject of separate control as a sub-category under the German Gerätesicherheitsgesetz.

41. In all the cases where the SDOC regime applies, manufacturers must follow administrative prescriptions for recordkeeping (technical documentation). Mandatory CE labelling to indicate compliance with regulatory requirements is another feature of the EC's regulatory regime.

42. Table 2 summarises the CA regime applicable in the three sectors before SDOC was introduced, as well as the type of SDOC used. More detailed information of the EC's regulatory regime for the products studied is provided in Annex 5.

**Table 2. CA regime change**

Product category	Previous regime	Type of SDOC (1,2,3,4)*	SDOC Implementation deadline**
Telecom terminal equipment: wireless or radio (only a part is eligible for SDOC)	3 <sup>rd</sup> -party type approval	Closest to ITA Type 4, but with additions	(Directive 1999/5/EC) April 2000
Telecom terminal equipment: non-wireless	3 <sup>rd</sup> -party type approval	Closest to ITA Type 4, but with additions	(Directive 1999/5/EC) April 2000
Machinery (excluding most hazardous)	Varied between EU countries. No comprehensive comparison identified. <i>Examples:</i> Germany used more 3 <sup>rd</sup> party type approval, UK used more SDOC	Closest to ITA Type 4 but with additions	(Directive 89/392/EEC) 31 December 1992
Medical devices (low-risk Class I)	Various. No comprehensive comparison identified. <i>Examples:</i> Germany and UK had no mandatory <i>ex ante</i> third-party CA	Closest to ITA Type 3, but with additions	(Directive 93/42/EEC) January 1995

Notes: \* refers to the typology of SDOC shown in Box 2. \*\* The date refers to the deadline by which member states were required to have the relevant Directive transposed into national law. In a few instances implementation occurred prior to the deadline, and in a few other cases the stipulated deadline in transposition was missed; however, there is no evidence of formal legal actions taken by the EC that would suggest that the delays that occurred had practical consequences on the market.

#### IV. The empirical study

43. To measure the effect of SDOC introduction on trade, we use the gravity model, which has found wide application in empirical trade analysis. The model seeks to explain trade flows between pairs of countries by a set of trade-enhancing or trade-restraining variables. Because empirical studies have found geographical distance, adjacency and income (GDP) to be important determinants of bilateral trade, these usually represent "core variables" in a gravity equation. To these variables can be added other variables representing trade-influencing factors that modellers wish to explore, such as institutional characteristics or trade policy variables. Various studies have provided formal theoretical foundations for the gravity model.

44. Gravity equations have been used to analyse preferential trade agreements, forecast potential trade flows between countries and estimate border effects. Applications have also addressed the trade impact of various types of non-tariff barriers (NTBs), with the barriers usually modelled by way of some indicators or proxies (e.g. frequency ratios of NTBs, restrictiveness ranking). This strand of work includes attempts to measure the trade effects of standards and technical regulations (e.g. Otsuki et al, 2000, Moenius, 1999, Vancauteran, 2004). These studies investigate the extent to which such measures and changes thereof over time have influenced trade flows.

45. While most gravity modelling has used bilateral trade flows and measured trade impact at the aggregate level of trade, some empirical work has used one-way trade flows and highly disaggregated trade involving specific product categories. Gravity models have also been used in studies looking at the evolution of trade over time (ex ante and ex post) in relation to a change of policy (e.g., Swann and Temple, 1996, Vancauteran, 2004, Baller, 2007). We therefore consider the gravity model an appropriate tool for investigating the effect of the transition to SDOC on EU imports in relevant subsets of the sectors machinery, radio and telecom terminal equipment and medical devices.

### ***1. Hypotheses and model specification***

46. To investigate whether exporting to the EU market was facilitated by the replacement of a more onerous conformity assessment system by a unified SDOC system, we construct two broad types of models aimed at answering two sets of questions:

1. Has the introduction of SDOC in the EU facilitated trade? From our earlier discussion, imports from all partner countries (intra and extra EU) should increase, for all three product groups. The reasons are that a single SDOC regime replaced different national CA regimes of EU members, which on average were more burdensome for firms.
2. Can one distinguish differences in import response that can be attributed to differences in markets' previous CA regimes? For example, Germany's pre-SDOC regime for machinery frequently required mandatory third-party certification, whereas the regime of the United Kingdom did not. If these differences influence the size of firms' cost savings resulting from SDOC, imports into, say, Germany should rise by more than imports into the United Kingdom. For Class I medical devices, the United Kingdom's previous regime required no pre-market approval and hence we would expect UK imports to not change much as a result of SDOC being introduced. Germany had a similar, liberal CA system. We have no information on the pre-SDOC CA regimes of other major European economies but include France and Italy in our investigation; ideally we should be able to infer from the results of the estimation how restrictive their previous CA regimes had been.

47. Modelling the trade effect has to take account of the broader EC regulatory context of the introduction of SDOC in the three sectors. One question that arises is whether the EC Directive which introduced SDOC in each sector introduced further regulatory changes that may have also influenced EU import performance.

48. In the case of RTTE, the SDOC change was clearly separated in time from other important regulatory measures affecting sector. Harmonized technical regulations had already been introduced by Directive 91/263/EEC in 1991 and the only significant change introduced by the 1999/5/EC Directive consisted of removing the harmonized requirement for third-party testing and introducing SDOC. For machinery and medical devices, the transition to SDOC coincided with other regulatory reforms, notably the harmonization of essential requirements, specifications or standards across the EU for the first time, in the same EC Directives. We control for these other potential determinants of imports into EU member markets in two ways.

49. A control sub-group of SDOC-non-eligible products is included in the product dataset of each sector. Moreover, product fixed effects are included in the equation to control for any effects that SDOC-unrelated regulatory changes introduced by the Directives could have had on sector-wide imports.<sup>27</sup> By including country, year and product fixed-effects specifications, the impact of non-SDOC related

---

<sup>27</sup> A first estimation was run with a separate dummy variable representing a proxy for the Directives, but the high possibility of its co-linearity with the SDOC variable led us to discard this option.

regulatory changes introduced by the Directives ought to be adequately controlled for and the risk of overestimating the influence of SDOC on imports of our product groups minimised.

50. We chose to work with a model specification where the import data are disaggregated for the individual EU members (again with Luxembourg and Belgium data omitted) and the products also enter at the disaggregated (HS 6-digit) level. In this way the evolution of imports between EU members (and hence the evolution of intra-EU imports) as well as between EU and non-EU trading partners can be analysed. The countries from which the imports originate consist of OECD and a set of 12 non-OECD trading partners – mostly higher income developing countries including Brazil, China, India, Russia and South Africa (see Annex 7 for a list of countries covered).

51. Three major economies - Australia, Japan and the United States – are included in the model as a country control group. These economies did not implement SDOC when the EU's regime change took place. If we do not add control group countries, perhaps the phenomenon captured by the SDOC variable could be caused by characteristics or trends specific to the EU market and unrelated to SDOC. Together with the use of a control group of products in each sector, this element of the model's specification creates sufficient confidence that any observed significant change (increase or decrease) in imports into EU markets is caused by the introduction of SDOC.

52. The model permits also a comparison of how SDOC introduction affects the imports of individual EU members. Such country analysis is carried out for select EU economies – Germany, France, Italy and UK – in the sectors of machinery and medical devices.

53. There is a large number of zero import observations in the data set, notably for imports into the EU from non-EU countries included in the sample<sup>28</sup>. Dealing properly with zero trade values requires that the information provided by these zero imports is taken into account. We therefore apply a Heckman procedure for selection, which for example Baller (2007) uses in her empirical study of the trade impact of MRAs and harmonisation of product standards.

54. A theoretical framework explaining zero trade flows has been developed by Melitz (2003). Firms wishing to export face certain per unit costs (such as transportation costs, tariffs) as well as certain fixed costs that do not vary with the volume of exports. Fixed costs can arise from various requirements, including the need to adapt the product so that foreign regulatory requirements are met.<sup>29</sup> These costs often must be sunk *prior to entry into the export market* and are most appropriately modelled as independent (exogenous) of a firm's export volume decision.

55. How then are firms' export decisions influenced by the costs associated with having to meet foreign CA requirements (i.e., in obtaining any necessary certifications of a product so that it can be sold in a foreign market) and changes in these costs resulting from CA regime changes? Having to meet the CA

---

<sup>28</sup> For telecom products, for trade between 1995 and 2005, we have 3081 (23.48%) zero flows for country pairs constituting intra-EU country imports, and 10086 (39.67%) zero flows for country pairs constituting imports into the EU from extra-EU source countries and 15763 (33.33%) zero flows for the overall sample (with control group of countries included). For medical devices, for trade between 1990 and 2000, the distribution is 3150 (25.05%) zero flows and 9824 (48.04%) zero flows respectively and 15301 (38.41%) zero flows for the overall sample (with control group of countries). For machinery, for trade between 1988 and 1998, the distribution is 18058 (32.59%) zero flows and 36710 (54.81%) zero flows respectively and 66184 (43.98%) zero flows for the overall sample (with control group of countries included).

<sup>29</sup> Fixed costs are caused also by the need to find and inform foreign buyers, learn about a foreign market, set up distribution channels in a foreign country, etc. See Marc J. Melitz, The impact of trade on intra-industry reallocations and aggregate industry productivity, *Econometrica*, Vol. 71, No. 6, November 2003, p. 1695-1725 (here p. 1706).

requirements of a given export market raises firms' costs of foreign market entry, affects expected profits or increases the uncertainty of the profitability of exporting. This will influence a firm's decision of whether or not to enter the foreign market. A given cost can inhibit entry, whereas a cost reduction can encourage entry. The decision of whether or not to export is modelled by the Heckman procedure as a selection process (first stage) where the probability of trade flows switching from zero to a positive value for each possible destination is estimated. This information then is used to estimate exports (or imports, if viewed from the foreign market) (second stage). The two-step procedure allows a distinction to be made between a trade relationship being established between two countries for products not traded before (known as the 'extensive margin', but here referred to as *market entry*) and the change in already ongoing trade (the 'intensive margin', but here referred to as *import intensity*). Further details of the equations of the model are shown in Annex 6.

## V. Data

### 1. Trade data

56. Because in each of the three sectors SDOC applies only to a subset of products, import data had to be collected for eligible products. The EU Directives were not drafted with any conscious attempt to ensure comparability between their scope (related to common classes of risk or hazard) and the product classifications used for collecting trade data.<sup>30</sup> For each of the three broad product sectors, we had to identify specific products that are covered by the SDOC regimes of the applicable EC Directives and match these with corresponding HS product codes (at 6-digit level). Product classifications were derived in two steps: 1) taken from the list of the EU's Combined Nomenclature (CN) codes published in Regulation 1719/2005 of the European Commission and 2) converted to COMTRADE 6-digit codes by checking the EU classification against the COMTRADE list.<sup>31</sup> The trade data were extracted from WITS.

57. There are important differences between the three sectors in terms of coverage, and only for one of the three sectors – RTTE – was correlation between HS codes and the scope of the Directive confirmed. In the light of this difficulty, we chose a sample of products for each sector, for product codes clearly falling under the Directives' provisions for SDOC treatment. For machinery and Class I medical devices, only sub-categories were used because no set of codes could be established which covered the entire part of the sector affected by the transition to SDOC. The products and HS codes compatible with the relevant technical regulation are shown in Annex 8. The pragmatic way in which the products samples were chosen sets limits to our study and in particular to the interpretation of the results. They represent the effect of SDOC on imports for the sample of products covered by the study and cannot be generalised to all SDOC-eligible products in each sector.<sup>32</sup>

---

<sup>30</sup> For illustration, the Machinery Directive defines machinery as “an assembly of linked parts or components, at least one of which moves, with the appropriate actuators, control and power circuits, etc., joined together for a specific application, in particular for the processing, treatment, moving or packaging of material...”.

<sup>31</sup> Eurostat staff provided valuable guidance to the selection of codes, and to methods of correlating HS codes used in trade with un-harmonised codes used by countries outside EU (e.g., United States).

<sup>32</sup> We calculated the share of the imports of SDOC products covered in this study in total EU imports of the sector, using the HS-4digit product level as approximation for the calculation of total imports in each sector. In 1995, the beginning of the time period studied for telecom equipment, our SDOC product sample represented 52% of total telecom equipment imports. The corresponding figure for our sample of SDOC medical devices, for 1990 as the first year of the time period studied for that case is 16%. For the sample of machinery is 67% in 1988, the first year of the time period studied for the machinery case.



58. For each sector, we also identified and collected import data for subsets of products to which SDOC does not apply and which are used as product control groups, to separate out the effect on imports clearly attributable to SDOC.

59. All data are annual nominal import values collected for five years before the entry into force of the SDOC regime applicable to each sector, and five years after.

## **2. Data on SDOC**

60. SDOC was introduced as a result of specific EC Directives. Member States were required to transpose SDOC in the case of machinery by January 1993, for medical equipment by January 1995 and for RTTE by April 2000. Our primary interest is to evaluate whether there is a significant change in imports as a result of the introduction of SDOC. We therefore included in the equation dummies that take the values of zero before the relevant Directive entered into effect and one after it became effective.

61. It is useful to examine the raw import data to see if they offer any clues as to the expected effect of SDOC introduction. Figures 1a -3a in Annex 9 show the total imports into the EU from the set of external trading partners, as well as the corresponding intra-EU imports for each of the three product groups (RTTE, medical devices and machinery). From these graphs it is not obvious to anticipate import shifts due to SDOC introduction, given the general, at times staged, positive trend in imports over the years. Distinguishing between intra-EU, extra-EU OECD and non-OECD sources of imports, the graphs 1b, 2b and 3c show the various evolutions of import shares for the 3 years corresponding to the first and last year of the 10-year period studied, plus the year of entry into force of SDOC. For RTTE, despite a growth trend, between 1995 and 2000 intra-EU source countries still account for the largest and extra-EU non-OECD for the smallest share. By 2005, this pattern had changed, however, with extra-EU OECD and non-OECD source countries taking the lead. For machinery, between 1993 and 1998, intra-EU imports remain stable whereas for extra-EU imports the increase is significant (more than 100% for extra-EU OECD countries). For medical devices, a steady increase is observed for the three sources of imports, with non-OECD countries lagging in 1990 but then leading in 2000. Initial inspection of trade data suggests a significant and positive impact of SDOC for imports from the group of non-OECD countries. Note also that the share of extra-EU imports consistently exceeds intra-EU imports (by almost two times), whatever the year considered.

## **3. Other data**

62. In addition to the sector-specific SDOC dummy variables, following the standard gravity model we included in the equation GDPs of the exporting and importing countries or regions. Exporter and importer GDPs can be interpreted as the traded-goods production and absorption capacities of the exporting and importing countries, respectively. Nominal GDP values were used because deflating GDP by the international price index could introduce a bias. It would have been preferable to use instead of GDP some expenditure indicators more closely linked to each of the sectors studied; however, such data are not readily available.

63. Bilateral distance between two countries is generally associated with transportation costs; more distance suggests greater transit costs. The distances used here are calculated as the Great Circle distance between the countries' geographic centres. We considered for inclusion a number of other geographic variables having been found being significant determinants of bilateral trade flows. These are: (1) whether exporting and importing country sharing a common land border (contiguity); (2) whether the countries share a common language; (3) whether one country was ever a colony of the other; (4) whether either or both countries are landlocked; and (5) whether either or both are islands.

64. With the exception of distance, which is used to model transport costs, all other geographical variables are dummy variables.

65. We further augmented the standard gravity model with dummy variables controlling for the effects of the introduction of the Euro (to proxy removal of a currency barrier, or the cost of using different currencies when selling products in foreign markets), for capturing the specific effects of a country being a member of the EU, and for any preferential trade arrangements (customs unions, economic integration agreements, free trade agreements) existing between the countries in our set. It can be argued that a dummy variable denoting if a country is a member of a preferential trade arrangement is a proxy for the absence or presence of tariff barriers.

66. In a trial run of our model we found that some of these variables made no significant contributions to explaining imports in our gravity model or raised issues of correlation with other variables. As a result we omit the landlocked, island, and WTO membership variables from our equation. A table describing all variables used, and their data sources, is shown in Annex 10.

## VI. Results

### 1. *Radio and telecommunications terminal equipment (RTTE)*

67. As explained in Chapter III, the sector of radio and telecommunications terminal equipment (RTTE) can be considered the “purest” case in this study in the sense that the removal of mandatory third-party CA was the key regulatory change initiated by the 1999 RTTE Directive, and SDOC can be assumed to have had a rather strong trade-facilitating effect because the earlier national CA regimes of the Member States consisted of mandatory third-party assessment. We would expect SDOC to have a positive effect on EU imports of RTTE from all trading partners.

68. A first estimation applied the Heckman procedure using disaggregated data for wireless and radio as well as non-wireless SDOC eligible equipment, and a control group of equipment for which we know third-party assessment remained in place. The SDOC dummies captured the respective effects of SDOC for intra-EU and extra-EU imports in the initial version of the regression. Non-EU source countries were split further into OECD and non-OECD (developing) countries.

69. Regression results are shown in Annex 11. Measuring how SDOC affected the probability of shipment of any RTTE product taking place from a source country to an EU market - in other words that an EU member started to import from a country an SDOC product previously not imported from that country (*market entry*), the results of the Probit regression (first stage) show a positive and statistically significant effect indicating that SDOC did facilitate market entry for firms in non-EU countries. This was not the case for EU-based firms but, as Baller (2007) has pointed out, trade relations within the European Union are well established, which the much lower incidence of zero trade values for intra-EU imports than for extra-EU imports in our data set confirms (see footnote 29) This may explain why the coefficient measuring the probability of market entry associated with SDOC is not significant or slightly negative for intra-EU country pairs in the Probit regression.

70. Analysis of the exporting country fixed effects shows that the United States, China, Japan, Korea, Germany and Malaysia were the countries with the greatest propensity to export the study’s sample of RTTE.

71. The results of the second-stage OLS regression (trade intensity) show that SDOC affected existing intra-EU imports of SDOC products positively. For extra-EU imports there is no statistically significant effect, but from Annex 11b a more nuanced picture emerges when imports from OECD and non-OECD (developing) countries are analysed separately: the coefficient of the SDOC variable is positive

and significant for imports into EU markets from non-OECD countries, but not significant as far as the EU's imports from its OECD partners (i.e., Australia, Canada, Czech Republic, Hungary, Iceland, Japan, Korea, Mexico, New Zealand, Norway, Poland, Slovakia, Switzerland, Turkey and United States) are concerned.

72. The coefficient of the dummy variables in the Heckman model estimations cannot be interpreted directly. In order to better gauge the substantive impact of SDOC, we calculated the marginal effects for the Probit estimation and applied the Kentucky formula to obtain percentage impact values for the SDOC dummy variable in the OLS regression specification which includes country, year and product fixed-effects.

73. Table 3 shows the marginal effects of the change in import value attributable to the introduction of SDOC at the mean value of imports in the sample. As for new market entries by EU partners, the marginal impact is negative but not large (on average -3%). The probability of OECD and non-OECD countries starting to supply any of the SDOC products in the sample is shown to have risen by 3% and 6%, respectively, which is consistent with the assumption that some of the costs savings achieved through SDOC relate to firms' fixed costs. Existing imports of SDOC products from non-OECD countries grew by 26% and existing intra-EU imports by 11%. This positive effect suggests that the transition to SDOC affected not only fixed costs but also firms' variable costs of selling to the EU market. What is unexpected is that while SDOC applied to all suppliers and therefore there should be no trade bias, the positive trade impact was not all around: imports from non-EU OECD countries hardly changed.

74. Also shown in Annex 11b, the results generated for the standard control variables included in gravity models are in conformity with those presented in the existing empirical literature. The sign and coefficient of the variables for distance, contiguity and common language all conform to expectations. The RTA and Euro currency variable are found to affect imports positively in both stages whereas EU membership impacts mainly when trade relationships are already established.

**Table 3:** Impact of SDOC on market entry and trade intensity - RTTE

SDOC	Market entry	Trade intensity
	Marginal Effects	Kennedy
intra-EU	<b>-3%</b>	<b>11%</b>
extra OECD	<b>3%</b>	-
extra non OECD	<b>6%</b>	<b>26%</b>

Note: Non-significant coefficients are not shown. Since a dummy variable cannot by itself be interpreted in percentage terms, we use the method of transformation suggested by Kennedy (1981). See explanation in Annex 6.

## 2. *Class I medical devices*

75. The 93/42/EEC Directive introduced comprehensive regulatory changes across products in this sector. Apart from introducing SDOC, perhaps the most important other change resulting from the Directive was the EU-wide harmonisation of standards. In her study of the trade effects of regional harmonisation of standards, Baller (2007) points out that the expected effect is ambiguous because it depends on whether standards are harmonised up or down. Including data on two harmonising regions, the EU and ASEAN, in her model, she finds that the effect on the development of new trade ties between

partner countries of harmonisation in the medical devices sector is not significant and impacts negatively on already existing trade. On the other hand, harmonisation facilitates market entry of firms in countries outside the harmonising regions (in Baller's study from OECD countries rather than developing countries) and does not change existing trade. To investigate in detail the role of standard harmonisation is not our aim. Therefore, rather than model any SDOC-unrelated provisions included in the Directive, such as standards harmonisation, by means of separate dummy variable in the regression, we controlled for SDOC-unrelated effects through our fixed-effects model specification, as explained earlier. The specification is intended to control also for the separate harmonisation effect of SDOC being introduced region-wide.

76. We applied the two-stage estimation procedure of Heckman to our data set of Class I medical devices. Detailed results of the regressions are shown in Annexes 12a+12b. Like for RTTE, the switch to SDOC increased the odds that extra-EU countries begin to export an eligible product. For intra-EU imports the effect is more ambiguous and becomes statistically insignificant in the equation with all three fixed effects. The sign and significance of the coefficient in the second-stage OLS regression indicates that, for intra- and extra-EU trade, SDOC is also associated with a higher level of imports of products already taking place. Again, this positive effect is particularly large for imports from non-OECD countries.

77. The analysis of the exporting country fixed effects show that for our sample of medical products the United States, Germany, the UK, Japan, France and China are the countries with the greatest propensity to export to the EU market.

78. Table 4 shows the marginal effects and the percentage impact of the SDOC dummy variable for the Probit and OLS regressions with country, year and product fixed-effects. With SDOC in place, the probability to observe positive flows between an importing country of the EU and a non-OECD country is 6% higher but there is no statistically significant effect for either intra-EU trade or imports from extra-EU OECD. For already existing imports the effect of SDOC is unambiguously positive: existing imports from EU partners increase on average by 35% annually, from OECD partners by 20% and from non-OECD countries by 79%. The estimate for imports from non-OECD countries is very high, cautioning us to treat the estimates in Table 4 as strictly suggestive. One must also keep the figures in perspective: the results are for a sample of imports of medical devices that represent a very small portion of the EU's total imports of medical devices (an estimated 16% as of 1995).

**Table 4:** Impact of SDOC on market entry and trade intensity – Class I medical devices

SDOC	Market entry	Trade intensity
	Marginal Effects	Kennedy
intra-EU	-	<b>35%</b>
extra OECD	-	<b>20%</b>
extra non OECD	<b>6%</b>	<b>79%</b>

Note: Non-significant coefficients are not shown. Since a dummy variable cannot by itself be interpreted in percentage terms, we use the method of transformation suggested by Kennedy (1981). See explanation in Annex 6.

*Country specific analysis*

79. As the next step of inquiry, we looked for statistical evidence that the impact of SDOC introduction on trade depends on the nature of the CA regimes that previously were in place in different national markets, i.e., how burdensome the previous CA procedures were, compared to SDOC.

80. Separate regressions were run for imports of three EU members that are major players in this sector – France, Germany and the UK – to test for possible differences in SDOC impact due to differing national pre-SDOC conformity assessment regimes. These estimations involved a new specification where control group of countries was dropped and a Poisson regression was applied.<sup>33</sup> Results are shown in Annex 12C. Because the model differs from the Heckman procedure used for the previous analysis, the respective results cannot be compared directly.

81. We would expect SDOC to have a positive effect where it replaces a more restrictive CA regime, notably one requiring manufacturers to undergo third-party certification in the market of sale. We know that neither Germany nor the UK required third-party certification for the set of medical devices in our sample. It would seem that transition to SDOC in these cases should not change imports much, and certainly less than where SDOC replaced mandated third-party approval. Because prior national regimes are not well documented it was impossible to identify EU member countries of the latter type, against which the results for Germany and UK could then be compared. Although information about its pre-SDOC regime was unavailable, we decided to include France, another large market, as the third country in this analysis. For ease of interpretation, the figures in Table 5 report marginal effects for estimates obtained:

- For Germany there is a positive and statistically significant effect of SDOC on imports from other EU members and an even larger positive effect on imports from non-EU suppliers: German imports from other EU members increased by an annual average of US\$ 32 026 and from non-EU suppliers by US\$ 87 828. These are not large figures; they are calculated on the basis of the sample mean value, which is not very high because of the presence of zero flows. Taking the mean value of Germany's total (intra + extra-EU) imports for the sample of medical devices over the 10-year period as the base rate, SDOC has had a positive marginal effect of 25%.
- For the UK the marginal effect is also positive (6%) but smaller than for Germany. All of the increase is attributable to non-EU suppliers.
- Total French imports were on average 32% higher, with exporters based in other EU countries being the primary beneficiaries.

---

<sup>33</sup> 'Colony after 45', the instrumental variable used for the Heckman model, is not relevant for the country case analysis. The control group of countries was omitted because it comprises only distant countries (Japan, Australia and United States), which for some regressions run caused the coefficient of the distance variable in the gravity equation to turn positive. For the SDOC variable, versions of Poisson run with and without control groups showed similar results.

**Table 5:** SDOC impact on selected EU members – Class I Medical devices

<b>Country</b>	<b>Marginal Effects</b>
<b>Germany</b>	<b>25%</b>
<b>UK</b>	<b>6%</b>
<b>France</b>	<b>32%</b>

Note: For Poisson regression, the percentage value of marginal effects is obtained from the ratio of marginal effects in level on the mean sample value of imports.

82. In summary, all three countries saw increases in imports when SDOC was introduced. Margins vary but all are positive. The estimate for Germany's imports is high; from what is known about countries' pre-SDOC regimes one would have expected margins for Germany and the UK to be similar and relatively small. French imports increased strongly, which suggests that firms faced pre-SDOC CA procedures in this market that were more burdensome than in the other two markets. We note further that France is the only country showing more imports from EU partners than from non-EU countries, and that SDOC left UK imports from EU partners unchanged.

### **3. Machinery**

83. This is the weakest dataset. Unlike the import data for medical devices, the sample of SDOC-eligible machinery products covers a major part of the machinery sector and is large but includes only one control product - sawing /cutting-off machines. While this would not necessarily undermine the robustness of the gravity model, the evolution of intra-EU imports for the relevant period of time – 1993 until 2003 – exhibits a decline around 1993, when the Directive 89/292/EEC entered into force. This can be seen from Figure 3a in Annex 9. This decline is broad based, affecting many subgroups of SDOC-eligible machinery as well as the control product. It is a most unusual evolution that contrasts with the tendency – shown in Figure 3b in Annex 9 – of sustained growth of machinery imports into the control group of countries from the exporting countries included in the sample, except for imports originating in EU members, which remain flat.

84. These diverging EU and control countries' import performances suggest that an event specific to the EU market occurring around the time when the Machinery Directive was adopted, penalised EU trade in this sector, and especially intra-EU imports. The complete model specification involving all types of fixed-effects, control group of products and control group of countries aimed to account for all kinds of possible omitted variables and particular events, to make sure that the SDOC dummy variable only captured the SDOC implementation impact on EU imports. There is no obvious explanation for what may have been responsible for the observed decline, but the consequence is that the gravity model specification does not perform well. The coefficients of the SDOC variables become unrealistically negative. What happened just before the transition to SDOC in the EU machinery market seems to be magnified by the inclusion in our model of import flows into the set of control group countries which exhibit a very different evolution. We therefore run, for the purpose of comparison, another version of the Heckman selection model that excludes the control group of countries.

85. In both versions of the model, the two-stage Heckman estimation procedure is applied to bilateral imports over the period 1993-2003. Like for medical devices, the fixed effects specification of the model takes into account that the Directive 89/392/EEC introduced in the machinery sector comprehensive

regulatory changes alongside SDOC. The results for both versions of the specification are shown in Annex 13.

86. Running the equation with the control group of countries results in a negative and significant effect of SDOC introduction on market entries involving EU suppliers, but no effect for non-EU suppliers. The coefficients of the SDOC variable are also negative and statistically significant in the OLS regression, indicating that both intra-EU and extra-EU import flows declined following the transition to SDOC. Further separation of non-EU countries reveals that SDOC brought non-OECD suppliers benefits, easing entry into the EU market and intensifying EU members' imports from these countries.<sup>34</sup> The contrast between groups of trading partners is particularly pronounced for existing imports; here the impact of SDOC on OECD countries and intra-EU imports is negative or strongly negative.

87. Expressed as marginal effect, the switch to SDOC decreased by 19% the probability of imports from other EU partners taking place, i.e. that new market entries occur. The negative effect of SDOC also includes a very substantial average annual decline of existing intra-EU import flows (by 62%) and import flows from non-EU OECD countries (by 32%). This decline is offset by growth in imports from non-OECD suppliers (43%) (see Table 6).

**Table 6:** Impact of SDOC on market entry and trade intensity – Machinery  
(with control group of countries included)

SDOC	Market entry	Trade intensity
	Marginal Effects	Kennedy
intra-EU	<b>-19%</b>	<b>-62%</b>
extra OECD	<b>-3%</b>	<b>-32%</b>
extra non OECD	<b>7%</b>	<b>43%</b>

Note: Since a dummy variable cannot by itself be interpreted in percentage terms, we use the method of transformation suggested by Kennedy (1981). See explanation in Annex 6.

88. When control group countries are omitted from the equation, coefficients for the SDOC variable improve for imports from all three groups of source countries, producing results shown in Annex 13c and in Table 7 below that are more in line with the trade-facilitating role that theory would predict SDOC to have. Though SDOC is observed to still have had a negative impact on market entry decision for intra-EU flows, this is no longer the case for extra-EU imports (for OECD and non-OECD). For existing import flows (second stage regression), the coefficient of the SDOC variable is positive and significant for extra-EU imports, whereas it is not statistically significant for intra-EU imports. The estimated impact of SDOC on imports from non-OECD countries in this variant of model specification now is even stronger, as the coefficient of the SDOC variable exceeds the value 1.

<sup>34</sup> Prior to SDOC implementation, the Czech Republic, Slovakia and Vietnam exhibit zero trade flows at the aggregate level of trade for the machinery product in the sample.

89. In conclusion, the decision to include a control group of countries or not has a significant impact on the regression results for machinery. When variants of the specification were run for the other sectors, RTTE and medical devices, the SDOC coefficients remained much more stable.

**Table 7:** Impact of SDOC on market entry and trade intensity – Machinery  
(without control group of countries: Australia, Japan and USA)

	Market entry	Trade intensity
	Marginal Effects	Kennedy
intra-EU	<b>-13%</b>	-
extra OECD	<b>4%</b>	<b>66%</b>
extra non OECD	<b>12%</b>	<b>217%</b>

#### *Country specific analysis*

90. We again examine specific EU member cases – here France, Germany, Italy and the UK – to test for differences in SDOC effect on individual countries' imports. The difference in results for the overall analysis due to the choice of the model specification (with or without control group countries) is also found in the country specific analysis: SDOC impact is significant and negative when the control group of countries is included and significant and positive when these countries are omitted. Here only the results of the Poisson regression estimations omitting the control group of countries are presented. Results of the regression including the control group of countries are shown in Annex 14.

91. One would expect to find differences in impact at the country level given that, for example, Germany had a third-party CA regime prior to harmonised transition to SDOC across the EU in 1993, whereas the UK is known to have had a liberal CA regime. In other words, for Germany, imports should increase from all source countries, whereas we might expect UK imports to rise by less or not significantly. Information about the pre-SDOC CA regimes of France, Italy and Spain was unavailable.



**Table 10:** SDOC impact on individual EU countries – Machinery

<b>Country</b>	<b>Marginal Effects</b>
<b>Germany</b>	<b>30%</b>
<b>UK</b>	<b>-</b>
<b>France</b>	<b>36%</b>
<b>Italy</b>	<b>37%</b>

Note: For Poisson regression, the percentage value of marginal effects is obtained from the ratio of marginal effects in level on the mean sample value of imports. Non-significant coefficients are not shown.

92. The results of the Poisson regression confirm the hypothesis: SDOC had no statistically significant effect on UK imports. The significant increase in Germany's imports is also consistent with what one would expect given Germany's previous policy of third-party certification. The baseline being the means of the value of a country's imports from all sources for the sample of machinery products, Germany imported 30% more each year after 1993, when SDOC became effective. We have no information about the pre-SDOC regimes of France and Italy, but the strong and similar marginal effects in both cases would be consistent with pre-SDOC regimes of the third-party certification type. Combined imports from non-EU and EU countries into the two countries rose by 36% and 37%, respectively (Table 10).

## **VII. Conclusions**

93. The objective of this study was to test for the impact of SDOC on imports into the markets of the European Union. In theory SDOC should facilitate trade by virtue of lowering firms' (fixed and variable) costs of exporting. The study draws on estimation procedures used in other recent work interested in the potential trade effects of other regulatory policies in the TBT field. Several findings emerge from this first attempt to more firmly assess the impact of SDOC on trade.

94. First, introduction of SDOC in the EU region was indeed one factor that influenced positively the evolution of imports during the time period studied. Results from the two-stage Heckman estimation show that replacement by SDOC of CA regimes that EU members applied to RTTE and Class I medical devices and that on average were stricter, made trade easier. For the products studied, the switch to SDOC enabled trade (imports) of SDOC products among country pairs that did not trade these products before, and it raised the level of trade that already existed. The situation for machinery is less clear; we have less confidence in the estimates obtained because of the peculiar behaviour of the EU machinery market, which renders the coefficients of the SDOC variables unstable across alternative equations.

95. Second, the regression analysis reveals an intriguing feature of the import behaviour observed. While the EU's SDOC policy applies without discrimination to all producers, regardless of where they are located, the impact varies across different groups of source countries. Imports from non-OECD (developing) countries have benefited most.

96. Third, the regression analysis confirms that bilateral trade flows between EU markets and with extra-EU countries are influenced by a host of factors other than SDOC, some of which were explicitly taken into account in the specification of the gravity equations. These were however not the variables of prime interest to this study.

97. The results from both the first stage selection and second-stage regression of the Heckman model indicate that SDOC has facilitated non-EU countries' entry of EU markets for eligible RTTE and Class 1 medical devices, and that in particular firms located in non-OECD (developing) countries have rather consistently profited from the EU-wide switch to SDOC in all three sectors. This lends support to the notion that the testing and other requirements of the national CA regimes previously in place created important fixed costs that effectively acted as a barrier to exporting. Such costs do not vary with the volume exported to a foreign market, but they can deter firms from pursuing sales opportunities abroad. SDOC appears to have lowered firms' fixed costs.

98. The evidence in this paper furthermore suggests that SDOC affects firms' variable costs more than their fixed costs. This is because while new market entries occurred, this response is weaker than the positive change found for already existing imports. Results from second-stage OLIS regressions confirm that the introduction of SDOC created more export opportunities for countries with firms already supplying EU markets. Here again, there was a very favourable impact of SDOC on imports from non-OECD (developing) countries, which emerge as clear winners from the change of the CA system. For extra-EU OECD countries and for intra-EU trade, results tended to be positive and statistically significant, but less consistently so - e.g., SDOC facilitated imports from OECD countries of eligible medical devices, but not of RTTE, and it contributed to higher intra-EU imports of RTTE and medical devices, but not machinery. This observed stronger impact on the level of existing imports differs from what Baller (2007) found in her study of MRAs. SDOC apparently has only a modest influence on a firm's decision whether it should enter a market, but once a supplier has entered a market SDOC makes a difference and strengthens sales. In the case of MRAs Baller found the market entry effect to dominate.

99. The question whether firms actually adjust their practices of demonstrating conformity with given requirements in ways that would allow them to take advantage of the cost savings that the CA regime change offers is answered affirmatively by the results of this study. This clearly happened in the case of the EU's SDOC initiative, an additional incentive perhaps being that SDOC was introduced EU-wide so that potential gains were amplified by the prospect of further gains resulting from selling to a unified large market. Note also that the size of cost savings and hence the trade facilitation potential depends on the magnitude of the regime change. As this paper has explained, SDOC regimes can vary greatly in their complexity, and the EC opted for a relatively simple form of SDOC, which replaced national regulations that on average were more restrictive. The analysis of individual Member States' imports of medical devices and machinery represent the first attempt to formally estimate how variation in the magnitude of regime change affects the trade response.

100. That the estimation results of the Heckman model show that the trade effects vary depending on the different groups of exporters and that the difference is particularly strong for OECD and non-OECD countries does not appear to be consistent with a policy measure (SDOC) that by design is non-preferential. Logic and non-statistical evidence may offer some help in understanding why the variations have emerged.

- It is widely accepted that in what is sometimes called the SQAM field (Standards, Quality, Accreditation, Metrology) the technical infrastructure in developing countries is weak, and that its poor quality constitutes a barrier to development. In many technical assistance programmes, the SQAM field is an identifiably separate field for aid. While SQAM infrastructure remains poor, complex processes of conformity assessment will be harder to master for local producers than for producers in more developed markets. The problem is compounded when mandatory third-party conformity assessment is coupled with the requirement to use a conformity assessment body (CAB) in the destination market: for suppliers from most OECD member countries at similar stages of development, it will be relatively easy to develop a relationship with a highly competent CAB in another country - not so for a developing country supplier. The removal of mandatory

third-party CAB in a destination market will therefore be an even greater benefit to a developing country supplier who did not have the capability to master it in the first place.

101. That argument, however, does not explain why imports between EU countries would be affected differently by SDOC than imports coming from other OECD countries outside the region – i.e., why exporters located in OECD countries benefit less from SDOC than their counterparts in EU countries.

- A logical explanation for that might be simply that EU suppliers would be generally keener to take advantage of significant new benefits offered *in their home market*, which in many cases will count for a higher proportion of total revenues than for suppliers outside.

102. One less palatable argument may also be mentioned – and indeed sometimes is mentioned – to explain the apparently disproportionate benefit to developing countries: that imports from non-OECD countries into the EU have increased because of widespread rogue practices of manufacturers operating in developing countries. They self-certify compliance with the standards in the EU but in practice may not verify. This way they save most of the costs associated with SDOC and can offer their products at very competitive prices. Concern about the dangers to public safety presented by the abandonment of *ex ante* technical checks by bodies under the direct authority of government in the import market is well known and understood, and is consistent with this fear of rogue practice. We have, however, not come across official records that would indicate that such practices are indeed common in the three sectors studied.

103. A special comment is needed on the results for machinery, which are partly ambiguous and partly contradict the statistical conclusions from the other two sectors. Only for non-OECD (developing) countries are the results for machinery consistent with those for the other two sectors: SDOC can be demonstrated to have led to increased exports by developing countries to the EU. But for intra-EU trade and for imports from OECD countries, the results are ambiguous or negative. No statistical explanation for this exception emerges from the study, and a wider debate may be justified.

104. We do feel, however, that it is possible to offer a logical hypothesis to explain the difference. It is based on the complexity of the other changes to EU technical regulation introduced simultaneously by the same technical regulation which introduced SDOC in this sector: notably, the commissioning of an entire new generation of European standards which may have led in some cases to radical changes in manufacturing processes or documentation even for established, domestic suppliers. The changes were far more complex than those involved in the other two cases in this study – remember notably that in the (admittedly often complex) medical devices sector, this study covered only the simple Class I medical devices, with a relatively limited number of standards. In machinery, on the other hand, several hundred new standards were involved, and the process of identifying the combination standards applicable to a specific product was initially complex, and complicated further by the fact that for many products, product-specific standards took years to develop, forcing suppliers to determine for themselves – or with the help of external specialists – how to meet the – also new – essential requirements of the directive itself. The process of adaptation might have been more disruptive for producers in developed countries than for new suppliers in the developing world, who would have seen the simplification and uniformity across the entire EU as an opportunity rather than a burden.

105. There are two ways in which regulatory complexity affects measurement of the trade impact of SDOC in the case of the EU. First, when SDOC was introduced it *replaced all previous national systems at the same time*; i.e. SDOC was harmonised across the region for applicable product classes. Second, in two of our three sectors the Directives which introduce SDOC also introduce *other changes unrelated to SDOC*, such as the harmonisation of standards. This study's model specification has tried to separate SDOC introduction from its EU-wide harmonisation and from the Directives' other provisions by including a set of products in each sector that are not eligible for SDOC and taking into account also the

imports of three countries that did not join the EU's SDOC initiative. In addition, we have worked with product fixed effects that should also cover effects such as those generated by SDOC harmonisation. These are first estimates, and while we think our model has been well specified, it would be useful to replicate this study for individual countries that have adopted SDOC in the absence of other regulatory changes.

106. Factors such as economic growth and technological developments, have undoubtedly contributed to a significant expansion over the last decade of exports of RTTE and other manufactured products from such countries as Brazil, China and India, which are included in this study's sample of non-OECD countries. But exports from these countries driven by such factors have increased not only with respect to Europe but also with respect to the United States and other major markets of the world. By differentiating the EU from the control group countries and adding country and time fixed effects, the specifications of the gravity equation have controlled for the interference of these factors in the measurement of SDOC impact.

107. The econometric procedures used are appropriate and, with the exception of the machinery sector, the specifications have performed well enough to create confidence about the sign of the coefficients of the SDOC variable. The size of the effect (i.e., size of SDOC coefficients) is best taken as indicative, for two reasons:

- First, the effect of SDOC is for the set of (SDOC and non-SDOC) products included in the study, and the specific products covered could explain the big effects observed for SDOC in our estimations. Import behaviour in other sectors could be different, although it would be reasonable to expect to find SDOC having a positive effect where the transition is from a more restrictive regime.
- Second, the gravity model is most widely used and has proven itself when modelling uses bilateral flows of trade at the aggregate level. Here, it was applied to trade in product segments in three sectors, making use of highly disaggregated trade data. Other empirical work has shown that the gravity model remains a useful analytical tool even at a disaggregated level of trade; however, disaggregation heightens the sensitivity of explanatory variables and this may lead to surprising results. This warrants caution not to take the magnitude of the coefficients of the SDOC variable at face value. At this time it is not possible to provide external tests for our estimates, as other studies assessing SDOC's trade effects are nonexistent to our knowledge.

## BIBLIOGRAPHY

- Asia-Pacific Economic Cooperation (2006), Report on case study to clarify effectiveness of Mutual Recognition Agreements (MRAs). Submitted by Japan to Sub-Committee on Standards and Conformance Meeting Da Nang, Viet Nam, 8-9 September 2006, 2000/SOM3/SCSC/006.
- Baller Silja (2007), Trade effects of regional standards liberalization: A heterogeneous firms approach, World Bank Policy Research Working Paper 4124, February.
- Bogers Mark, DG Enterprise, European Commission, (2000), The Radio and Telecommunications Terminal Equipment Directive (1999/5/EC) – Addressing a globalising sector. Powerpoint presentation October 2000.
- Chen, Maggie Xiaoyang and Mattoo, Aaditya (2004), Regionalism in standards: Good or bad for trade? World Bank Policy Research Working Paper 3458, October.
- Communications Industry Association of Japan (CIAJ) (2001), Comments of 19 June 2001 submitted by the CIAJ to Gazette Notice No. SMSE-016-01 Public Discussion on simplifications to the conformity assessment process for telecommunications terminal equipment, April 24, Canada.
- Consumer Research Associates, Ltd., UK (2007), Certification and marks in Europe. Study commissioned by European Free Trade Association (EFTA). (<http://www.efta.int/content/publications/EFTA-CERTIFICATION%20AND%20MARKS>)
- Crosby Steve, Lucent Technologies (2000), Improving speed-to-market and accelerating technology access through memorandums of understanding, mutual recognition agreements and arrangements and supplier's declarations of conformity, GSC6/RAST9, Sapporo, Japan, 29 August-1 September 2000, 4 ([http://www.tc.or.jp/e/external\\_relations/gsc/gsc6/contents/pd38.pdf](http://www.tc.or.jp/e/external_relations/gsc/gsc6/contents/pd38.pdf))
- Döfnäs, Per (2005), A manufacturer's experiences: Transition to SDoC in the IT/Telecom sector in the European Communities, Telefonaktiebolaget LM Ericsson. Presentation to the WTO TBT Workshop on SDoC, 21 March 2005 ([http://www.wto.org/english/tratop\\_e/tbt\\_e/sdocdofnas\\_e.ppt](http://www.wto.org/english/tratop_e/tbt_e/sdocdofnas_e.ppt))
- Eucomed Medical Technology (2007), Competitiveness and innovativeness of the European medical technology industry. Evaluation of the survey results. Brussels, Belgium, 30 May 2007. (<http://www.eucomed.org/press/~media/pdf/tl/2007/portal/publications/compsurvey.ashx>)
- European Commission (2007), "EnginEurope": For a thriving European Mechanical Engineering industry in the 21<sup>st</sup> century. Report and recommendations of the "EnginEurope" high-level discussion group, Brussels.
- European Commission (1998), The Single Market Review. Subseries III: Dismantling of barriers, Vol. 1: Technical barriers to trade, Brussels.

- European Communities (1999), Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:091:0010:0028:EN:PDF>)
- European Communities (1993), Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, Brussels (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF>)
- European Communities (1989), Council Directive of 14 June 1989 on the approximation of the laws of the Member States relating to machinery Directive 89/392/EEC. (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31989L0392:EN:HTML>)
- Eurostat (2007), European business: Facts and figures, Statistical books, 2007 edition.
- Fliess, Barbara and Schonfeld, Raymond (2006), Trends in conformity assessment practices and barriers to trade: Final report on survey of CABs and exporters, OECD Trade Policy Working Paper No. 37, OECD, Paris.
- Heckman, J.J. (1979), Sample selection bias as a specification error, *Econometrica*, 47, p. 153-161.
- Hogan & Hartson LLP (2003), The Economic Impact of Mutual Recognition Agreements on Conformity Assessment: a review of the costs, benefits, and trade effects resulting from the European Community's MRAs negotiated with Australia and New Zealand. Prepared under contract for the European Commission.
- International Organisation for Standardization (ISO) and International Electrotechnical Commission (IEC) (2004), Conformity Assessment – Supplier's Declaration of Conformity, ISO/IEC 17050:2004 Parts 1 and 2, Geneva.
- Kennedy, P. (1981), Estimation with Correctly Interpreted Dummy Variables in Semilogarithmic Equations", *The American Economic Review*, Vol. 71 No.4. Ling, David (2005) Supplier's Declaration of Conformity for ICT regulations, Hewlett Packard, presentation to the WTO TBT Workshop on SDoC, 21 March 2005 ([http://www.wto.org/english/tratop\\_e/tbt\\_e/sdocling\\_e.ppt](http://www.wto.org/english/tratop_e/tbt_e/sdocling_e.ppt))
- Linders, Gert-Jan M., and Henri L.F. de Groot (2006), Estimation of the gravity equation in the presence of zero flows, Tinbergen Institute Discussion Paper TI 2006-072/3, Tinbergen Institute, Amsterdam.
- Melitz, Marc J. (2003), The impact of trade on intra-industry reallocations and aggregate industry productivity, *Econometrica*, Vol. 71, No. 6, p. 1695-1725.
- Moenius, Johannes (1999), Information versus product adaptation: The role of standards in trade. Manuscript, Department of Economics, University of California.
- OECD (2007), Communications Outlook 2007, Paris.
- OECD (2006), Final report on private standards and the shaping of the agro-food system AGR/CA/APM(2006)9/FINAL.
- OECD (1992), Telecommunications Type Approval: Policies and Procedures for Market Access, Paris.

- Otsuki, Tsunekiro, Wilson, John and Sewadeh, Mirat (2000), Saving two in a billion: A case study to quantify the trade effect of European food safety standards on African exports. World Bank, Washington, D.C.
- Pammolli, Fabio, Riccaboni, Massimo, Oglialoro, Claudia, Magazzini, Laura, Baio, Gianluca and Salerno, Nicola (2005), Medical devices competitiveness and impact on public health expenditure. Study prepared for the Directorate Enterprise of the European Commission, July 2005.
- Shortall, David (2007), Regulatory reform and market openness: Processes to assess effectively the trade and investment impact of regulation, OECD Trade Policy Working Paper No. 48, OECD, Paris.
- Steg Horst and Thumm Nikolaus (2001), Single-market regulation and innovation in Europe's medical devices industry, *International Journal of Technology Assessment in Health Care*, 17:3 , p. 421-432.
- Swann, Peter, and Temple, Paul (1996), Standards and trade performance: The UK experience. *The Economic Journal*, 106 (438), pp. 1297-1313.
- Vancauteran, Mark (2004), Harmonisation of regulations and trade: Empirical evidences for the European manufacturing sector. Doctorate thesis, Department of Economics, Université Catholique de Louvain, Belgium.
- Wilson John Sullivan (1999), Facilitating access to information technology through Supplier's Declaration of Conformity, paper presented on behalf of the Information Technology Industry Council to The World Trade Organization Technical Barriers to Trade Committee: Symposium on Conformity Assessment Procedures, June 8-9 1999, Washington, D.C.
- WTO, Committee of Participants on the Expansion of Trade in Information Technology Products (2005), Guidelines for EMC/EMI Conformity Assessment Procedures, G/IT/25 17 February.
- WTO Committee on Technical Barriers to Trade (2007), Report on the case study to clarify effectiveness of MRAs. Submission by Japan. G/TBT/W/276, 19 March 2007.
- WTO, Committee on Technical Barriers to Trade (2005), Minutes of the meeting of 22-23 March 2005. G/TBT/M/35, 24 May 2005.
- WTO Committee on Technical Barriers to Trade (1998), Conformity assessment procedures: Supplier's declaration of conformity. Contribution from the United States. G/TBT/W/63, 7 April 1998.

## ANNEX 1: SDOC - WIDER PUBLIC POLICY ISSUES

1. The case for extending the use of SDOC is based largely on the belief that it makes international trade easier, by avoiding or eliminating burdens which would otherwise exist in the form of requirements for third-party conformity assessment. The focus of this study – to determine whether there is any statistical evidence of improvements in trade flows following SDOC introduction – is not intended to minimise or ignore the broader public policy issues which may be raised by the introduction of SDOC.

2. Most notably, the use of SDOC eliminates a form of independent *ex ante* control of products: controls applied before a product reaches the market, as distinct from *ex post* controls applied after a product reaches the market. Governments can be understandably reluctant to abandon *ex ante* controls in cases where potential hazards to people or to the environment are significant.

3. It is not the task of the present study to propose the optimum balance between *ex ante* and *ex post* controls, but it may be helpful to offer the following comments:

- Regulatory authorities in different countries may reach widely different conclusions on when and where *ex ante* controls are justified, as the following examples illustrate:
  - The examples have been frequently quoted of electrical products and automotive products, where the EU and the USA have – in each case – adopted opposite positions: for most household electrical products, the EU requires no *ex ante* controls while the USA does, while in the automotive sector the positions are reversed.
  - A separate example comes from the 2007 case in which several million toys were withdrawn from the market in the USA and the EU by a supplier, on the grounds that safety limits for lead in paint had not been respected. In the main markets affected, the products had benefited from SDOC. At least one government outside Europe and North America is known to have publicly announced that consumers on its own territory were not subject to the same risk precisely because the government in question had rejected SDOC in favour of *ex ante* third-party inspection. It may also be noted, however, that the EU re-examined its own toy safety regulations after the 2007 product withdrawals, and concluded that a general change in the SDOC regime was not necessary
- Two regulatory tools are frequently cited as necessary to support an SDOC regime: effective *ex post* market surveillance, and dissuasive product liability regulation to penalise suppliers of non-compliant products. The absence of one or both of these tools is sometimes cited as a reason for maintaining independent *ex ante* controls. In other words, *ex ante* and *ex post* controls can be considered to be alternatives in some cases – though not in all, because in the most sensitive areas both may co-exist, such as in sensitive medical applications. There is no international standard which specifies the “right” level of control under either heading, and therefore objective comparison of their relative costs and effectiveness is difficult or impossible.

4. The proof of economic benefits from the introduction of SDOC has so far focussed on evidence from the supply side. The OECD itself has undertaken studies of the burdens to business created by



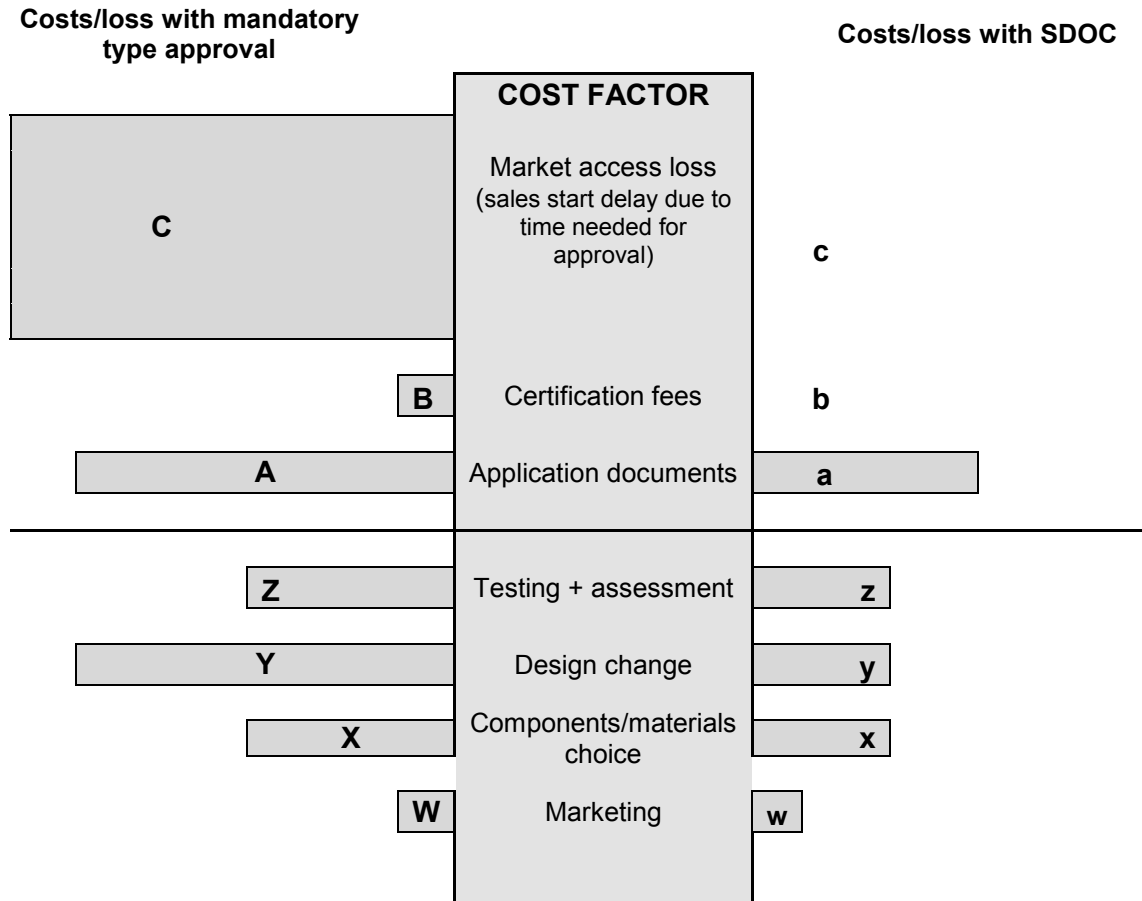
divergent rules for standards and/or conformity assessment, and has concluded that those rules increase cost and reduce innovation by creating delays in time-to-market for new products. While some governments regard a reduction in unnecessary administrative burden as a valid objective in its own right, it is difficult to prove conclusively, in a given case, that the resulting benefits to business are in fact passed on to consumers: the effect of such reductions may be indirect rather than direct.

## ANNEX 2. EXAMPLES OF USE OF SDOC

Country	Year	Product category*
Australia/New Zealand	late 1990s	Telecommunications equipment, computers and computer peripherals
Brazil	2001-2006	Disposable cigarette lighters, installation systems for vehicle natural gas, steel profile for power transmission
Canada	1950s	Broadcasting equipment
	1971	Motor vehicles and components
	1980s	Low-risk radio equipment
	2002	Telecom terminal equipment
EU	1990	Toys
	1992	Personal protective equipment
	1995	Medical products (Class I)
	1993	Machinery
	1996	Electrical/electronic products
	1996	Recreational craft
	1996	Equipment for use in potentially explosive atmospheres
	2000	Radio and telecom terminal equipment
Japan	2004	Certain radio and telecommunication terminal equipment
Korea	2003	Automotive sector
	2007	Certain low-risk consumer products (47 items)
Taiwan	2002	19 items mainly parts or accessories of IT products such as electronic calculators, hard disk devices, storage units and power supply
United States	1966	Motor vehicles and motor vehicle equipment
	1999	Computers and computer peripherals
	2001	Telecommunications terminal equipment

\* Where broad product categories are mentioned, SDOC may apply only to certain subcategories of product.

**ANNEX 3. CONCEPTUAL MODEL OF SDOC ECONOMIC BENEFITS**



Source: Comments of 19 June 2001 submitted by the Communications Industry Association of Japan (CIAJ) to Gazette Notice No. SMSE-016-01 Public Discussion on simplifications to the conformity assessment process for telecommunications terminal equipment, April 24, 2001, Canada. **Using the CIAJ conceptual model, total SDOC economic benefits = (A+B+C) plus (W+X+Y+Z) minus (a+b+c) minus (w+x+y+z).**

## ANNEX 4: PARTIAL LIST OF POSSIBLE VARIANTS OF SDOC

	No registration with a competent authority	Registration by manufacturer regardless of location	Registration by importer or representative in country of import
No test reports or documentation beyond SDOC	Toy Directive 88/378, Art. 8.1.b (test reports only where relevant) ITA TYPE 4	ITA TYPE 3	
Test reports		ITA TYPE 3	
Test reports by accredited laboratory	Disposable lighters (Decision 2006/502) ITA TYPE 2	ITA TYPE 1	
Technical file	Machinery Directive 89/392/EEC and 98/37/EC, Art. 8.2.a [test reports required <i>where [the relevant standard] requires that</i> ]		Medical devices Class I. Directive 93/42, Art. 11.5 and Art. 14.1
Technical file + test reports	Telecommunications terminal equipment 1999/5, Art. 10.3 Machinery Directive and Toy Directive (see above – test reports <i>where relevant</i> )	Cosmetics, Art. 7a.1 and 7a.4 (+ requirement that tests respect principles of GLP, but without formal accreditation requirement)	
Technical file + test reports by accredited lab			

Note: A full presentation of variants of SDOC would be very large: perhaps around 50 could be identified relatively easily. This table does not aim to be exhaustive, but to illustrate the complexity. Variants ignored in the table include 1) fees for registration where that is necessary, and 2) liability or other responsibilities of importers in the importing country. The references to EU Directives are solely to the products in those directives that are covered by SDOC. In some cases, limited category products lie outside the scope of SDOC and are not covered.

## ANNEX 5. THE EC'S REGULATORY REGIME FOR THE PRODUCTS STUDIED

### a) Medical Devices

1. The global market for medical devices is dominated by the USA, the EU and Japan. One study<sup>35</sup> shows that those three countries/regions account for around 85% of a global market estimated at around €185 billion. In the EU, the most important markets are Germany and France. The EU exports a majority of its production. The sector is rather fragmented and dominated by SMEs, most of them with fewer than 50 employees. A recent EU study estimates total employment in the sector at 435000, spread over 11000 companies, or an average of around 40 employees per company.<sup>36</sup>

2. The EU medical devices market has in recent years seen an increase in the volume and quality of devices and components manufactured in Asia. A growing number of companies have moved aspects of their business to Asia to take advantage of lower operating costs. It is reported that one disadvantage of manufacturing in Asia is that distribution costs to the EU market are high, but that the significantly lower overheads and wages levels in Asia to more than compensate for this. Competition notably from manufacturers in Asia has increased in recent years. Products from Asia used to be mostly commodity items (such as drapes and gowns or single-use surgical devices), but an increasing acceptance of more complex devices manufactured outside the EU and United States has been noted in recent years.

### Medical devices subject to SDOC in EU

3. Because the benefits of medical devices are almost invariably accompanied by certain attendant risks, product utilisation is often of regulatory concern and the sale of devices is controlled by public health authorities. Literally thousands of types of products are regulated as medical devices, ranging from simple dental fillings and bandages to complex and life-sustaining implantable devices such as pacemakers and heart valves. National regulatory regimes can differ in device classifications, product requirements and approval systems – as was the case in the EU prior to the harmonisation initiative launched in the 1980s.

4. EC regulation of medical devices grew out of the adoption in the mid-1980s of the so-called New Approach legislation, a programme launched in the mid-1980s and which grew steadily to cover over 20 product sectors by the end of the 1990s, including medical devices.

5. Since January 1995, all medical devices sold in the EU must meet the requirements of the *Medical Devices Directive, 93/42/EEC (MDD)*. Together with the Active Implantable Devices Directive 90/385/EEC and the in vitro diagnostic devices Directive 98/79/EC, MDD has created a Europe-wide harmonised system for the safety approval and control of medical devices. The New Approach regulation, under which the directives governing medical devices fall replaces the different regulation systems on the national level, which created barriers to free movement of such devices within the EU's internal market.

---

<sup>35</sup> [http://ec.europa.eu/enterprise/medical\\_devices/c\\_f\\_f/md\\_final\\_report.pdf](http://ec.europa.eu/enterprise/medical_devices/c_f_f/md_final_report.pdf). The report was prepared for the European Commission.

<sup>36</sup> [http://www.eucomed.be/sitecore/shell/Controls/Rich%20Text%20Editor/~media/pdf/tl/2007/portal/publications/comp\\_survey.ashx](http://www.eucomed.be/sitecore/shell/Controls/Rich%20Text%20Editor/~media/pdf/tl/2007/portal/publications/comp_survey.ashx)

The Directive sets forth essential requirements that all medical devices placed on the EU market must meet.

6. In order to meet the Directive, manufacturers must (1) determine the class of their product, (2) comply with the essential requirements, (3) issue a Declaration of Conformity, (4) implement the appropriate conformity assessment scheme, and (5) apply the CE marking.

7. Medical devices are categorised by risk, and the regulatory requirements increase with attendant risk increase. In the case of the EU, the more risky or complex the device, the higher the class. The higher the class, the more complex the compliance procedure for the manufacturer. This is because the degree of external intervention by a notified body varies according to the classification of the device. As in the case of other New Approach directives, the compliance procedures are drawn from a set of standardised modules that are part of the so-called global approach.

8. *Class 1 medical devices* are the simplest devices with the lowest overall risk to the user and patient. They are in turn subdivided into 4 main categories: (1) devices which are non-sterile and have no measuring function; (2) non-sterile devices with a measuring function; (3) sterile devices with no measuring function; and (4) sterile devices with a measuring function. With rare exceptions, Class I devices are non-invasive and low-risk.<sup>37</sup>

9. Only category (1), *Class 1 medical devices*, require no intervention by a notified body and are subject to SDOC.<sup>38</sup> This means that for this lowest class of devices the manufacturer<sup>39</sup> does not need a certificate issued a third party but certifies himself that the device conforms to the requirements of 93/42/EEC (for *performance* and for *quality system*).<sup>40</sup> The company must also register with the regulatory authorities as a manufacturer of Class 1 devices. This is the simplest compliance process and consequently the simplest (and likely also quickest) way for placing a product on the EU market. The manufacturer must apply a CE mark to the device to demonstrate compliance with the MDD, but this will not have an associated notified body number. The CE mark makes the product valid for use in any of the Member states or other countries which recognise the European system (e.g. EFTA countries).

10. Responses from surveys of the EU medical device industry<sup>41</sup> show a general positive evaluation of the Directive's overall effects, in terms of easier access to the European markets since market introduction is now possible in all European countries at the same time.

---

<sup>37</sup> The official definition of Class I products appears in Annex IX of the MDD 93/42/EEC.

<sup>38</sup> Categories (2), (3) and (4) require Notified Body certification for the sterility and/or measuring aspects of the device.

<sup>39</sup> A company that places a device on the EU market under its name is considered the "manufacturer" according to the MDD. That company is responsible for the conformity assessment even if it contracts the manufacturing and/or design and development of its product to another firm.

<sup>40</sup> If the product is *sterile* or has a *measuring* function, an application must first be made with a Notified Body. The notified body will assess those sterile or measuring elements. The extent of the assessment will depend on the circumstances.

<sup>41</sup> See Horst Steg and Nikolaus Thumm, Single-market regulation and innovation in Europe's medical devices industry, *International Journal of Technology Assessment in Health Care*, 17:3 (2001), p. 421-432. A more recent study by Eucomed with similar conclusions is on <http://www.eucomed.be/sitecore/shell/Controls/Rich%20Text%20Editor/~media/pdf/tl/2007/portal/publications/compsurvey.ashx>

11. This study takes sample categories from statistical calculations used in trade which can reasonably be associated with Class I products as defined in the medical devices directive.

**b) Radio and telecommunications terminal equipment (RTTE)**

12. *Radio equipment* enables wireless communication using radio frequencies and containing a transmitter and/or a receiver. Examples are mobile phones, satellite terminals, CB equipment, broadcast transmitters, and cordless telephones. *Telecommunications terminal equipment* is equipment intended to be connected to an interface of a public telecommunications network. Examples are cord-connected telephones, answering machines and modems.

13. In the OECD region this sector has benefited from continuous growth and rapid technological innovation. RTTE revenues surpassed US\$1 trillion in 2005, with markets expanding and revenues increasing each year since 1980. The wireless market has grown particularly rapidly, becoming one of the most important revenue generators for telecommunications firms.

14. The value of OECD countries' global trade in RTTE has grown by 65% in the past eight years, offering consumers an increasing variety of products and leading to increasing specialisation of firms involved in the manufacture of these products, to extended networks of subcontractors and hence fragmentation of production across the globe. Intra-OECD imports rose by 72% between 1996 and 2004, and OECD imports from non-member countries rose even faster (112%).<sup>42</sup>

15. As far as the EU-27 market is concerned, in 2004 around 28 500 enterprises operated in this sector and Germany, France, Finland and the UK were in the leading contributors of the EU's total value added. The EU features a trade deficit for radio, television and communications equipment. In 2006, imports of equipment from non-member countries into the EU-27 were valued at €100 billion, the majority of this coming from Far East Asian countries like China, South Korea and Japan. Intra-EU imports accounted for a small majority (54%) of the value of total EU (intra and extra-EU) RTTE imports. The UK and Germany were the main traders accounting for a combined share of 42% of the value of EU-27 (intra and extra-EU) exports, and 38% of their imports.<sup>43</sup>

16. Prior to EU harmonisation, radio and telecommunications terminal equipment was regulated through a mix of a limited number of EU Common Technical Regulations (e.g. for electromagnetic compatibility, electrical safety) and more than 1000 national market entry approval regimes - diverging administrative provisions, technical requirements setting out detailed performance parameters and CA procedures, which hampered movement across the EU market.<sup>44</sup> A first phase of harmonisation was introduced in 1991.<sup>45</sup> This took an important first step towards rationalisation: notably, it established the basis for harmonisation of standards, and it swept away the monopoly rights of national telecommunications authorities to authorise telecommunications equipment. But it left third-party conformity assessment as a requirement.

---

<sup>42</sup> The information in this and the preceding paragraphs is taken from *OECD Communications Outlook 2007*, OECD, 2007, Chapters 1 and 8.

<sup>43</sup> *European business: Facts and figures*, Eurostat, Statistical books, 2007 edition.

<sup>44</sup> Mark Bogers, DG Enterprise, European Commission. *The Radio and Telecommunications Terminal Equipment Directive (1999/5/EC) – Addressing a globalising sector*, powerpoint presentation October 2000.

<sup>45</sup> Directive 91/263/EEC

## Equipment subject to SDOC in EU

17. The Directive that is the focus of this study followed that first step. On April 8, 2000 the *Radio Equipment and Telecommunications Terminal Equipment Directive (R&TTE Directive 1999/5/EC)* came into effect and removed the old system of national market access controls (type approval). With some minor exceptions<sup>46</sup>, the directive covers all terminal equipment and all radio equipment. It moved standards harmonisation one stage further forward, and substantially deregulated conformity assessment. It prescribes essential requirements (health and safety) that equipment has to comply to before it can be placed on the market in the whole of the Community. Non-radio telecoms terminals need to meet requirements for electrical safety and EMC. Radio equipment also must avoid harmful interference. Member states can set additional national approval requirements only in exceptional circumstances.

18. In 1999, the introduction of SDOC, and the removal of mandatory third-party type approval, was central to the changes. Even if there were some other very minor changes,<sup>47</sup> the change to SDOC dominated, and this directive can therefore be considered the “purest” case of a transition to SDOC in this study.

19. A Commission decision of April 2000 distinguishes between RTTE which can be placed on the market and be put into service without restrictions whatsoever (defined as Class 1) and RTTE for which Member States apply restrictions (defined as Class 2). Class 1 comprises several subclasses covering terminal equipment, receive-only radio equipment, and radio equipment which transmits under the control of a network.

20. For Class 1 equipment self-declaration as defined by Annex II applies. The manufacturer himself can ensure that the product meets the requirements of the directive and involvement of a notified body is not mandatory. He may of course, if he wishes to do so, involve the services of test laboratories, in which case he can freely decide which ones to use; they do not have to be accredited. The manufacturer makes a written Declaration of Conformity. A copy of the Declaration must be included with the product and the appropriate CE mark must be affixed to the product, the packaging and the documentation. Furthermore, the manufacturer must compile a technical construction file to enable conformity to be assessed. This file is available for at least 10 years. The manufacturer also ensures the continued compliance of the product, usually through suitable quality control.

21. For radio equipment that uses frequencies where the usage is not harmonised throughout Europe, the services of a notified body will need to be used, either by submitting the technical construction file to a notified body for assessment (Annex IV) or by obtaining certification of the manufacturer’s quality control system for product design, manufacturing and testing by a notified body (Annex V).

---

<sup>46</sup> Some equipment is excluded from the Directive, notably certain marine equipment, traffic management systems, and defence equipment.

<sup>47</sup> For example, for radio transmission products using un-harmonised frequencies, a notification requirement (to competent authorities) was applied. And the precise wording of the *essential [technical] requirements* was modified in the interest of clarity. Those other changes do not affect the central conclusion in this paragraph.



**c) Machinery**

**Machinery subject to SDOC in EU**

22. The definition of machinery in the case in this study is so simple and so broad that it makes statistical classification difficult. The essential definition in the EU's *Machinery Directive (89/392/EC)* is *an assembly of linked parts or components, at least one of which moves*,<sup>48</sup> excluding most products where the only source of power is manual effort, such as scissors. The Directive also excludes a number of sectors subject to separate, sector-specific regulation, such as medical devices, automotive products, and telecommunications products.

23. Despite the difficulty of classification, the importance of machinery to the global economy and to trade is unquestioned. Machinery is often considered to be a central part of what is called the 'mechanical engineering' sector. A recent EU study<sup>49</sup> estimates that the machinery sector in the EU has annual sales of €420 billion, and that that figure represents 41% of the global market, which – by mathematical extrapolation – is therefore estimated at €1 trillion. In Europe alone, the sector has 24000+ companies, employing 2.6 million people in total, and of all sizes; SMEs inevitably make up the majority of companies.

24. The EU Directive in this study introduced a harmonised system of SDOC across most of the sector – once again, excluding specialised sectors such as those listed above. Only a limited list of high-risk machines remains subject to mandatory conformity assessment by a third-party, and even for those formal type-approval is only needed where harmonised standards have not been developed or have not been recognised by the EU authorities. Examples of *high-risk* machines in that sense are circular saws, portable chain-saws, and manually-loaded injection-moulding machines.<sup>50</sup>

25. For those products covered by SDOC under this Directive, a technical file must be made available to competent authorities upon their reasonable request, which must show in detail how the manufacturer or his representative has achieved compliance with the essential safety requirements of the directive.

26. This Directive introduced a comprehensive measure of harmonisation across the sector, and included other measures beyond SDOC: notably, the formal recognition of harmonised standards.

27. Because of the difficulty of isolating products covered by the Directive in statistical classifications, except at the broadest level, this study uses major sample product classifications from trade statistics, that are known to fall under the SDOC regime.

---

<sup>48</sup> The definition appears in Art. 1.2 of Directive 89/392/EC, subsequently consolidated into Directive 98/37/EC, which forms the basis for this case in this study.

<sup>49</sup> [http://ec.europa.eu/enterprise/mechan\\_equipment/engin/engineurope\\_frep.pdf](http://ec.europa.eu/enterprise/mechan_equipment/engin/engineurope_frep.pdf). Some figures for the mechanical engineering sector are higher than this. For example, a study available on [http://ec.europa.eu/enterprise/electr\\_equipment/statistics/index.htm](http://ec.europa.eu/enterprise/electr_equipment/statistics/index.htm) reports production values for Japan, the USA, and the EU alone for the wider mechanical engineering sector at €1.4 trillion.

<sup>50</sup> The full list appears in Annex IV of Directive 98/37/EC.

## ANNEX 6. GRAVITY EQUATIONS

### 1. *The gravity equation*

Measurement of the impact of SDOC implementation on Trade for the three selected sectors is based on the gravity model. This model is derived from the simple gravity equation:

$$M_{ij} = Y_i Y_j / d_{ij} T_{ij} \quad (1)$$

$M_{ij}$  denotes imports to country  $i$  from country  $j$  (in value),  $Y$  represents demand (i.e. GDP),  $d_{ij}$  is distance between the trading partners and  $T_{ij}$  symbolise trade costs.

An estimable version of equation (1) can be written in the log-linear following general form :

$$\ln(\text{imports}_{ijt}) = \beta_0 + \beta_1 \text{sum}(\ln \text{GDP}) + \beta_2 \ln(\text{distance}_{ij}) + \beta_3(\text{contiguity}_{ij}) + \beta_4(\text{colony}_{ij}) + \beta_5(\text{comlang\_off}_{ij}) + \beta_6(C_{ijt}) + \varepsilon_{ijt} \quad (2)$$

where the independent variables are for  $i$  the importing country and  $j$  the exporting country :

- sum of the log of GDP (joint GDP)
- log of the distance between  $i$  and  $j$  ( $\text{dist}_{ij}$ )
- dummies reflecting whether  $i$  and  $j$  : share a common border ( $\text{border}_{ij}$ ), have had a colonial relationship since 1945 ( $\text{col45}_{ij}$ ), have the same common official language ( $\text{comlang\_off}_{ij}$ ) and are both members in a regional trade agreement or of a currency union ( $C_{ijt}$ )
- $\varepsilon_{ijt}$  is the residual error.

As the dependent variable the model uses import values disaggregated for the individual EU members (again with Luxembourg and Belgium data omitted) for the same three product sectors and distinguishes between imports between EU members (intra-EU imports) and imports between EU and non-EU countries (extra-EU imports).

The standard gravity model is augmented with dummy variables controlling for the effects of the introduction of the Euro, for capturing the specific effects of a country-pair belonging to the EU, and for any preferential trade arrangements (customs unions, economic integration agreements, free trade agreements) existing between the countries covered.

The SDOC dummy will discriminate between intra-EU imports and extra-EU imports. Thus,  $\text{SDOC\_intra}$  will be 1 if both countries are members of EU and SDOC is implemented at a given date.  $\text{SDOC\_extra}$  will be 1 if only the importing country is an EU member and SDOC is implemented at a given date.

The gravity equation can then be written as follow:

$$\ln(\text{imports}_{ijt}) = \beta_1 \ln(\text{nominal GDP}_{it}) + \beta_2 \ln(\text{nominal GDP}_{ij}) + \beta_3 \ln(\text{dist}_{ij}) + \beta_4(\text{border}_{ij}) + \beta_5(\text{colony}_{ij}) + \beta_6(\text{comlang\_off}_{ij}) + \beta_7(\text{EURO}) + \beta_8(\text{RTA}_{ij}) + \beta_9(\text{EU}) + \beta_{10}(\text{SDOC\_intra}_{ijt}) + \beta_{11}(\text{SDOC\_extra}_{ijt}) + \varepsilon_{ijt} \quad (3)$$

We also test for the significance of whether the non-EU source country is a member of the OECD, by creating two additional SDOC\_extra dummies: SDOC\_extra\_oecd and SDOC\_extra\_non\_oecd.

Because highly disaggregated trade data (products at HS 6-digit level) are used there are a large number of zero import observations in the data set, notably for imports into the EU from the non-EU countries of the sample.<sup>51</sup> Failing to account for this can bias the estimates.<sup>52</sup> Dealing properly with zero flows requires that the information provided by these flows is taken into account. One way to solve this problem is to use a two-stage Heckman procedure, which first models a selection process where the probability that a country-pair will trade is estimated using a probit estimation, and then uses this information in a second-step estimation of the impact on already existing positive trade flows (Heckman, 1979).<sup>53</sup>

## 2. *The Two-Stage Heckman Selection Model*

From the general equation (3), we derive two equations following the two-stage Heckman Selection Model.

### (i) Heckman selection equation (probit)

The first stage models a selection process where the probability that a country-pair will trade is estimated using probit estimation:

$$\rho_{ijt} = \text{PR}(T_{i,j,t} = 1 \mid \text{observed variables}) = \alpha_i + \alpha_j + \alpha_k + \alpha_t + \beta_1(\text{sumlnGDP}) + \beta_2(\text{Indistwces}) + \beta_4(\text{contig}) + \beta_5(\text{comlang\_off}) + \beta_6(\text{col45}) + \beta_7(\text{RTA}) + \beta_8(\text{EU}) + \beta_9(\text{EURO}) + \beta_{10}(\text{sdoc\_intra}) + (\beta_{11} \text{sdoc\_extra}) + u_{ijt} \quad (4a)$$

<sup>51</sup> For telecom products, for trade between 1995 and 2005, we have 3081 (23.48%) zero flows for country pairs constituting intra-EU country imports, and 10086 (39.67%) zero flows for country pairs constituting imports into the EU from extra-EU source countries and 15763 (33.33%) zero flows for the all sample (with control group of countries included). For medical devices, for trade between 1990 and 2000, the distribution is 3150 (25.05%) zero flows and 9824 (48.04%) zero flows respectively and 15301 (38.41%) zero flows for the all sample (with control group of countries). For machinery, for trade between 1988 and 1998, the distribution is 18058 (32.59%) zero flows and 36710 (54.81%) zero flows respectively and 66184 (43.98%) zero flows for the all sample (with control group of countries included).

<sup>52</sup> Censored or truncated regressions, or replacing zero flows with arbitrary numbers, have been criticised on the grounds that this leads to misleading results, and estimation of the gravity model with OLS suffers from a similar selection bias because OLS estimates only consider non-zero values. See Gert-Jan M. Linders and Henri L.F. de Groot, *Estimation of the gravity equation in the presence of zero flows*, Tinbergen Institute Discussion Paper TI 2006-072/3, Tinbergen Institute, Amsterdam, 2006.

<sup>53</sup> J.J. Heckman, Sample selection bias as a specification error, *Econometrica*, 47, 1979, p. 153-161.

## (ii) Heckman regression (OLS)

In order to ensure the identification of the regression equation, the COL45 (colonial link after 1945 between a pair of countries) variable was dropped from the model, after it was established that this variable is only significant in the first stage. Other variables like WTO and OECD membership were also tested but appeared to be not relevant. Heckman selection bias is corrected by introducing the probabilities estimated in stage 1 of the specification

$$\ln(\text{import}) = \alpha_i + \alpha_j + \alpha_k + \alpha_t + \beta_1 (\text{sumlnGDP}) + \beta_2 (\text{Indistwces}) + \beta_3 (\text{contig}) + \beta_4 (\text{comlang\_off}) + \beta_5 (\text{RTA}) + \beta_6 (\text{EU}) + \beta_7 (\text{EURO}) + \beta_9 (\text{sdoc\_intra}) + \beta_{10} (\text{sdoc\_extra}) + \rho^{es*}_{ijk} + \eta^{es*}_{ijk} + e_{ijk} \quad (4b)$$

where  $\rho^{es*}$  are the predicted probabilities estimated in the first stage and  $\eta^{es*}$  is the inverse Mills ratio which corrects for Heckman selection bias. The predictions as to the direction of effects could be different we have no reason to expect that the direction of the effects of SDOC changes from stage 1 to stage 2. Note however that the interpretation is different to the extent that the first stage explains the impact on the probability that a country begins to export (market entry) and the second stage shows the growth of existing trade flows (trade intensity).

### 3. Interpretation of coefficient

Since a dummy variable cannot by itself be interpreted in percentage terms, we use the method of transformation suggested by Kennedy (1981). Kennedy notes that the correct transformation of a dummy variable is given by the following formula:  $\hat{g} = \exp(\hat{c} - \frac{1}{2}\hat{Y}(\hat{c})) - 1$ , where  $\hat{g}$  is the estimated coefficient of the dummy variable on the dependent variable (e.g., Imports),  $\hat{c}$  is the coefficient on the dummy variable and  $\hat{Y}$  is the variance of  $\hat{c}$ .

### 4. Robustness

Specifications using country-specific and year fixed effects in the regression equation provide robustness checks. Indeed, in the absence of fixed effects, the econometric model cannot control for the heterogeneity of exporters, importers and time so that the estimation is potentially biased (Cheng and Wall, 2005).

We include fixed effects estimators for importing and exporting countries; these country dummies control for unobserved determinants of trade flows that are country-specific and vary over time, and are commonly used in the more recent gravity literature to correct for ‘multilateral trade resistance’ factors.<sup>54</sup> Year fixed effects are added to pick up the effect of any variables affecting bilateral imports that vary over time, are constant across trading pairs and have not been included in the set of independent variables, e.g. the effects of business cycles. Finally, product fixed effects are added to control for determinants of imports that are specific to each product of the sample but unrelated to introduction of SDOC. Product fixed effects should in particular control for “harmonisation” of SDOC and other provisions in the EC’s Directives. If not taken into account, unobserved variables can be expected to directly affect the dependent variable (imports) so it is important to control for them in the models. All the regressions were run with robust standard errors under heteroskedastic conditions.

<sup>54</sup> I.e., the more a country is resistant to trade with all other trading partners, the more it is pushed to trade with a given bilateral partner. Multilateral trade resistance introduces substitutability between trade with a country’s different partners; for example trade between France and Italy depends on how costly it is for each to trade with the other relative to the costs involved for each of them in trading with other countries.

To be sure that we measure the effect of SDOC, we add in a first step a ‘Directive’ variable as a proxy for factors other than from SDOC that emanate from the same Directives that introduced SDOC in each sector, and which may also influence imports. We model the variable for the same date as the SDOC variable. We find colinearity between the SDOC dummy and the Directive variable. Therefore, working at a disaggregated level of products, by augmenting the country and year fixed-effects by product fixed-effects, we feel that the impact of Directive-related factors on the products are well accounted for.

## ANNEX 7. COUNTRIES INCLUDED IN THE DATA SET

<i>Australia</i>	Korea	<u>Non-OECD countries:</u>
<b>Austria*</b>	Mexico	Brazil
Canada	<b>Netherlands*</b>	China
Czech Republic	New Zealand	India
<b>Denmark*</b>	Norway	Indonesia
<b>Finland*</b>	Poland	Israel
<b>France*</b>	<b>Portugal*</b>	Malaysia
<b>Germany*</b>	Slovakia	Philippines
<b>Greece*</b>	<b>Spain*</b>	Russian Federation
Hungary	<b>Sweden*</b>	Singapore
Iceland	Switzerland	South Africa
<b>Ireland*</b>	Turkey	Thailand
<b>Italy*</b>	<b>United Kingdom*</b>	Vietnam
<b>Japan</b>	<i>USA</i>	

Note: All countries shown are exporting countries. Countries shown **in bold** are both exporting and importing countries. “\*” indicates that the corresponding country is a member of EU-12 (or EU-15 after 1995). Control group importing countries are shown **in bold and italics**.

## ANNEX 8. PRODUCTS INCLUDED IN THE STUDY (HS 6-DIGIT LEVEL)

### **Radio and Telecommunications Terminal Equipment: (a) wireless or radio and (b) non wireless communications equipment**

852510 transmission apparatus for radiotelephony etc.  
852520 Idem

851711 Line telephone sets with cordless handsets  
851719 Telephone sets other than above  
851721 Fax machines  
851722 Teleprinters

#### Telecommunications control group:

852610: Radar apparatus  
852691: Radio navigational aid apparatus  
852692: Radio remote control apparatus

### **Group 3: Machinery**

841510\* Air-conditioning machines  
842010 Calendring or rolling machines  
8425 *Pulley-tackle hoists*  
842511 Pulley tackle & hoists other than skip hoists/hoists of a kind used for raising ...  
842519 Pulley tackle & hoists other than skip hoists/hoists of a kind used for raising ...  
842520 Pit-head winding gear; winches specially designed for use underground  
842531 Winches (excl. of 8425.20), powered by elec. motor; capstans, powered by el ...  
842539 Winches (excl. of 8425.20 & 8425.31); capstans (excl. of 8425.31)  
842541 Built-in jacking systems of a kind used for raising vehicles, of a type use ...  
842542 Jacks (excl. of 8425.41) & hoists of a kind used for raising vehicles, hydr ...  
842549 Jacks & hoists of a kind used for raising vehicles (excl. of 8425.41 & 8425 ...  
8426 Cranes  
842611 Overhead travelling cranes on fixed support  
842612 Mobile lifting frames on tyres & straddle carriers  
842619 Overhead travelling cranes (excl. those on fixed support), transporter cran ...  
842620 Tower cranes  
842630 Portal/pedestal jib cranes  
842641 Lifting mach. n.e.s. in 84.26, self-propelled, on tyres  
842649 Lifting mach. n.e.s. in 84.26, self-propelled, other than on tyres  
842691 Lifting mach. n.e.s. in 84.26, designed for mounting on road vehicles  
842699 Lifting mach. n.e.s. in 84.26  
842710 Self-propelled fork-lift trucks  
844400 Machines for extruding, drawing, texturing or cutting man-made textile materials  
845020\* Household/laundry-type washing machines (incl. machines which both wash & d ...  
845811 Numerically controlled lathes  
8501\* *Electric motors and generators*  
850110 Electric motors of an output not >37.5W

- 850120 Universal AC/DC motors of an output >37.5 W
- 850131 DC motors (excl. universal AC/DC motors); DC generators (excl. generating s ...
- 850132 DC motors (excl. universal AC/DC motors); DC generators (excl. generating s ...
- 850133 DC motors (excl. universal AC/DC motors); DC generators (excl. generating s ...
- 850134 DC motors (excl. universal AC/DC motors); DC generators (excl. generating s ...
- 850140 AC motors (excl. of 8501.10 & 8501.20), single-phase
- 850151 AC motors (excl. of 8501.10 & 8501.20), multi-phase, of an output not >750W ...
- 850152 AC motors (excl. of 8501.10 & 8501.20), multi-phase, of an output >750W but ...
- 850153 AC motors (excl. of 8501.10 & 8501.20), multi-phase, of an output >75kW
- 850161 AC generators (alternators), of an output not >75kVA
- 850162 AC generators (alternators), of an output >75kVA but not >375kVA
- 850163 AC generators (alternators), of an output >375kVA but not >750kVA
- 850164 AC generators (alternators), of an output >750kVA
- 860400 Railway maintenance service vehicles

Machinery control group:

- 846150 Sawing/cutting-off machines working by removing metal/cermets

**Group 4: Medical devices Class I**

*3005 Medical gauze, bandages etc.*

- 300510 Adhesive dressings & oth. articles having an adhesive layer
- 300590 Wadding, gauze, bandages & similar articles [see complete text #29]
- 401511 Surgical gloves of vulcanised rubber
- 900140 Spectacle lenses made of glass
- 900150 Spectacle lenses made of other materials
- 901831 Syringes, with / without needles

Medical devices control group:

- 901811 Electrocardiographs
- 901820 Ultraviolet or infra-red ray apparatus

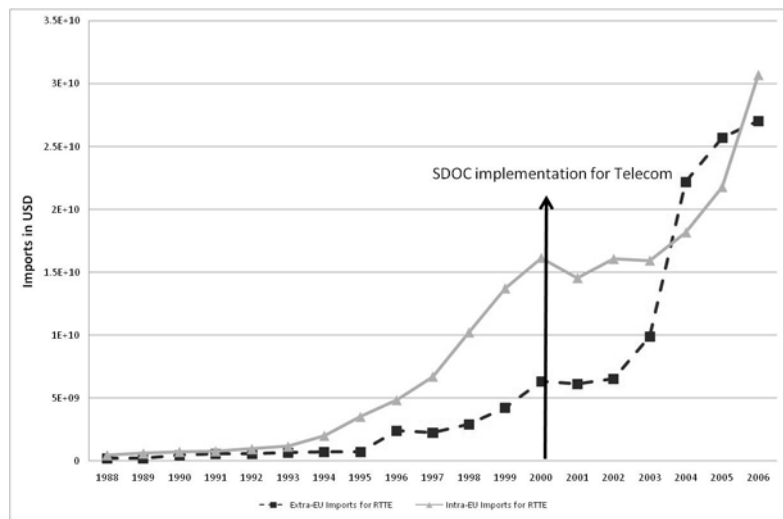
---

\* Asterisked items are items included in the 2006 EU proposal to the WTO (NAMA) as candidates for global use of SDOC.

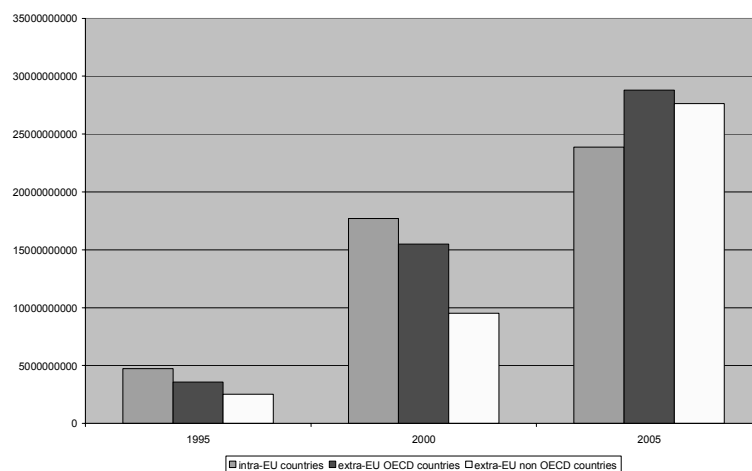


**ANNEX 9: EVOLUTION OF INTRA- AND EXTRA-EU IMPORTS FOR RTTE, MACHINERY AND MEDICAL DEVICES**

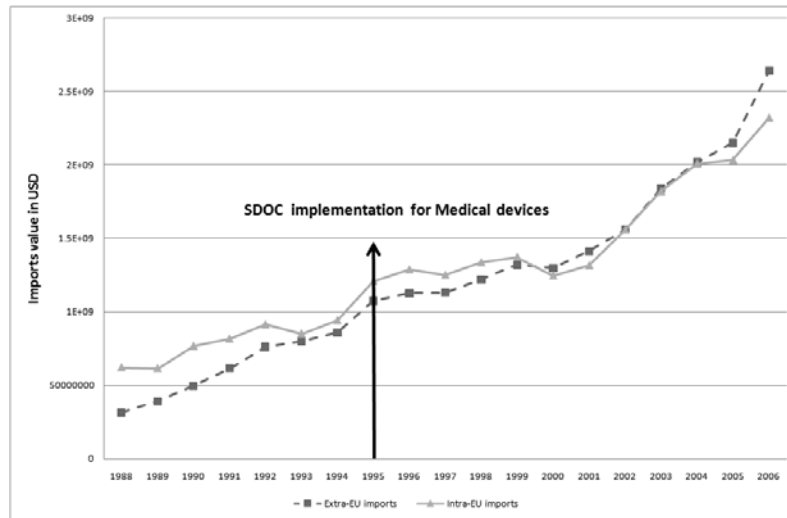
**Figure 1.a. Intra-EU and extra-EU imports evolution of RTTE products (6-digit products) from 1988 to 2006**



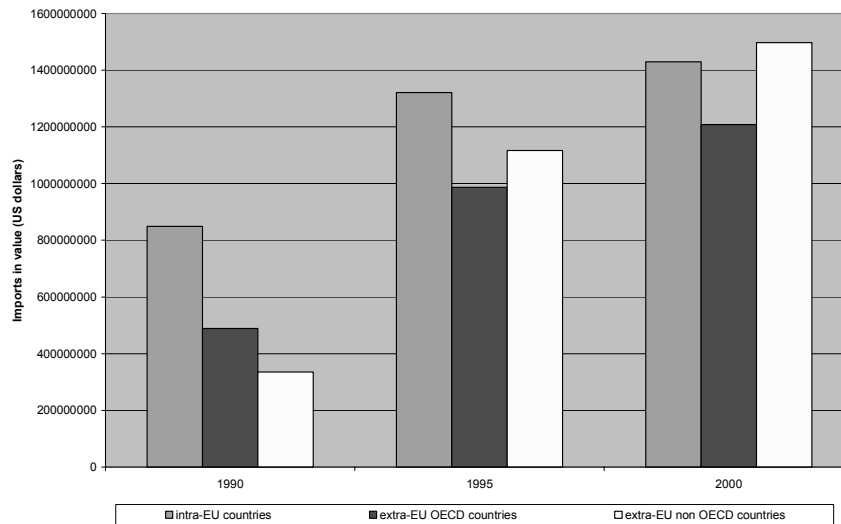
**Figure 1.b. EU imports from intra-EU, extra-EU OECD and extra-EU non-OECD countries of RTTE products for years 1995, 2000 and 2005**



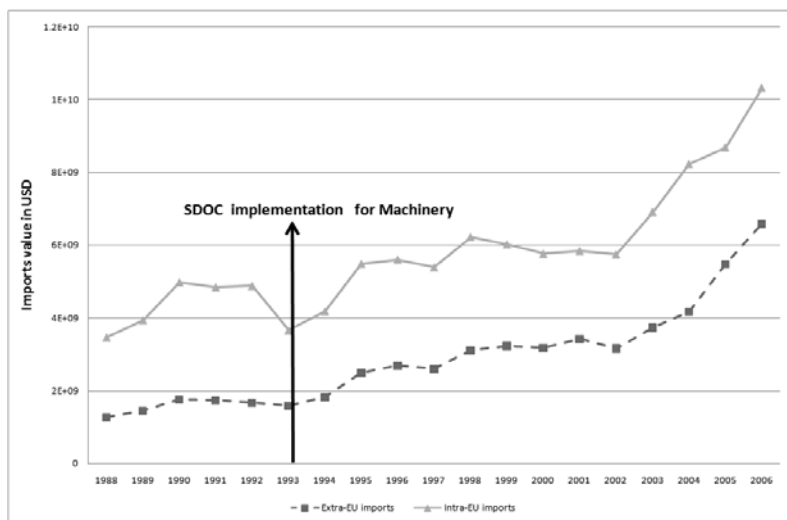
**Figure 2.a. Intra-EU and extra-EU imports evolution of Medical devices products (6-digit products) from 1988 to 2006**



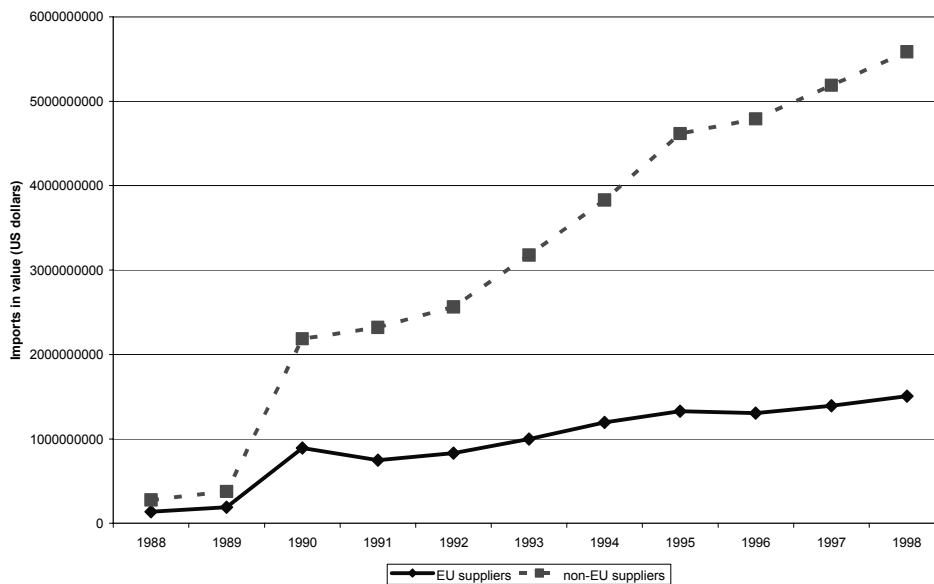
**Figure 2.b. EU imports from intra-EU, extra-EU OECD and extra-EU non-OECD countries of Medical devices products for years 1990, 1995 and 2000**



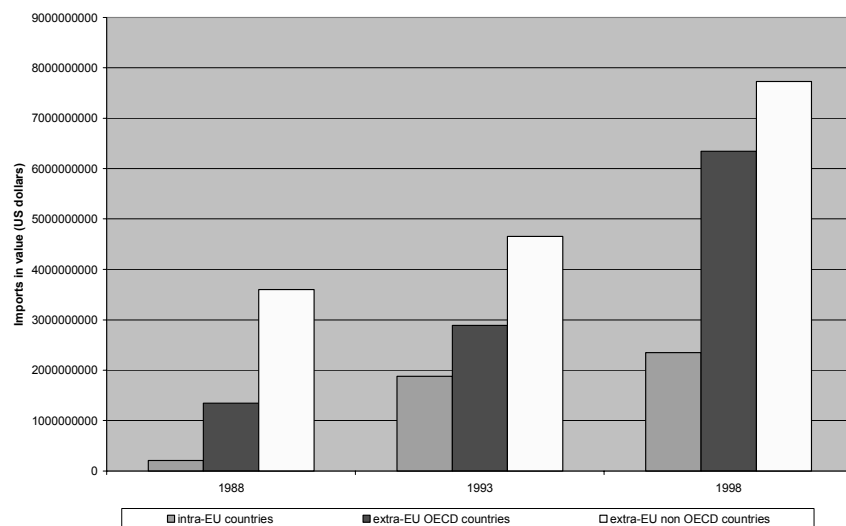
**Figure 3.a. Intra-EU and extra-EU imports evolution of Machinery products (6-digit products) from 1988 to 2006**



**Figure 3.b. Machinery imports of the control group of countries (Australia, Japan and USA) from EU and non-EU suppliers between 1988 and 1998**



**Figure 3.c. EU imports from intra-EU, extra-EU OECD and extra-EU non-OECD countries of Machinery products for years 1988, 1993 and 1998**



## ANNEX 10. DATA AND SOURCES

Independent variable	Description	Source
Stage 1 : Prob(import)	Indicates whether there were positive import flows between a country-pair for a given year and for a given product (market entry)	OECD
Stage 2 : ln(import)	Log of import flows between a country-pair for a given year and for a given product (trade intensity)	OECD
Joint GDP	Sum of log of nominal GDP value for importing and exporting	World Development Indicators (2007)
Distance	Geographical distance (great circle formula) between exporting and importing country	CEPII
Contiguity	Whether the trading partners share a common border	CEPII
Language	Whether the exporting and importing countries share a common official language	CEPII
Colony	Whether the exporting country was at some point in time a colony of the importing country	CEPII
Regional trade agreements (RTA)	Whether an importing country has a RTA with an exporting country in a given year (excluding EU)	WTO
SDOC intra-EU	Whether SDOC is in force or not, in the EU in a given year and both countries are EU members	EC
SDOC extra-EU	Whether SDOC is in force or not, in the EU in a given year and only the importing country is an EU member	EC
SDOC extra-EU OECD	Whether SDOC is in force or not, in the EU in a given year and the importing country is an EU member and the exporting country is an OECD member	EC
SDOC extra-EU non OECD	Whether SDOC is in force or not, in the EU in a given year and the importing country is an EU member and the exporting country is not an OECD member	EC
EU membership	Whether the importing and the exporting countries both are members of the EU in a given year	EC
Euro currency union	Whether the Euro was the official currency in a given year	EC

**ANNEXE 11A : SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU AND NON-EU SUPPLIERS OF RTTE SECTOR**

Importer and Exporter Fixed Effects			Importer-, Exporter- and Year-Fixed Effects			Importer-, Exporter-, Year- and Product- Fixed Effects		
RTTE_ALL	Heckman selection	Heckman regression	RTTE_ALL	Heckman selection	Heckman regression	RTTE_ALL	Heckman selection	Heckman regression
Dependent variable	Prob import > 0	Log import	Dependent variable	Prob import > 0	Log import	Dependent variable	Prob import > 0	Log import
SumlnGDP	0.2103124*** (10.66)	0.2021327*** (4.34)	SumlnGDP			SumlnGDP		
LnDistance	-0.2445891*** (-14.33)	-0.6692058*** (-17.74)	LnDistance	-0.2412707*** (-17.13)	-0.6471629*** (-14.00)	LnDistance	-0.344718*** (-18.68)	-0.7742673*** (-22.58)
Contiguity	0.2622504*** (6.51)	0.5256808*** (6.95)	Contiguity	0.2645466*** (6.04)	0.526416*** (7.82)	Contiguity	0.4893242*** (10.36)	0.6631883*** (10.86)
Language	0.1315888*** (4.47)	0.4650777*** (6.75)	Language	0.130555*** (4.19)	0.4473945*** (5.93)	Language	0.2206439*** (5.80)	0.5875532*** (9.93)
Colonial	0.1092787* (1.74)		Colonial	0.1105933* (1.70)		Colonial	0.1329226* (1.70)	
Regional Trade Agreement	0.0351871 (1.45)	0.2318966*** (3.91)	Regional Trade Agreement	0.0555234*** (2.10)	0.3039046*** (5.19)	Regional Trade Agreement	0.0848387*** (2.62)	0.4424385*** (7.82)
EU membership	0.0204472 (0.47)	0.9207796*** (8.34)	EU membership	0.0336937 (0.73)	0.9453715*** (8.42)	EU membership	0.0563088 (1.15)	0.9979119*** (9.62)
Euro currency union	0.1796499*** (6.89)	0.1150771* (1.64)	Euro currency union	0.1602537*** (4.53)	0.191824*** (3.18)	Euro currency union	0.1522891*** (4.14)	0.2923381*** (5.09)
<b>SDOC_intra-EU</b>	<b>-0.0266842</b> <b>(-0.89)</b>	<b>1.080067***</b> <b>(16.55)</b>	<b>SDOC_intra-EU</b>	<b>-0.0478007*</b> <b>(-1.71)</b>	<b>1.313984***</b> <b>(16.08)</b>	<b>SDOC_intra-EU</b>	<b>-0.1018974***</b> <b>(-2.73)</b>	<b>0.1118588*</b> <b>(1.87)</b>
<b>SDOC_extra-EU</b>	<b>0.3083578***</b> <b>(18.80)</b>	<b>0.9527475***</b> <b>(16.31)</b>	<b>SDOC_extra-EU</b>	<b>0.2873864***</b> <b>(14.51)</b>	<b>1.217756***</b> <b>(20.66)</b>	<b>SDOC_extra-EU</b>	<b>0.1370934***</b> <b>(4.95)</b>	<b>0.0575619</b> <b>(1.12)</b>
Observations		47299	Observations		47299	Observations		47299
Censored		15763	Censored		15763	Censored		15763
rho		0.48	rho		0.45	rho		0.75
sigma		2.78	sigma		2.756	sigma		2.56
lambda		1.34***	lambda		1.25***	lambda		1.92***

Notes: Time and country fixed effects are not reported. All the regressions were run with robust standard errors under heteroskedastic conditions. Values of t-statistics are in parentheses. Values marked (\*\*\*) (\*\*\*) and (\*) are significant at the 1%, 5% and 10% levels, respectively. GDP was dropped from the second and third specification because it was found collinear with country and year fixed-effects.

**ANNEXE 11B : SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU, NON-EU OECD AND NON-EU NON-OECD SUPPLIERS OF RTTE SECTOR**

Importer and Exporter Fixed Effects				Importer-, Exporter- and Year-Fixed Effects				Importer-, Exporter-, Year- and Product- Fixed Effects			
RTTE_ALL_OECD	Heckman selection		Heckman regression	RTTE_ALL_OECD	Heckman selection		Heckman regression	RTTE_ALL_OECD	Heckman selection		Heckman regression
Dependent variable	Prob import > 0		Log import	Dependent variable	Prob import > 0		Log import	Dependent variable	Prob import > 0		Log import
SumlnGDP	0.2138126*** (9.27)		0.2247807*** (4.03)	SumlnGDP				SumlnGDP			
LnDistance	-0.2501836*** (-15.88)		-0.6977073*** (-16.37)	LnDistance	-0.2458723*** (-13.80)		-0.6725267*** (-16.35)	LnDistance	-0.3491233*** (-19.23)		-0.7858193*** (-18.96)
Contiguity	0.2540243*** (6.09)		0.5236616*** (7.28)	Contiguity	0.2575318*** (6.26)		0.5241225*** (6.58)	Contiguity	0.4822773*** (12.10)		0.651367*** (10.31)
Language	0.1349629*** (3.66)		0.4837886*** (7.63)	Language	0.1334667*** (3.94)		0.4644977*** (7.09)	Language	0.2233127*** (7.67)		0.5961669*** (11.31)
Colonial	0.1065823 (1.53)			Colonial	0.108133* (1.60)			Colonial	0.1322868*** (2.12)		
Regional Trade Agreement	0.0352018 (1.25)		0.2305285*** (3.52)	Regional Trade Agreement	0.0574806** (1.85)		0.3065699*** (4.99)	Regional Trade Agreement	0.0874792*** (3.26)		0.4410492*** (7.98)
EU membership	0.0148762 (0.30)		0.9158294*** (7.30)	EU membership	0.0292927 (0.62)		0.942749*** (7.78)	EU membership	0.0520138 (1.36)		0.9930756*** (8.79)
Euro currency union	0.1794143*** (5.39)		0.1292337*** (2.45)	Euro currency union	0.1604793*** (4.79)		0.2030949*** (2.47)	Euro currency union	0.1523544*** (3.92)		0.2948794*** (4.94)
<b>SDOC_intra-EU</b>	<b>-0.027516</b> <b>(-1.05)</b>		<b>1.077026***</b> <b>(15.86)</b>	<b>SDOC_intra-EU</b>	<b>-0.0479575*</b> <b>(-1.68)</b>		<b>1.310368***</b> <b>(18.36)</b>	<b>SDOC_intra-EU</b>	<b>-0.102411***</b> <b>(-2.78)</b>		<b>0.1090227*</b> <b>(1.66)</b>
<b>SDOC_extra-EU_OECD</b>	<b>0.2452085***</b> <b>(10.95)</b>		<b>0.875368***</b> <b>(16.03)</b>	<b>SDOC_extra-EU_OECD</b>	<b>0.2327852***</b> <b>(8.47)</b>		<b>1.140465***</b> <b>(17.83)</b>	<b>SDOC_extra-EU_OECD</b>	<b>0.0848003***</b> <b>(2.86)</b>		<b>-0.05778</b> <b>(-0.76)</b>
<b>SDOC_extra-EU_nonOECD</b>	<b>0.3811287***</b> <b>(14.13)</b>		<b>1.131194***</b> <b>(14.27)</b>	<b>SDOC_extra-EU_nonOECD</b>	<b>0.3523565***</b> <b>(12.04)</b>		<b>1.389208***</b> <b>(20.71)</b>	<b>SDOC_extra-EU_nonOECD</b>	<b>0.1960282***</b> <b>(6.76)</b>		<b>0.2297148***</b> <b>(3.56)</b>
Observations		47299		Observations		47299		Observations		47299	
Censored		15763		Censored		15763		Censored		15763	
rho		0.55		rho		0.51		rho		0.76	
sigma		2.82		sigma		2.79		sigma		2.57	
lambda		1.54***		lambda		1.42***		lambda		1.96***	

Notes: Time and country fixed effects are not reported. All the regressions were run with robust standard errors under heteroskedastic conditions. Values of t-statistics are in parentheses. Values marked (\*\*\*), (\*\*) and (\*) are significant at the 1%, 5% and 10% levels, respectively. GDP was dropped from the second and third specification because it was found collinear with country and year fixed-effects.

**ANNEXE 12A: SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU AND NON-EU SUPPLIERS OF MEDICAL DEVICES SECTOR**

Importer and Exporter Fixed Effects				Importer-, Exporter- and Year-Fixed Effects				Importer-, Exporter-, Year- and Product- Fixed Effects			
<b>MEDICAL DEVICES</b>				<b>MEDICAL DEVICES</b>				<b>MEDICAL DEVICES</b>			
Dependent variable	Heckman selection		Heckman regression	Dependent variable	Heckman selection		Heckman regression	Dependent variable	Heckman selection		Heckman regression
	Prob import > 0		Log import		Prob import > 0		Log import		Prob import > 0		Log import
SumlnGDP	0.2268778*** (8.55)		0.186765*** (3.09)	SumlnGDP				SumlnGDP			
LnDistance	-0.3312569*** (-20.27)		-0.7978551*** (-20.17)	LnDistance	-0.3459536*** (-18.56)		-0.7863669*** (-26.14)	LnDistance	-0.3526808*** (-23.63)		-0.9184582*** (-22.85)
Border	0.2831623*** (7.06)		0.3610532*** (4.91)	Border	0.2699924*** (6.19)		0.3536087*** (5.66)	Border	0.2842403*** (7.56)		0.4082566*** (5.28)
Language	0.1433858*** (4.95)		0.431878*** (6.45)	Language	0.1469254*** (4.85)		0.4275953*** (6.89)	Language	0.170866*** (4.54)		0.5537414*** (9.64)
Colonial	0.2433773*** (3.66)			Colonial	0.2437667*** (3.55)			Colonial	0.2347061*** (4.03)		
Regional Trade Agreement	0.1274833*** (2.55)		0.0522268 (0.63)	Regional Trade Agreement	0.0629543 (1.31)		0.1035706 (0.97)	Regional Trade Agreement	0.0918096*** (2.09)		0.1704024* (1.87)
EU membership	0.1404934*** (4.02)		-0.0592351 (-0.74)	EU membership	0.1271102*** (2.86)		0.0353679 (0.48)	EU membership	0.1737406*** (5.23)		0.1656499* (1.95)
<b>SDOC_intra-EU</b>	<b>0.3565298*** (10.83)</b>		<b>1.081357*** (25.33)</b>	<b>SDOC_intra-EU</b>	<b>0.3525777*** (10.17)</b>		<b>1.271276*** (22.92)</b>	<b>SDOC_intra-EU</b>	<b>-0.018569 (-0.49)</b>		<b>0.3396887*** (4.28)</b>
<b>SDOC_extra-EU</b>	<b>0.3628943*** (17.99)</b>		<b>0.7487734*** (20.06)</b>	<b>SDOC_extra-EU</b>	<b>0.4497535*** (26.06)</b>		<b>1.097152*** (19.64)</b>	<b>SDOC_extra-EU</b>	<b>0.1078642*** (3.88)</b>		<b>0.3294168*** (5.80)</b>
Observations		39833		Observations		39833		Observations		39833	
Censored		15301		Censored		15301		Censored		15301	
rho		0.40		rho		0.38		rho		0.73	
sigma		2.31		sigma		2.30		sigma		2.45	
lambda		0.94***		lambda		0.88***		lambda		1.78***	

Notes: Time and country fixed effects are not reported. All the regressions were run with robust standard errors under heteroskedastic conditions. Values of t-statistics are in parentheses. Values marked (\*\*\*) (\*\*\*) and (\*) are significant at the 1%, 5% and 10% levels, respectively. GDP was dropped from the second and third specification because it was found collinear with country and year fixed-effects.



**ANNEXE 12B: SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU, NON-EU OECD AND NON-EU NON-OECD SUPPLIERS OF MEDICAL DEVICES SECTOR**

Importer and Exporter Fixed Effects				Importer-, Exporter- and Year-Fixed Effects				Importer-, Exporter-, Year- and Product- Fixed Effects			
<b>MEDICAL DEVICES OECD</b>				<b>MEDICAL DEVICES OECD</b>				<b>MEDICAL DEVICES OECD</b>			
Dependent variable	Heckman selection		Heckman regression	Dependent variable	Heckman selection		Heckman regression	Dependent variable	Heckman selection		Heckman regression
SumInGDP	Prob import > 0		Log import	SumInGDP	Prob import > 0		Log import	SumInGDP	Prob import > 0		Log import
LnDistance	0.2240363*** (10.06)		0.1709106*** (2.54)	LnDistance	-0.3496788*** (-22.09)		-0.8028093*** (-20.18)	LnDistance	-0.3585176*** (-20.72)		-0.9479704*** (-28.66)
Border	-0.3326936*** (-21.55)		-0.813408*** (-20.75)	Border	0.2644906*** (6.12)		0.3399998*** (5.44)	Border	0.2757958*** (6.82)		0.3802772*** (6.15)
Language	0.2810248*** (6.14)		0.3491496*** (5.26)	Language	0.1492503*** (3.85)		0.4354415*** (5.40)	Language	0.1743864*** (5.67)		0.5677467*** (9.77)
Colonial	0.1443054*** (4.38)		0.4395181*** (6.07)	Colonial	0.2435923*** (4.28)			Colonial	.2340713*** (2.98)		
Regional Trade Agreement	0.2432671*** (4.14)			Regional Trade Agreement	0.0745539* (1.67)		0.1236372 (1.29)	Regional Trade Agreement	0.1104962*** (2.23)		0.2132287*** (2.18)
EU membership	0.1326145*** (3.19)		0.0722944 (0.71)	EU membership	0.1274852*** (3.67)		0.0462256 (0.66)	EU membership	0.1747214*** (4.89)		0.1883633*** (2.40)
<b>SDOC_intra-EU</b>	<b>0.3550129*** (11.21)</b>		<b>1.079924*** (19.90)</b>	<b>SDOC_intra-EU</b>	<b>0.3479473*** (8.82)</b>		<b>1.266298*** (22.19)</b>	<b>SDOC_intra-EU</b>	<b>-0.0293814 (-0.73)</b>		<b>0.2998588*** (4.42)</b>
<b>SDOC_extra-EU_OECD</b>	<b>0.3499406*** (17.19)</b>		<b>0.7041257*** (14.47)</b>	<b>SDOC_extra-EU_OECD</b>	<b>0.41738*** (14.83)</b>		<b>1.043151*** (17.02)</b>	<b>SDOC_extra-EU_OECD</b>	<b>0.0538076* (1.72)</b>		<b>0.1826077*** (2.41)</b>
<b>SDOC_extra-EU_nonOECD</b>	<b>0.3782096*** (14.43)</b>		<b>0.8708782*** (12.27)</b>	<b>SDOC_extra-EU_nonOECD</b>	<b>0.487357*** (18.35)</b>		<b>1.232165*** (12.95)</b>	<b>SDOC_extra-EU_nonOECD</b>	<b>0.1631058*** (4.72)</b>		<b>0.5852547*** (6.62)</b>
Observations		39833		Observations		39833		Observations		39833	
Censored		15301		Censored		15301		Censored		15301	
rho		0.43		rho		0.42		rho		0.75	
sigma		2.32		sigma		2.32		sigma		2.47	
lambda		0.99***		lambda		0.99***		lambda		1.84***	

Notes: Time and country fixed effects are not reported. All the regressions were run with robust standard errors under heteroskedastic conditions. Values of t-statistics are in parentheses. Values marked (\*\*\*), (\*\*), (\*) are significant at the 1%, 5% and 10% levels, respectively. GDP was dropped from the second and third specification because it was found collinear with country and year fixed-effects.

**ANNEX 12C: MEDICAL DEVICES - POISSON REGRESSION ESTIMATIONS WITHOUT CONTROL GROUP COUNTRIES AND  
COUNTRY-, YEAR-, AND PRODUCT FIXED EFFECTS SPECIFICATION**

	UK	DEU	FRA
LogGDP_exporter	0.087216 (0.20)	0.726019** (2.13)	1.007104** (2.00)
distance	-1.348715*** (-3.62)	-1.077766*** (-4.56)	-1.283473*** (-4.41)
contiguity	-	0.2035434 (0.16)	0.2975453 (1.05)
Comon language	-1.041202 (-0.82)	0.6870231 (0.92)	1.658406 (1.55)
RTA	-0.3466147 (-0.69)	-0.0711901 (-0.23)	0.1281447 (0.24)
EU membership	0.272375 (0.81)	-0.3131729 (-1.24)	0.0237229 (0.08)
<b>SDOC intra-EU</b>	<b>0.4066957 (1.51)</b>	<b>0.6281264** (2.45)</b>	<b>0.5455155* (1.92)</b>
<b>SDOC extra-EU</b>	<b>0.5061001* (1.87)</b>	<b>0.5706721** (2.23)</b>	<b>0.5603733** (2.26)</b>
Observations	2927	3131	2781
<b>Pseudo-R<sup>2</sup></b>	<b>0.5937</b>	<b>0.5798</b>	<b>0.6103</b>

**ANNEXE 13A: SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU AND NON-EU SUPPLIERS OF MACHINERY SECTOR [WITH CONTROL GROUP OF COUNTRIES]**

Importer and Exporter Fixed Effects				Importer-, Exporter- and Year-Fixed Effects				Importer-, Exporter-, Year- and Product-Fixed Effects			
<b>Machinery</b>		Heckman selection	Heckman regression	<b>Machinery</b>		Heckman selection	Heckman regression	<b>Machinery</b>		Heckman selection	Heckman regression
Dependent variable		Prob import > 0	Log import	Dependent variable		Prob import > 0	Log import	Dependent variable		Prob import > 0	Log import
SuminGDP		0.3207369*** (23.65)	0.7334419*** (19.38)	SuminGDP				SuminGDP			
LnDistance		-0.254317*** (-33.92)	-0.7739912*** (-28.19)	LnDistance		-0.273258*** (-33.90)	-0.805386*** (-26.73)	LnDistance		-0.4154748*** (-56.22)	-1.217482*** (-65.36)
Border		0.2402072*** (12.43)	0.3624087*** (10.95)	Border		0.2284386*** (14.07)	0.3429207*** (11.30)	Border		0.2908829*** (14.09)	0.4637924*** (12.14)
Language		0.1425778*** (8.72)	0.5150301*** (16.23)	Language		0.1440231*** (8.27)	0.5146259*** (11.61)	Language		0.2165375*** (12.09)	0.7740291*** (22.21)
Colonial		0.0783563*** (2.46)		Colonial		0.0725813*** (2.31)		Colonial		0.1617136*** (3.76)	
Regional Trade Agreement		0.0798517*** (3.69)	0.1895121*** (3.24)	Regional Trade Agreement		-0.0430964 (-1.58)	-0.0074751 (-0.15)	Regional Trade Agreement		-0.0298485 (-1.24)	-0.0271506 (-0.42)
EU membership		0.2708292*** (17.38)	0.2082555*** (5.52)	EU membership		0.2485618*** (12.89)	0.1627382*** (4.20)	EU membership		0.2784453*** (14.90)	0.270961*** (6.59)
<b>SDOC_intra-EU</b>		<b>-0.2779392*** (-17.19)</b>	<b>-0.3747598*** (-10.33)</b>	<b>SDOC_intra-EU</b>		<b>-0.4579148*** (-23.32)</b>	<b>-0.6132133*** (-12.62)</b>	<b>SDOC_intra-EU</b>		<b>-0.4721833*** (-18.52)</b>	<b>-0.9223823*** (-17.83)</b>
<b>SDOC_extra-EU</b>		<b>0.0135559 1.20</b>	<b>-0.200378*** (-8.53)</b>	<b>SDOC_extra-EU</b>		<b>-0.0230921 (-1.47)</b>	<b>-0.2130452*** (-5.35)</b>	<b>SDOC_extra-EU</b>		<b>0.0209311 (1.12)</b>	<b>-0.1776123*** (-4.02)</b>
Observations		150277		Observations		150494		Observations		150494	
Censored		65969		Censored		66184		Censored		66184	
rho		0.60		rho		0.59		rho		1.00	
sigma		2.37		sigma		2.37		sigma		3.05	
lambda		1.42***		lambda		1.40***		lambda		3.05***	

Notes: Time and country fixed effects are not reported. All the regressions were run with robust standard errors under heteroskedastic conditions. Values of t-statistics are in parentheses. Values marked (\*\*\*) , (\*\*) and (\*) are significant at the 1%, 5% and 10% levels, respectively. GDP was dropped from the second and third specification because it was found collinear with country and year fixed-effects.

**ANNEXE 13B : SUMMARY OF THE HECKMAN SELECTION MODEL REGRESSION RESULTS FOR THE IMPACT OF SDOC ON FLOWS WITH EU, NON-EU OECD AND NON-EU NON-OECD SUPPLIERS OF MACHINERY SECTOR [WITH CONTROL GROUP OF COUNTRIES]**

Importer and Exporter Fixed Effects				Importer-, Exporter- and Year-Fixed Effects				Importer-, Exporter-, Year- and Product- Fixed Effects			
<b>Machinery OECD</b>				<b>Machinery OECD</b>				<b>Machinery OECD</b>			
Dependent variable	Heckman selection		Heckman regression	Dependent variable	Heckman selection		Heckman regression	Dependent variable	Heckman selection		Heckman regression
SumInGDP	Prob import > 0		Log import	SumInGDP	Prob import > 0		Log import	SumInGDP	Prob import > 0		Log import
LnDistance	0.2990518*** (19.76)		0.7163291*** (17.42)	LnDistance	-0.2846813*** (-42.80)		-0.841943*** (-30.02)	LnDistance	-0.4280417*** (-63.58)		-1.251644*** (-66.38)
Border	-0.2643088*** (-40.79)		-0.8129886*** (-24.12)	Border	0.2136304*** (11.29)		0.3222625*** (11.14)	Border	0.274979*** (16.03)		0.4268938*** (14.80)
Language	0.2274404*** (12.97)		0.3479498*** (11.03)	Language	0.1474744*** (8.27)		0.5266195*** (12.12)	Language	0.2204741*** (14.34)		0.7798521*** (23.73)
Colonial	0.1454061*** (10.18)		0.5304798*** (15.60)	Colonial	0.0611765 (1.56)			Colonial	0.1493096*** (4.67)		
Regional Trade Agreement	0.0684798*** (2.14)			Regional Trade Agreement	0.0270363 (1.11)		0.0846049*** (1.53)	Regional Trade Agreement	0.0477787 (1.57)		0.1114759* (1.89)
EU membership	0.135291*** (7.20)		0.2694461*** (5.47)	EU membership	0.2623532*** (15.48)		0.1970841*** (4.94)	EU membership	0.2936135*** (13.03)		0.3066907*** (7.42)
SDOC_intra-EU	-0.2867386*** (-15.83)		-0.3998037*** (-10.73)	SDOC_intra-EU	-4.788149*** (-25.59)		-6.620562*** (-12.08)	SDOC_intra-EU	-0.4949407*** (-22.42)		-0.9615267*** (-22.91)
SDOC_extra-EU_OECD	-0.0558041*** (-4.20)		-0.2974294*** (-13.62)	SDOC_extra-EU_OECD	-1.22019*** (-7.14)		-3.611592*** (-9.98)	SDOC_extra-EU_OECD	-0.0874363*** (-4.89)		-0.3876232*** (-8.53)
SDOC_extra-EU_nonOECD	0.1587667*** (10.24)		0.1443961*** (3.81)	SDOC_extra-EU_nonOECD	0.1358527*** (7.01)		0.1602642*** (2.76)	SDOC_extra-EU_nonOECD	0.1901574*** (8.97)		0.3570008*** (6.97)
Observations		150277		Observations		150494		Observations		150494	
Censored		65969		Censored		66184		Censored		66184	
rho		0.65		rho		0.63		rho		1.00	
sigma		2.41		sigma		2.39		sigma		3.07	
lambda		1.56***		lambda		1.50***		lambda		3.07***	

Notes: Time and country fixed effects are not reported. All the regressions were run with robust standard errors under heteroskedastic conditions. Values of t-statistics are in parentheses. Values marked (\*\*\*) , (\*\*) and (\*) are significant at the 1%, 5% and 10% levels, respectively. GDP was dropped from the second and third specification because it was found collinear with country and year fixed-effects.

**ANNEX 13C: HECKMAN MODEL ESTIMATIONS WITH COUNTRY-, YEAR- AND PRODUCT FIXED EFFECTS [WITHOUT CONTROL GROUP OF COUNTRIES (AUSTRALIA, JAPAN, USA)], FOR MACHINERY**

Importer-, Exporter-, Year- and Product- Fixed Effects

<b>Machinery OECD</b>	Heckman selection		Heckman regression
Dependent variable	Prob import > 0		Log import
LnDistance	-0.5843703*** (-38.44)		-1.278195*** (-48.92)
Border	0.123869*** (7.32)		0.2750277*** (7.62)
Language	0.2185995*** (12.50)		0.9632685*** (24.39)
Colonial	0.2577328*** (6.88)		
Regional Trade Agreement	0.0131345 (0.47)		-0.0711333 (-1.24)
EU membership	0.2964886*** (13.30)		0.0750076 (1.54)
<b>SDOC_intra-EU</b>	<b>-0.3343936***</b> (-5.90)		<b>-0.1431836</b> (-1.39)
<b>SDOC_extra-EU_OECD</b>	<b>0.09695*</b> (1.80)		<b>0.5142131***</b> (4.73)
<b>SDOC_extra-EU_nonOECD</b>	<b>0.3334811***</b> (6.14)		<b>1.153459***</b> (11.31)
Observations		122384	
Censored		54768	
rho		1.00	
sigma		2.99	
lambda		2.989***	

Notes: Time and country fixed effects are not reported. All the regressions were run with robust standard errors under heteroskedastic conditions. Values of t-statistics are in parentheses. Values marked (\*\*\*) , (\*\*) and (\*) are significant at the 1%, 5% and 10% levels, respectively. GDP was dropped from the second and third specification because it was found collinear with country and year fixed-effects.

**ANNEX 14: MACHINERY - POISSON REGRESSION ESTIMATIONS WITH CONTROL GROUP COUNTRIES (AUSTRALIA, JAPAN AND USA) AND COUNTRY-, YEAR-, AND PRODUCT FIXED EFFECTS SPECIFICATION**

	UK	DEU	FRA	ITA
sumlgdp	0.7570076*** (27.24)	0.7626234*** (24.76)	0.7955175*** (26.87)	0.7705978*** (2.73)
distance	-4.174399*** (-6.25)	-5.961293*** (-10.59)	***0.2504264 (-4.06)	-0.231479*** (-3.64)
contiguity	1.931434*** (7.88)	0.6161443*** (4.62)	1.019279*** (7.60)	0.8096366*** (5.10)
comon language	1.122114*** (9.14)	0.7983297*** (7.82)	0.6286389*** (6.04)	0.9296655*** (8.31)
RTA	0.493107*** (2.09)	0.4596754*** (2.39)	0.5833607*** (2.50)	0.6198236*** (2.55)
EU membership	0.8130222*** (4.83)	0.6762854*** (5.37)	0.8759183*** (5.44)	1.402379*** (9.22)
<b>SDOC intra-EU</b>	<b>-.3570889*** (-3.04)</b>	<b>-0.83589*** (-6.52)</b>	<b>-0.5207715*** (-4.05)</b>	<b>-.5084142*** (-3.88)</b>
<b>SDOC extra-EU</b>	<b>-.4526064*** (-6.39)</b>	<b>-0.6020526*** (-7.74)</b>	<b>-0.7107744*** (-6.88)</b>	<b>-0.7679374*** (-8.79)</b>
Observations	40763	40283	38355	39824
Pseudo R <sup>2</sup>	<b>0.6481</b>	<b>0.6115</b>	<b>0.6226</b>	<b>0.6410</b>

Notes: Time and country fixed effects are not reported. All the regressions were run with robust standard errors under heteroskedastic conditions. Values of t-statistics are in parentheses. Values marked (\*\*\*) (\*\*\*) and (\*) are significant at the 1%, 5% and 10% levels, respectively.