Working Party of the Trade Committee

FINAL REPORT ON DEVELOPING-COUNTRY CASE STUDIES ON CONFORMITY ASSESSMENT PROCEDURES

Purpose and action required: This final report on case-study work investigating experiences by developing-country exporters with conformity assessment procedures is submitted for discussion. An interim report was presented to the WP in May 2005 [TD/TC/WP(2005)17]. The consultant responsible for the research will attend the meeting and be available to respond to questions.

Timing: If Delegations agree, the paper will be derestricted under the written procedure, taking into account comments made at the meeting. Alternatively, a revised version of this paper could be discussed at the December meeting of the Working Party.

Context and consultations: This work builds on initial analysis contained in TD/TC/WP(2004)13/REV1 and complements a questionnaire survey of conformity assessment bodies and exporters presently being analysed. The research has benefited from consultations of and support and input provided by experts at UNIDO, WTO/ITC as well as experts, government and industry officials in Brazil, Nigeria and South Africa.

Programme of work and resource implications: Output area 3.1.3. This work is being completed within the resources allocated for that output in the PWB for 2003-2004.

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EXECUTIVE SUMMARY

This report aims to help clarify, using the case study technique, the nature and potential impact on trade of conformity assessment procedures. The cases are presented from the perspective of three developing countries: South Africa, Brazil, and Nigeria. Charting the conditions surrounding exporters in three industry sectors, cosmetics, furniture, and seafood, the cases explore health, safety, and environmental issues, regulation, and the relevant conformity assessment procedures in both the developing countries and in their targeted export markets.

The case studies give specificity to two generally accepted tenets regarding conformity assessment and developing countries: (1) the lack of an adequate conformity assessment infrastructure severely hampers (or prevents altogether) the ability of developing country exporters to export to more developed countries; and (2) the ability to comply with the conformity assessment requirements of developed countries is key to participation in the global trading system. The effects of conformity assessment-related challenges experienced by exporters, notably the lack of regulatory harmonization and duplicative conformity assessment requirements, can also be gauged from this case material.

The South Africa case involves a sub-sector of the cosmetics industry that manufactures products made from indigenous plant extracts and exports primarily to the European Union. While the industry is domiciled in a country where a CA infrastructure exists and is being used by larger multinational companies, the advantages of an affordable, one-stop service provider seemingly elude this group of South African manufacturers. Many small companies find the alternative, a multiple provider system of consultants, financially exhausting and give up efforts to export.

In Brazil, the wood furniture industry faces increasing challenges to meet formaldehyde emission restrictions for particleboard set by importing countries, including the European Union. There are no laboratories in Brazil that are equipped with the chamber required by the European standard test method for testing formaldehyde emissions. The costs of having particleboard tested abroad plus more stringent legal requirements for particleboard with lower emission levels has made exporting to countries within the European Union and other countries a financial impossibility for Brazilian manufacturers of furniture.

The case in Nigeria demonstrates a developing country’s success in gaining the confidence of the European Union in its conformity assessment infrastructure and its implementation of a set of internationally accepted conformity assessment principles, the Hazard Analysis Critical Control Point (HACCP) system. While there are differences in the implementation of HACCP regulations between countries, in theory, Nigeria’s shrimp, having qualified for exporting to the market of the European Union, should qualify for access to the U.S. and other markets that also base their requirements for entry on HACCP. Why Nigeria currently does not export wild capture shrimp to the US market, for example, appears to be the result of factors other than conformity assessment capabilities or requirements.
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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ABIMOVE</td>
<td>Brazilian Association of Furniture Manufacturers</td>
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<td>ABNT</td>
<td>Associacao Brasileira de Normas Técnicas (the Brazilian Standards Organisation)</td>
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<tr>
<td>ASTM</td>
<td>ASTM International (American Society for Testing and Materials)</td>
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<td>CA</td>
<td>Conformity Assessment</td>
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<td>COLIPA</td>
<td>European Cosmetic, Toiletry, and Perfumery Association</td>
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<td>CTFA</td>
<td>Cosmetic, Toiletry, and Fragrance Association of South Africa</td>
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<td>DTI</td>
<td>Department of Trade and Industry</td>
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<td>EA</td>
<td>European Accreditation</td>
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<td>EN</td>
<td>European Norm</td>
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<td>ESA</td>
<td>European Sealing Association</td>
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<td>EU</td>
<td>European Union</td>
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<td>FAO</td>
<td>Food and Agriculture Organization of the United Nations</td>
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<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
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<td>GLP</td>
<td>Good Laboratory Practice</td>
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<td>HACCP</td>
<td>Hazard Analysis Critical Control Point</td>
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<td>IAF</td>
<td>International Accreditation Forum</td>
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<td>ILAC</td>
<td>International Laboratory Accreditation Co-operation</td>
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<td>INMETRO</td>
<td>The National Institute of Metrology, Standardization and Industrial Quality of Brazil</td>
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<tr>
<td>IPT</td>
<td>Instituto de Pesquisas Tecnologicas, (The Research Institute of the State of Sao Paulo)</td>
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<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>MLA</td>
<td>Multi-Lateral Agreement</td>
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<td>MS</td>
<td>Member State</td>
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<td>NAFDAC</td>
<td>The Nigerian National Agency for Food and Drug Administration and Control</td>
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<td>NIOMR</td>
<td>Nigerian Oceanographic Marine Research Institute</td>
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<td>NITOA</td>
<td>Nigerian Trawler Owners Association</td>
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<td>SABS</td>
<td>South African Bureau of Standards</td>
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<td>SACEC</td>
<td>South African Cosmetics Export Council</td>
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<td>SANAS</td>
<td>South African National Accreditation System</td>
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<td>SBAC</td>
<td>Brazilian System of Conformity Assessment</td>
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<tr>
<td>SMEs</td>
<td>Small and Medium Enterprises</td>
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<td>SMMEs</td>
<td>Small, Medium, and Micro Enterprises</td>
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<td>SON</td>
<td>Standards Organization of Nigeria</td>
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<td>SPS</td>
<td>Sanitary and Phytosanitary Measure</td>
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<td>TBT</td>
<td>Technical Barrier to Trade</td>
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<td>TISA</td>
<td>Trade and Investment South Africa</td>
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<td>UNCTAD</td>
<td>United Nations Conference on Trade and Development</td>
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<td>UNIDO</td>
<td>United Nations Industrial Development Organization</td>
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<td>USAID</td>
<td>U.S. Agency for International Development</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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I. Introduction

1. As part of an ongoing investigation of the nature and trade effects of particular types of non-tariff barriers, the Working Party last year decided to study conformity assessment (CA) procedures. The objective is to deepen the understanding of the ways and circumstances in which CA requirements affect trade, \textit{i.e.}, how conformity assessment can facilitate trade or hinder it.

2. The project on CA procedures consists of two elements of research. First, the Secretariat has prepared an initial analysis [TD/TC/WP(2004)13 REV1] describing the policy context for studying CA procedures. This analysis takes stock of concerns and issues related to CA practices and their trade impact that have arisen during the discussions in the WTO TBT Committee since 1995 or have been documented by other sources of data.

3. Second, because data on the costs and the different market access effects of CA procedures that countries use are scarce, a systematic effort -- using survey and case study techniques -- has been made to gather such data and contribute greater specificity to the discussion of TBT issues in the WTO and elsewhere.

4. This report presents a small set of case studies that aim to document the effects CA regimes and requirements affect exporters' ability to participate in international trade. The focus of this work is on developing-country experiences and complements a survey of OECD exporters and CA bodies which the Secretariat carried out between October 2004 and July 2005 and is in the process of analysing.

II. Objectives of this study

5. Exporting in developing countries often begins with regional trade. Increasing numbers of developing-country exporters, however, are targeting larger, developed-country markets, whose technical regulations and CA procedures evolve in tandem with rapidly advancing technologies. One of the goals of the set of three cases selected for study is to illustrate, in a small way, \textit{how exporters of these developing countries meet, or fail to meet, the CA requirements in developed-country markets}.

6. A second and interrelated goal is to better understand the nature of CA challenges facing developing-country exporters. Operating an internal quality management system, or having products inspected, tested, and/or certified raises the cost of production for all exporters, increases the time to market, and may make life so complicated that potential exporters give up. This is particularly true of developing country exporters where resources are scarce.

7. The capacity and credibility of a CA system is directly related to a country’s ability to export products successfully, whether or not that country is developing or developed. In the case of many

\footnote{The study of conformity assessment procedures also complements earlier work of the Trade Committee in the area of technical barriers to trade, such as work on TBTs in specific sectors and on the benefits of using international standards. See \textit{Standardisation and Regulatory Reform: Selected Cases}, TD/TC/WP(99)47/FINAL, and \textit{Non-tariff Measures in the ICT Sector: A Survey}, TD/TC/WP(2001)44/FINAL.}

\footnote{This paper is being revised by the Secretariat in the light of comments received from several Delegations.}

\footnote{This component of research is being carried out in collaboration with Helen Delaney, consultant.}

\footnote{See Interim Report TD/TC/WP(2005)16}. 

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developing countries, capacity and credibility are undermined by the lack of resources; hence the ability to secure the confidence of the importing country becomes more challenging, or impossible. For the set of studies reported here, this point is illustrated in the case of Brazil (see Annex III), where the price of equipment (resources = capacity) was the single factor that prevented the use of a European test method, and in the case of South Africa (see Annex II), where the price of credibility was tantamount to fees (resources = credibility) required by a trade association whose standards and conformity assessment guidelines were aligned with the requirements of the importing country.

8. The CA infrastructure, the availability and accessibility of information, expertise, and acceptance by international peers varies in developing countries. It is therefore useful to document, as part of this research, the state of national conformity assessment regimes and gauge the extent to which regime deficiencies reduce opportunities to trade, and conversely, illustrate some of the benefits that traders and economies can draw from well functioning CA systems.

9. Finally, conformity assessment is best approached from a sector-specific and/or product-specific vantage point, especially in developing countries where CA problems can be idiosyncratic. Therefore, the case studies aim to reinforce the need for specificity in any discussion of CA issues, and to increase the understanding that especially in developing countries, one size does not fit all.

10. These objectives are reflected in the structure of the case studies, which is outlined in Annex I.

III. Research methodology

A. Selection of cases

11. The countries were selected based on certain characteristics of the national CA regimes. The set of countries represents CA systems at various stages of maturity. The case studies illustrate how exporters deal with such regimes. The specific industry or company cases have been selected in each of the countries based on issues identified during initial conversations with government and industry representatives and the willingness of the exporters concerned to provide information.

1. South Africa

12. This lower middle-income country, by World Bank classification, was selected because its CA infrastructure is established, credible, and non-governmental.

13. In this, it is not unlike the European Union and the United States, and an anomaly among developing countries. Standards and test methods for the cosmetics industry, which furnishes the case investigated, are developed by technical committees comprised of company members of the trade association, many of whom are globally successful multinational companies attracted to South Africa because of its “gateway” status to the rest of the continent. CA procedures are carried out in company laboratories, by private consultants, and university laboratories, or by CA providers abroad. South Africa has an established, credible Bureau of Standards, and an accreditation body (SANAS) that is part of an international network. The CA regime, while not totally encompassing every industry sector or sub-sector, is present and viable; and the private sector involvement of the cosmetics industry in CA practices is a conceivable rationale for the self-regulatory environment. In this, South Africa is rare, and perhaps unique. But viable conformity assessment regimes (or the lack of them) in themselves are not enough to lead us to understand why certain exporters fail to access the markets of their choice. In the context of South Africa, however, we are able to view the process against a backdrop of non-governmental organisations.

14. The extract cosmetics sector was selected as the specific case to be investigated because of the opportunity it presents to view the CA problems of the indigenous component of an “expatriate” industry...
whose multinational companies are domiciled in highly developed countries and used to standards and CA
practices that are grounded in advanced and advancing technologies. Although the products are different
in nature (made of natural ingredients), they are nevertheless required to meet CA requirements that are
applied to more traditional and more chemically complex products.

2. Brazil

15. Brazil is also a lower middle-income country and, like South Africa, has a relatively well-
developed CA infrastructure. However, unlike South Africa, the CA system is government-owned.

16. Brazil presents an interesting economy in terms of conformity assessment because the Brazilian
Government’s new administration, unlike those in many other developing countries, is highly aware of the
importance of conformity assessment and its role in increasing foreign trade. One example of its support
of national businesses in this area is INMETRO’s Alerta Exportador, an electronic information service
designed to alert Brazilian exporters of newly issued notifications to the WTO of Members’ technical
regulations and conformity assessment procedures.

17. INMETRO, which is Brazil’s National Institute of Metrology, Standardization and Industrial
Quality, accredits laboratories and has signed several international accreditation recognition agreements.
Besides the agreement with ILAC for laboratories and with IAF for systems of quality management, the
Institute has had a bilateral agreement with the European cooperation for Accreditation (EA) for
laboratories since 2001. Accreditation organisms in Brazil, the USA, Canada, and Mexico signed mutual
recognition agreements in 2002 for accreditation of laboratories within the InterAmerican Accreditation
Cooperation (IAAC).

18. Despite the significant contributions of INMETRO and the government’s commitment to
improving the credibility of Brazil’s conformity assessment system, there are limits to its capacity to serve
all of Brazil’s industries. The case chosen for study is one such example: the testing of formaldehyde
emissions from particleboard used in the manufacture of wood furniture. This case illustrates the problems
not only of lack of information and capacity but also the challenge that the need to comply with
environmental requirements of developed-country trading partners poses.

3. Nigeria

19. Nigeria is a low-income country, with a CA infrastructure that is more limited than those of
South Africa or Brazil. Yet, in the case of one of its leading exports, wild captured shrimp, its capabilities
are sufficient and competent enough to win the confidence of a major world market, the European Union.

20. Nigeria has been the recipient of enough technical assistance to establish a national body for
standardization, the Standards Organization of Nigeria, which includes CA capabilities. Technical
assistance also established ISO 9000 training in 1994. ISO 9000 has been recognized as the national
standard for Nigeria and 230,000 standards and specifications have been compiled for the Information
Management Centre.

21. The case of Nigeria stresses the benefits of conformity assessment. Nigeria’s case is as much
about the harmonization of standards, conformity assessment procedures, and regulation as it is about the
industry’s ability to meet them. In a global trading system where national differences, duplicative
conformity assessment procedures, costly laboratory equipment, and divergent technologies can be barriers
to trade, the food safety requirements for seafood products are internationally accepted and implemented.
Nigeria, therefore, was able to benefit from a conformity assessment standard procedure that is based on
accepted principles of quality management.
22. The fact that shrimp is a relatively low risk product is an important element in this account; nevertheless, the food safety practices of the Nigerian trawlers and processing plants were able to inspire the confidence of one of the world’s most sought-after markets, the European Union and, in theory, the United States.

B. Collection of data

23. The collection of data was by literature searches, telephone and e-mail interviews with relevant government officials, representatives of industry associations, export organizations, consultants, conformity assessment providers, and locally based contacts including Embassy personnel.

24. For the South Africa and Brazil cases, interviews in person with companies were conducted on the margins of trade fairs in New York and Sao Paulo, respectively. The data for the Nigerian case were collected from literature, interviews with a representative from UNIDO, the Secretary General of the Standards Organization of Nigeria, members of academia, trade associations, and officials of the U.S. Government.

25. One-on-one interviews with exporters provided the centrepiece of the data collection for the South Africa and Brazil cases. Based on experience, the value of such interviews lay not only in the perceived “interpretation” of CA-related technical regulations and on the actual practices of importing countries, but also revealed the exporters’ ability to understand what was required.

26. It was made clear to companies who were interviewed or provided data for the case studies and for the description of capacity and needs that discretion, anonymity, and confidentiality would be strictly observed, unless the parties involved decided otherwise.

IV. Summary of the cases

A. South Africa

27. This case, documented in detail in Annex II, concerns small South African enterprises engaged in the manufacture of skin care products, massage oils, soaps, and other products that are based on indigenous natural raw materials and plant extracts, i.e., extract companies, that make up 30% of the SA cosmetics market. The European Union is the targeted export market.

28. While the industry is domiciled in a country where a CA infrastructure exists (mostly in-housed by larger, multinational manufacturers), the benefits of an affordable, one-stop service provider are not available to this sub-sector. Many small companies find the alternative, a multiple provider system of consultants, financially exhausting and give up efforts to export.

29. One of the most important services that a CA body normally renders to its clients is timely, accurate information regarding the technical requirements of the importing country. It was clear, from the interviews conducted, that the majority of the manufacturers in the sub-sector were either unaware of the requirements, dependant on importers and distributors for the needed information, or were conducting their exporting activities by trial and error. It was also clear that this lack of information contributed to errors being made in the process of exporting, which in turn prompted some companies to forego exporting.

30. Although cosmetics are governed by South African law, the cosmetics industry is self-regulated and standards and guidelines are voluntary, due largely to the Cosmetic Compendium developed by CTFA, the Cosmetic, Toiletry, and Fragrance Association of South Africa (which holds membership in its European counterpart, the European Cosmetic Toiletry and Perfumery Association (Colipa)). The Compendium brings cosmetic voluntary regulations in line with those of Europe and certification by CFTA
is required in some EU Member States. The majority of the small extract companies are unable to afford the cost of membership in CFTA.

31. CA requirements are not harmonized among European Union Member States, and they differ from country to country. These requirements, which can be more rigidly applied to products manufactured outside the EU than they are to products manufactured within the territory, place an additional burden on small, medium and micro enterprises (SMMEs), and add to the decision to forego exporting.

**B. Brazil**

32. Research carried out by the United Nations Conference on Trade and Development (UNCTAD) has shown that some developing countries have suffered considerable export losses due to an inability to respond to developed country environmental standards and regulations.5

33. This would appear to be the case in Brazil, where the wood furniture industry faces increasing challenges to meet formaldehyde emission restrictions in targeted export markets.

34. Formaldehyde is a known health hazard and may be a carcinogenic. The trend in developed countries is to lower the limits of formaldehyde that escapes from resin used in the manufacture of particleboard, used in the production of furniture. Particleboard used in these countries is classified as F1 or F0.

35. F2 particleboard (which emits more formaldehyde than F1) is the *de facto* acceptable material in the manufacture of furniture used in Brazil and that of its neighboring trading partners. F1 particleboard is calculated to be anywhere from 10 to 30% more expensive than F2. Largely due to the financial pressure that would be placed on its small and medium-size enterprises, Brazil has enacted no legislation that limits formaldehyde emissions for furniture.

36. The European Union is the most desired export market for many Brazilian furniture manufacturers, and for all of the companies interviewed for this case study. Of 12 companies interviewed, only two are currently exporting to EU countries and complying with EU conformity assessment requirements.

37. The EU test method, EN 717, calls for the use of specific equipment, the main component being a specially constructed chamber. There are no laboratories in Brazil that have such a chamber, although the Research Institute in the State of Sao Paulo (and others throughout Brazil) has scientists trained in the European method. Consequently, manufacturers who export to the EU must have particleboard tested in European laboratories. In addition, some EU Member States have regulations that permit only F1 particleboard.

38. The costs of having particleboard tested abroad plus more stringent legal requirements for particleboard with lower emission levels, has made exporting to countries within the European Union (and other developed countries) a financial impossibility for Brazilian manufacturers of furniture.

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5 UNCTAD’s 1998 Least Developed Country Report cites examples of least developed countries, such as Bangladesh, Madagascar, Mozambique, Nepal and Uganda having suffered significant export loses due to environmental, health and sanitary requirements in developed-country markets.
C. Nigeria

39. This case, described in more detail in Annex IV, shows a developing country’s success in gaining the confidence of a major market through a viable conformity assessment system. This, coupled with compatible conformity assessment requirements in export markets, has given it the potential for entering other foreign markets.

40. Nigeria is a maritime country where fishing plays an important role in the national economy, providing employment, food, income and foreign exchange earnings. The Nigerian wild capture shrimp industry is a significant export industry, generating US$57 million per annum in foreign exchange.

41. Nigeria has in place a competent conformity assessment authority, The Federal Department of Fisheries (FDF), which incorporates an official laboratory, plus a second official laboratory, the National Agency for Food and Drug Administration and Control (NAFDAC), which, with the FDF, certifies shrimp processing plants and freezer trawlers. A third laboratory is contained in the Nigerian Oceanographic Marine Research Institute (NIOMR).

42. Nigerian legislation makes the implementation of the Hazard Analysis Critical Control Point (HACCP) mandatory for each vessel or establishment where fishery products are produced, processed and packaged, as well as for each kind of fishery product. The HACCP system is a widely recognized system for assuring food safety that has been endorsed by many national and international scientific groups, corporations, government agencies, and academic organizations. HACCP principles are incorporated into the regulations of Nigeria, the European Union, and the United States. Nigeria was qualified by the European Commission to export shrimp into the European Union.

43. HACCP is an example of how harmonized standards and regulations work to facilitate international trade, and in particular, how they have benefited this developing country. While there are certainly differences in the implementation of HACCP regulations between the United States and the EU and other countries, in theory, Nigeria, having qualified for one, is qualified for other regimes that subscribe to HACCP principles.

44. Nigeria, however, does not export to the United States. From all observations, the reasons for not exporting to the United States are not related to conformity assessment, but to other issues, such as consumer preferences which affect pricing, a rapid increase in farmed shrimp from Asia and South America, which also contributed to lower prices in the United States, and distance to transport. It should be noted that Nigeria also does not export to Japan, the largest importer of shrimp in the world. 6

45. In terms of conformity assessment, however, Nigeria’s ability to satisfy the CA requirements for entry into the European Union must be considered a success story. Furthermore, the U.S. interest and investment in establishing a shrimp aquaculture in Nigeria portends well for the country’s ability to export to the United States as well.

V. Common threads and variations

A. Export markets

46. All three developing countries viewed the European Union as their leading export market. In the cases of South Africa and Brazil, the European Union is profiled as the export market. In the case of Nigeria, the export market profiled is the United States. One of the reasons for this is that Nigeria has

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6 The United States is the second largest importer of shrimp.
already succeeded in exporting its product to the European Union. Moreover, since the conformity assessment procedures for ensuring the safety of shrimp are compatible with those required by the United States, exporters have the potential for exporting there as well. Yet, it does not.

47. The case of Nigeria makes two points: First, the harmonization of standards and conformity assessment procedures makes it possible for exporters to penetrate multiple markets. Second, there are other market forces, such as pricing and distance to market that are more powerful determinants of market presence than the ability to successfully manage conformity assessment requirements.

B. Cost Data

48. Reliable cost data in the area of conformity assessment in these countries were non-existent. For South Africa and Brazil, exporters provided what must be considered very rough estimates. Only in one case, involving a Brazilian furniture manufacturer, were the company’s actual conformity assessment costs computed.\(^7\) No cost figures (or estimates) directly related to conformity assessment were available for Nigeria’s exporters. However, cost figures exist for implementation of HACCP by the U.S. Food and Drug Administration.

49. Furthermore, how the costs of conformity assessment presented in this report are estimated or calculated differs. Cost estimates in the South Africa case were based on the percentage of production costs; in Brazil on the price of particleboard that had undergone conformity assessment in the exporting territory; and in one export market, the United States, on average annual sales. As a sideline, conformity assessment costs published by a developing country, Bangladesh, reported costs based on one year’s export sales.

50. While the cost figures do not lend themselves to comparisons or conclusions, it is nevertheless interesting to note that when conformity assessment procedures were performed in the export markets (developed countries) or based on the export market’s cost to implement, estimates and computed costs (despite different definitions) ranged from 10-30%, while estimated costs of conformity assessment performed in two developing countries ranged from 1-9%.

C. The case of seafood

51. The TBT Agreement recognizes that developing countries may encounter special difficulties in the area of conformity assessment. The case studies in this report aim to deepen our understanding of conformity assessment from the developing country perspective.

52. Seafood is now the world’s most commonly traded food product.\(^9\)

53. The WTO Agreement on TBT Agreement includes industrial and agricultural products but does not apply to sanitary and phytosanitary measures.\(^10\) The case involving shrimp in Nigeria relates to a product sector and food safety issue that is within the purview of the Agreement on the Application of

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\(^7\) 13.8 % of production cost.

\(^8\) In the case of one exporter, the cost estimate provided (20%) fell outside the range established by the estimates provided by other respondents in the same industry.


\(^10\) As defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures.
Sanitary and Phytosanitary Measures (SPS), but it encompasses and gives credence to the principles on conformity assessment contained in the Agreement on TBT.

54. It underlines the important contribution that international standards and conformity assessment systems can make by improving efficiency of production and facilitating the conduct of international trade.

55. It also underlines the recognition of the contribution which international standardization (and conformity assessment systems based on international standards and guidelines) can make to the transfer of technology from developed to developing countries.

56. Also, conformity assessment procedures should not be prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade.

57. Conformity assessment procedures should be prepared, adopted and applied so as to grant access for suppliers of like products originating in the territories of other Members under conditions no less favourable than those accorded to suppliers of like products of national origin.

58. Moreover, conformity assessment procedures should be harmonized on as wide a basis as possible.

59. The case in Nigeria provides the study of conformity assessment with an example of how these principles work to benefit the exporters of a developing country.

VI. Conclusions

60. The study of conformity assessment and its effects on trade is in its infancy. The subject is extremely complex and information, including cost data, is scarce. Empirical data is practically non-existent. Much of it is proprietary.

61. The three case studies presented in this report are documented experiences, captured at a moment in time. Technology advances, legislative and regulatory changes, and other dynamic market forces will undoubtedly, if they have not already, change conditions. Change is inherent in any consideration of conformity assessment and the standards that drive it.

62. Each case presents multiple factors that are impossible to investigate fully in a project of this scope. The case studies are, therefore, incomplete. Each factor of conformity assessment presents an opportunity for further study. Some of the factors in this report in this category might include:

- The effect of information, or the lack of it, on exporters’ abilities to export successfully.

- The inexperience and lack of information on the part of customs officials (see the account of one company’s story in South Africa, Annex II, Box 1).

- The power of trade associations and large companies to set regulatory CA frameworks.

- The acceptance and accreditation of developing country conformity assessment infrastructures by developed countries.

- The ability or inability of industry representatives to understand the nature of conformity assessment or its impact on trade.
The differences in national interpretations of international CA principles (such as HACCP).

The effects of regulatory differences and lack of harmonization in particular product sectors.

63. Finally, in any study involving developing countries, there are inherent difficulties. The lack of a stable communications infrastructure, for instance, prevented satisfactory contacts with officials and exporters in Nigeria. This thwarted the collection of data, both in the United States by Nigerian export councils and embassy personnel, and by personnel on the ground in Nigeria.

64. In spite of these limitations, this research has contributed specificity to certain accepted tenets regarding conformity assessment. It has drawn attention to six or more pieces of national legislation and/or regulatory requirements that deal with conformity assessment, and the difficulties that they can present to exporters when they are not harmonized with one another. The report presents an illustration also of how a set of accepted international standards for conformity assessment has not only facilitated trade, but made it possible for at least one developing country.

65. The report presents real life versions of various forms of conformity assessment described in the initial analysis: risk assessment and quality management (HACCP), third party testing and certification (formaldehyde), internal quality control and self-declaration (cosmetics), and other fundamental practices associated with conformity assessment, such as record keeping and technical files.

66. It bears out, in three examples, the recognition by the Committee on TBT that developing countries may encounter special difficulties in the area of conformity assessment, and that these difficulties, among others, are related to the lack of resources and the inability to keep pace with the advancing technologies of more developed countries. Even Nigeria, which is now successfully exporting to the European Union, may find its conditions changing as its waters are overfished and if it cannot quickly move to the farming of shrimp and the conformity assessment requirements that may be associated with a different process.

67. Finally, this report breaks new ground and undoubtedly gives rise to more questions than it provides answers. In the field of conformity assessment, where research is at the tip of the iceberg, this is appropriate, and hopefully, useful to the research that will follow.
ANNEX I. STRUCTURE OF THE CASE STUDIES

I. Background

A. The developing country

1. While there are elements that are common to all countries, CA regimes in developing countries are at varying and uneven stages of development and need to be analysed case by case. Progress (or the lack of it) may depend on the industry, the demand for exports, technical assistance, or foreign investment and expertise provided by multinational companies and NGOs.

B. The industry

2. The industry is profiled and the product line is described. Export history, if it exists, and current export data are presented.

II. The costs and benefits of conformity assessment

3. Where estimates can be obtained, costs related to conformity assessment are presented. Benefits perceived to accrue to exporters are also described.

III. Capacity

4. The conformity assessment structure of the developing country is described, as are the institutions that control CA operations and their relationship (if any) to CA institutions in the international community.

IV. Legislative frameworks

A. The developing country

5. The legislative framework that regulates the industry or product within the developing country is described, in particular, the CA requirements. If there is no legislative framework, or if the legislative framework does not govern all conformity assessment aspects, market forces that control CA procedures are described, including voluntary standards and conformity assessment procedures.

B. The importing country

6. The legislative framework that regulates the industry or product within the importing country is described, in particular, the CA requirements. If there is no legislative framework, or if the legislative framework does not govern all conformity assessment aspects, market forces that control CA procedures are described, including voluntary standards and conformity assessment procedures.
V. The case

7. The issue of unsuccessful (or successful) market penetration is stated in terms of how the conformity assessment requirements were not (or were) met.

VI. Conclusions in regard to observations, lessons and attempts at resolution

8. Findings and conclusions are offered, including from the perspectives of the industry and, where available, CA institutions. Attempts at resolution are reported, as well as plans for the future development of the CA regime and trade.
ANNEX II

THE CASE OF THE EXTRACT COSMETICS INDUSTRY IN SOUTH AFRICA

A. The industry

9. In 2003, the South African cosmetics and toiletries market was estimated at USD 2.25 billion. It is expected to exceed USD 2.50 billion in 2005. In 2003, sales grew by about 15% from the preceding year, and the market has grown by more than 80% since 1996. Annual sales of products for ethnic hair and skin are estimated to account for between USD 175 and USD 246 million of the total market. This phenomenon mirrors the local socio-political changes that have taken place since the abolition of apartheid. South Africa’s black community accounts for around 60% of the total product sales across all categories, and the ethnic market is booming. Multinational cosmetic companies command approximately 70% of the market.

10. This case study is about the small South African enterprises that represent the other 30% of the market. This group of producers sees their customer base among those who favour an alternative lifestyle with strong exotic SA connotations, based on indigenous natural raw materials and plant extracts such as Rooibos, Buchu, Marula, Aloe Ferox, and African Potato. These extracts are used in the manufacture of skin care products, massage oils, aromatherapy products, soaps, and tanning products. In this, and in the fact that most do not make healing or anti-aging claims, they do not compete for market share with traditional and multinational cosmetic companies.

B. Exports

11. When sanctions imposed by the international community against South Africa ended, the new South Africa was immediately viewed not only as an interesting market but also as a springboard to neighbouring markets. The lifting of sanctions brought a considerable number of multinationals to South Africa, carrying new brands and increasing competition on the local market. Many domestic companies now see exporting as the only means of survival.

12. According to the National South African Budget Review for 2001, the influx of multinational companies contributed to the growth of more than 50% in South African beauty product exports to the rest of the continent from 1996 to 1999. There are no figures available that extrapolate the percentage of this growth that is attributable to extract companies.

13. Most extract companies have made their exporting debuts in countries neighbouring South Africa, such as Swaziland, Namibia, and Botswana. Angola, Mozambique, Zimbabwe and Kenya, however, are South Africa’s main foreign import clients for cosmetics. Some extract companies have made modest inroads into Middle Eastern markets and some European countries. The South African cosmetic sector as a whole is expanding its territorial footprint beyond Africa. South African exports of cosmetics to the European Union grew from USD 5 million in 2000 to $49 million in 2003. Again, there are no figures

11 The author would like to express her deep appreciation to Ms. Carmen Botef, Executive Director of the South African Cosmetic Export Council, without whose help and guidance this case study would not have been possible.
to extrapolate the percentage of extract companies from this figure. It would not be incorrect to surmise, however, that the percentage is negligible. Most small extract companies have been in business less than five years.

C. Costs and benefits of conformity assessment

14. Of 11 companies interviewed, three reported 1-4 % of production costs were related to conformity assessment. Two reported 5-9 %, one reported 20% or more, and five were unable to estimate a cost percentage.

15. Standards (The Cosmetic Compendium) must be purchased from the Cosmetic, Toiletry, and Fragrance Association of South Africa (CTFA). Costs are as follows:
   - CTFA members: R912 including VAT.
   - Non members: R1140 including VAT.
   - Cosmetic Compendium updates for 2003 were priced R342.

16. The above costs are related to documentation, i.e., test methods and good manufacturing practices that must be used in the required conformity assessment procedures. Whether or not purchased by the laboratory or the contract manufacturer, the cost of such documentation, which must be updated periodically, is passed on to the owner of the company.

17. The companies interviewed were unaware of the benefits of conformity assessment other than as a mechanism to satisfy mandatory requirements.

D. Capacity: The CA infrastructure

1. Standards: The Cosmetic, Toiletry, and Fragrance Association of South Africa

18. According to the CTFA, upon its establishment in 1994, South African Cosmetic Regulations for the manufacture of cosmetics were poor and this weakness was taken on as one of the first priority tasks of the fledgling Association. Industry technical committees produced the first Cosmetic Compendium. This consisted of Guidelines and Codes of Practice for most sectors of the industry and included the Ingredient Annexes used by the cosmetic industry in Europe.

19. CTFA is seen by the extract sector of the industry as a lobbying arm and the industry’s connection to the SA Government. Its corporate members, however, benefit from CTFA’s ability to acquire up-to-date information on the standards and regulations of export markets, namely the European Union. The main supporters are the multinationals, which, in turn, benefit from the information flow and CTFA’s membership in COLIPA, its European counterpart. Members also benefit from the Standards and Codes of Practice for the Cosmetic Industry, which is contained in the CTFA Compendium and which bring SA cosmetic regulations in line with those of Europe. This international harmonization is intended to benefit the South African industry locally and internationally.

20. The majority of the small extract companies are not members of CTFA, citing their inability to afford the cost of membership. Although cosmetics are governed by South African law, the industry in

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12 CTFA Codes of Practice are at SABS (South African Bureau of Standards) awaiting standards status.
South Africa is self-regulated, and standards and guidelines are voluntary. In other words, the South African Department of Health has issued no technical regulations under the law. This is, in all probability, due in no small part to the activities of the CTFA, which in effect creates the non-regulatory but virtual legal framework for the industry. CTFA also refers the SME extract companies to a network of consultants who perform conformity assessment procedures.

2. **Standards and testing activities: South African Bureau of Standards (SABS)**

21. SABS accredits microbiology testing activities of the Scientific Services group, which is a combination of microbiological, biological and chemical testing laboratories.

22. Tests performed are:
   - Bio-burden testing to determine requirements for irradiation treatment.
   - Identification of specific micro-organisms – Pseudomonas sp or Candida sp.
   - Microbial contamination – bacteria counts, yeast & mould counts.
   - Preservative challenge testing.
   - Testing of raw materials and environmental monitoring of process areas.

23. The laboratories are accredited to ISO/IEC 17025 by SANAS.

3. **Accreditation: South African National Accreditation System (SANAS)**

24. The South African National Accreditation System (SANAS) is an independent, not for gain, national accreditation body. It will ultimately be responsible for concluding Multi-Lateral Agreements (MLA) with bodies such as the International Laboratory Accreditation Co-operation (ILAC) and the International Accreditation Forum (IAF).

25. These will be in addition to the current MLA for calibration and test laboratories with European Accreditation (EA), NATA (Australia), IANZ (New Zealand) and with CNLA (Taiwan ROC). With the global trend towards forming economic regions, SANAS is also involved in initiatives of the Southern African Development Community (SADC) to form a sub-regional accreditation network.

26. The South African Government through the Department of Trade and Industry (DTI) recognizes SANAS in its capacity as National Monitoring Authority for compliance with the OECD Principles of Good Laboratory Practice. SANAS is responsible for international liaison on OECD Good Laboratory Practice (GLP) compliance monitoring issues, and represents South Africa on the OECD Working Group on GLP.

27. Organizations or facilities wishing to enter the SANAS Good Laboratory Practice Program do so voluntarily, as the Regulatory Authorities do not specify compliance with the OECD Principles of Good Laboratory Practice for studies submitted for regulatory purposes. The organizations or facilities entering the SANAS GLP Compliance Monitoring Program have done so to meet international client demands.
E. Legislative frameworks

1. South Africa


29. The act defines cosmetics in terms that include the products of extract companies, making no special provisions for natural products.

30. The act prohibits certain substances. Cosmetics must not be contaminated, impure or decayed, or is, in terms of any regulation, deemed to be harmful or injurious to human health. The law also covers containers, packaging and labelling, and empowers inspectors to enter manufacturing facilities, remove samples, demand information, and seize cosmetics which may not conform to the law. The law also provides for court-appointed analysts to examine samples. The law provides for regulations that prescribe the nature and composition of cosmetics, and standards for the composition, strength, purity or quality or any other attribute of any cosmetic or any ingredient or part of a cosmetic.

31. There are no regulations, i.e., prescribed conformity assessment procedures, at this point in time, issued by the Department of Health. Applicable CA procedures are embodied in the CTFA Compendium and pertain to the following:

32. To sell on the domestic market or to export, extract products must undergo - at a minimum - stability, microbial, and toxicology testing.

33. Depending on the product, sensitivity testing may be required, and for practically all extract products, container (the reaction of the product to its container) and climatic testing is also required.

34. Extract companies must also list ingredients, post a shelf life date on the labelling, and carry the “e” mark. 14

35. As most extract companies shy away from medical or cosmetic “claims” (healing or anti-aging, for example), clinical testing is not required. Good manufacturing practices and internal quality controls are also part of the non-regulatory regime.

36. Extract products are not required (by law or by market forces) to undergo third-party testing in South Africa or in their target export markets. A technical file is required, however, to be held by the manufacturer and made available to authorities in the exporting country when requested.

2. Export market law: The European Union 15

37. The European Union Directive requires a general toxicological profile of the ingredients, their chemical structure and their level of exposure, a specific assessment for cosmetic products intended for use

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14 The “e” mark is a legal requirement. SABS standard 1841:2000 is the specification for the control of the quantity of contents in pre-packed packages within the legal prescriptions of the Trade Metrology Act (Act 77 of 1993). These legal requirements cover the filling and packing of cosmetic products destined for local distribution and export and compliance with SABS 1841:2000.

on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene.

38. Also required by the Directive is the name and address of the qualified person or persons responsible for the assessment referred to above and declares that that person must hold a diploma in the field of pharmacy, toxicology, dermatology, medicine or a similar discipline, as well as the methods of analysis necessary for checking the composition of cosmetic products, and the criteria of microbiological and chemical purity for cosmetic products and methods for checking compliance with those criteria.

39. Furthermore, the law calls for laboratories to carry out the above assessments in accordance with the principle of good laboratory practice.16

40. No attempt is made here to compare the laws of South Africa and the European Union. It can be said, however, that the technical requirements, while not identical, are similar.

F. The CA practice for extract companies

41. There is no single CA service provider in South Africa for extract companies. Conformity assessment is accomplished in several ways:

1. Companies are referred to individual consultants who perform individual tests;
2. Companies use the services of laboratories connected with universities;
3. Companies rely on contracted manufacturers who may refine the formulae, manufacture the product and perform testing in-house;
4. Companies send products to the importing country for testing.

42. The consultant network consists of individuals, many of whom are former employees of multinational companies, who have set up shop as “mom and pop” CA providers. Since consultants are competent in only a single discipline, companies must rely on two, or three, or more, each imposing a fee, (described by companies as exorbitant) to compile a technical file that will be acceptable to authorities in export markets. Many small companies find this multiple provider system financially exhausting and give up efforts to export.

43. Although the CTFA may perform some oversight functions over this activity, consultants, according to extract companies, are not required to respect the confidentiality of formulae, and are not held liable for consumer complaints or injurious claims. While there is apparent scant confidence in their services, some extract companies see the consultant network as their only choice.

44. The smallest extract companies consist of the “owners”, who may be one individual or a small partnership who are the creators of the products’ formulae and the marketers of the product. These owners contract with laboratories or other enterprises to manufacture the product. Some larger owners manufacture the product themselves, and may even manufacture their own packaging and labels. These companies have direct control over the manufacturing process. Contract manufacturers, however, control whatever internal quality control is present, or employ

45. Good Manufacturing Practices in varying degrees of competency, and are responsible for testing the product. They may also prepare the technical file.

46. There is no legal oversight of contract manufacturers of extract products, and no verification process for test results. There is no visible concept of risk assessment or of research and development.

47. A small minority of companies with adequate resources send their products abroad (to an EU country) for testing. One company, an anomaly which has been in business for 35 years and sends its products to an EU country for testing, claims compliance to ISO 9000 quality management standards and ISO 14000 environmental standards.

G. Suppliers

48. Among the extract companies, there are no visible requirements on the suppliers of raw materials to supply data with the materials, and no visible mechanism to trace the sources of raw materials. No company reported inspecting farmer suppliers or harvesting practices.

H. The experiences of extract companies

49. Box 1 describes the experience of one producer of this industry. More than one other company reported difficulties with exporting to foreign markets whose population have an ethnic mix close to that of South Africa, and therefore have the same demographic customer base. One company reported one export market’s refusal to accept products that conformed to European guidelines and currently were sold in two European countries, Russia, the Ukraine, Australia, and New Zealand, the requirement to have an in-country representative, and the requirement to test the product in the importing country. Another company currently exporting to a market in a region that has a common legal framework, reported that a CA provider in one of the countries in that region wanted to test the product in-country, which would have raised the cost of the product by 50%.

I. Barriers to trade?

50. Is the incident involving the company manufacturing glycerine soap unique to this producer? What can one conclude about barriers to trade for this small industry? While the industry is domiciled in a country where a CA infrastructure exists and is being used by larger members, the benefits of an affordable, one-stop service provider apparently eludes this particular sub-sector. One of the most important services that a CA body normally renders to its clients is timely, accurate information regarding the technical requirements of the importing country. It was clear, from the interviews conducted, that the majority of the manufacturers in this sub-sector were either unaware of the requirements, vaguely familiar with the requirements, dependant on importers and distributors for the needed information, or were conducting their exporting activities by trial and error. It was also clear that this lack of information contributed to errors being made in process of exporting, which in turn prompted some companies to forego exporting.

51. Those who have persisted report that they have a hard time complying with what they perceive as constantly changing CA requirements of the European Union, which is their main export market and the market with which South Africa’s CTFA is attempting to align its technical requirements. The Cosmetics Directive permits EU Member States to add requirements to imports that go beyond those in the Directive. These requirements can be more rigidly applied, i.e., differently, to products manufactured outside the European Union than they are to products manufactured inside the European Union, and they differ from country to country. These discrepancies in CA requirements are, if not a barrier to trade, an additional burden on the SMEs and SMMEs interviewed for this study.
Box 1. One company’s experience

This company manufactures handcrafted glycerine soap with palm kernel oil*. In recent years it has been exporting small quantities of the product to several members of the European Union and Canada and has targeted also the U.S. market. When attempting to export its product to yet another member of the European Union, the manufacturer encountered difficulties.

A. The Company’s attempts at compliance

1. Documentation

Documentation was provided as follows:

a) A General and Chemical description of the product;
b) A notice that there are no environmental or health hazards connected with the product if handled and used properly;
c) First Aid Measures to be employed if the product was ingested, or if there was contact with eyes;
d) A notice that there were no special protective measures to be applied when using the product;
e) Instructions for handling and storage;
f) The Physical and Chemical Properties of The Product, including the flash point and pH value;
g) A stability and reactivity statement, saying that the product will not promote hazardous reactions and will decompose above 150 deg C;
h) A statement that the product is considered non-toxic and that it was not tested on animals;
i) An ecological statement that the product is fully biodegradable and in an aquatic environment will not promote eutrophication;
j) A disposal statement, noting that the material is not considered hazardous waste and that the packaging is suitable for a waste-disposal site approved by local authorities.

2. A CTFA certificate

The importer informed the manufacturer that proof was needed that the company was a recognized manufacturer in South Africa. The South African Embassy informed the manufacturer that the solution was to obtain a certificate of membership from the CTFA as the government of the importing country recognized the organization. The manufacturer complied and the CTFA sent through the certification. It was not accepted. It is not clear why the certificate was rejected.

3. A Pharmacist

The importer requested that the pharmacist controlling the production of the soap be identified. A document signed by the pharmacist was sent. The document was rejected. It is not clear why the document was rejected, but the importer informed the manufacturer that each batch had to be inspected by a pharmacist.

4. Registration

The importing country’s Ministry of Health requires registration of the product; and according to the importer, this is a recent requirement throughout the European Union and this specific importing country is one of the first countries applying it. The documentation for registration is described, and it matches the documentation already submitted (see A above). The manufacturer, after searching through several channels unsuccessfully, requested information on the proper form (similar to one already used in Canada and available on its website), but could not obtain it from the importer.

B. The product is destroyed

Finally, the product is destroyed and the importer informs the manufacturer that the Ministry of Health decided on one day to enforce a regulation that involved the registration of products containing poisons that had been on the books since 1998. According to the importer, there was no advance notice given to brokers or importers. The product contains no poisonous ingredients.* The glycerine is not derived from tallow.
52. In the case of the company whose experience is described in Box 1, the importing country’s requirement for batch-by-batch documentation may have been rescinded at the time the product was destroyed. No one who was involved in the process was aware of whether or not this was the case.  

53. Perhaps the most significant barrier to trade is the inability to obtain information critical to successful exporting. Extract companies obtain information about requirements of importing countries in a variety of ways. Many rely on the Export Council and the DTI. Others rely on distributors, representatives, customers, and the SA consulates within the importing country - none of whom are CA specialists. A small number who can afford membership, obtain information from the CTFA and still others rely on consultants who are CTFA members. Some do their own research on the Internet, and admit that foreign regulations are mind-boggling and not understandable. All report that rapidly changing regulations in the export market countries are a constant challenge, and the majority report learning by trial and error. European Directive Council Directive 79/661/EEC has been amended 27 times since it entered into operation in 1979.

J. The issue of assistance

1. South Africa Cosmetics Export Council

54. The South African Cosmetics Export Council (SACEC), set up in January 2001, is a non-profit organization with more than 170 members. Its stakeholders are manufacturers as well as the government. 95% of its members are SMEs, without extensive corporate experience, i.e., the extract companies, although not all extract companies are members of SACEC.

55. SACEC assists its members with direction and strategies for introducing South African brands into the global marketplace through access to a database of export leads, trade statistics and industry surveys, export training, mentoring and consulting. The Export Council is helping companies to better understand the global standards, quality, and CA requirements of export markets. In some cases, the SACEC is the only source of CA information available to small, medium and micro enterprises (SMMEs).

2. DTI and TISA

56. The Department of Trade and Industry (DTI) and its offshoot, Trade and Investment South Africa (TISA), promote the formation of industry-based export councils to assist exporters in reaching their targets, supplying funding for the formation of export councils and certain initiatives, including trade missions and exhibitions. Industry sectors organize into export councils to tackle the global marketplace as collective forces. The export council approach is specifically tailored to facilitate access to DTI support structures by SMMEs as well as by larger companies.

17 EU Notification Requirements for Cosmetic Manufacturing/Importation & Products, CEECTF, 14 December 2001. Following intervention from COLIPA and the Commission, all direct imports from non-EU countries are no longer required to provide customs with documentation on a batch-by-batch basis.
K. **Outlook**

57. The South African Cosmetics Export Council, while concentrating on the marketing opportunities for the extract companies, is aware of the CA needs of this small industry and is currently exploring ways to improve the current situation, including by lobbying the South African government to pursue free trade agreements that would cover the cosmetics industry and provide for the mutual recognition of CA results. It is also being recognised within the sub-sector of the industry and by the Council that a body is needed that would provide unbiased, affordable, professional service to the industry. Such a body might include a laboratory and would provide technical assistance with respect to product development, quality and other aspects of control, and above all, training in the area of CA.
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ANNEX III
THE CASE OF THE WOOD FURNITURE INDUSTRY IN BRAZIL

A. The industry

58. The Brazilian furniture industry consists of 13,500 very small, small, and medium-size domestic companies. These companies are located for the most part in central-south Brazil, concentrated in industrial centres like Bento Gonçalves (Rio Grande do Sul State), São Bento do Sul (Santa Catarina State), Arapongas (Paraná State), Mirassol, Votuporanga and São Paulo (São Paulo State), Ubá (Minas Gerais State) and Linhares (Espírito Santo State).

59. According to the Brazilian Association of Furniture Manufacturers (ABIMOVEL), the Brazilian furniture market was estimated to be worth approximately USD 3.9 billion in 2001, of which about USD 103 million were imports. Market analysts estimate that in the next 3-4 years, imports of institutional furniture, such as that used in hospitals and hotels, will increase considerably, mainly from the United States.

60. The Brazilian furniture market may be classified by the following categories - 60% residential, 25% office, and 15% institutional organizations, e.g., school, medical/hospital, hotels and restaurants (U.S. and Foreign Commercial Service and U.S. Department of State, 2003).

B. Exports

61. Mercosur presently accounts for only 1% of world furniture exports, of which Brazil holds the lion’s share. Brazil's trade ministry’s optimistic projection, however, is that Mercosur will surpass either Italy or China - the number one and number two of global furniture trade—by 2034. Brazil's furniture exports experienced on average annual growth of 29% from 1990 to 2003 and by mid 2004 were poised to easily exceed the previous year's record output of USD 661.6 million. (Raposa 2005).

62. Twelve Brazilian-owned companies were interviewed for this case study. The number of employees ranged from 50 to 800. All twelve identified the European Union as their primary export market, and with the exception of one, identified the United States as a future export destination. Only three of these companies are currently exporting to the European Union, and of these three, only two are complying with European conformity assessment requirements. These two companies have been in business less than 6 years and report also exporting to the United States, Japan, and Canada.

18 The author would like to express her thanks and deep appreciation to INMETRO, in particular Ms. Anna Camboim and Mr. Eduard Trajano Gadret, and to Dr. Otto Loesener and Dr. Octavio Maizza-Neto of UNIDO, without whose assistance and dedication this study would not have been possible.

19 Argentina, Paraguay, Uruguay, and Brazil
C. Capacity: The CA infrastructure

1. SINMETRO

63. The activity of conformity assessment in Brazil is systemically managed by means of the Brazilian System of Conformity Assessment – SBAC.

64. SBAC is a sub-system of the National System of Metrology, Standardization and Industrial Quality - SINMETRO. Within the ambit of SINMETRO, the activities of scientific, industrial and legal metrology, conformity assessment, standardization and accreditation of bodies and laboratories are managed organically.

2. CONMETRO

65. CONMETRO is responsible for formulating, coordinating and supervising Brazilian policy on metrology, standardization and certification. One of CONMETRO's goals is to promote the use of voluntary standards in Brazil. It is presided over by the Minister of Development, Industry and Foreign Trade and operates mainly through the work of committees on standardization, conformity assessment, metrology, the Codex, and technical barriers to trade.

3. INMETRO – The National Institute of Metrology, Standardization and Industrial Quality


67. INMETRO has signed several international accreditation recognition agreements. Besides the agreement with ILAC, for laboratories, and with IAF, for systems of quality management, the institute has had a bilateral agreement with the European cooperation for Accreditation (EA) for laboratories since 2001. Accreditation organisms in Brazil, the USA, Canada, and Mexico signed mutual recognition agreements in 2002 for accreditation of laboratories within the Interamerican Accreditation Cooperation (IAAC).

68. INMETRO is advised by CONMETRO's technical committees in its accreditation activities, and gives accreditation to bodies engaging in certification, inspection, training, calibration, and testing.

4. ABNT

69. The ABNT, Brazil’s standards body, represents Brazil in the ISO/IEC and in regional standardization fora. The ABNT also participates in several technical committees, such as ISO TC 176 (quality), ISO TC 207 (environment) and ISO/CASCO (conformity assessment). The ABNT has cooperation agreements with its counterparts in other countries. The development of national standards by the ABNT is carried out in accordance with internationally accepted criteria. The ABNT signed the WTO/TBT Code of Good Practice in 1995 and follows its Annex 3. The ABNT also adopts international standards. Standards are adopted through a process of consensus in which both the public and the private sector participate. Once standards have been approved, they are adopted by the ABNT, which also notifies them to ISO.
D. Testing and conformity assessment

70. Testing and calibration activities are executed by laboratories under the Brazilian Calibration Network (RBC) and the Brazilian Laboratory Network (RBLE). These laboratories must be accredited by INMETRO; they may be private or public. The bases for accreditation are ABNT, Copant, Mercosur and ISO/IEC guidelines.

71. Certification is generally voluntary in Brazil. Products and services subject to mandatory certification are those that may affect consumer health, safety or the environment. As of January 2004, 35 products were subject to mandatory certification. Certification is also mandatory for six types of services and three products are subject to mandatory verification of performance (advance signal registration equipment, liquefiers, and hair dryers).

72. Brazil recognizes product and system certification from foreign certification agencies that have a memorandum of understanding with a Brazilian certification body.

73. In spite of this relatively sophisticated and well-developed infrastructure, there is no facility in Brazil that can test for formaldehyde emissions using the test methods required by Europe or the United States and Canada. Manufacturers who export furniture to the European Union must rely on (1) suppliers of particleboard which has been tested in Europe, or (2) laboratories in Europe that will test the final product (See Box 2). The two companies interviewed that were successfully (and legally) exporting products into the European Union sent samples of particleboard (or their suppliers did) to laboratories in the UK and Germany for testing. One reported that the final furniture product (after sealing) had to be tested as well in the European Union.

E. The formaldehyde problem

74. Formaldehyde is present in urea formaldehyde aminoplastic resins, which are used in the manufacture of particleboard, which is, in turn, used to produce furniture. The acceptable levels of formaldehyde emissions from composite panel products have been continuously reduced over the last two decades.

75. Formaldehyde affects human beings in various ways. It is normally present at low levels, usually less than 0.06 ppm (parts per million), in both outdoor and indoor air. When present in the air at levels at or

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20 The complete list of products subject to compulsory certification, as well as the agencies responsible and the legal documents supporting the requirements are available online at INMETRO’S website: http://www.inmetro.gov.br/qualidade/prodCompulsorios.asp#10.

21 Brazil participates in a plurilateral mutual recognition arrangement in the field of quality management systems, as notified to the WTO in document G/TBT/10.7/N/40 of 12 December 2002. Parties to the agreement are bodies from Argentina; Australia and New Zealand (jointly); Austria; Belgium; Canada; China; the Czech Republic; Denmark; Korea; Finland; France; Germany; Hong Kong, China; India; Indonesia; Ireland; Italy; Japan; Malaysia; Mexico; the Netherlands; Norway; the Philippines; Poland; Romania; Singapore; Slovakia; Slovenia; and South Africa. In 2002, Brazil, through INMETRO, signed a Multilateral Recognition Arrangement for Accreditation Bodies of Quality Management Systems Certification Bodies with Canada and Mexico, which entered into force on 24 October of that year. Under this arrangement, each signatory recognizes the operation of the other signatories' quality management systems within the programmes defined as equivalent to its own. This arrangement was also notified to the WTO in WTO (document G/TBT/10.7/N/43 of 8 January 2003). Prior to those arrangements, Brazil had signed five mutual recognition agreements with respect to conformity assessment. Two were with Argentina; one with other Metrology Convention Members, one with the IAF-International Accreditation Forum; and one within the framework of LAIA.

29
above 0.1 ppm, acute health effects can occur including watery eyes; burning sensations in the eyes, nose and throat; nausea; coughing; chest tightness; wheezing; skin rashes; and other irritating effects. Sensitive people can experience symptoms at levels below 0.1 ppm. Formaldehyde has caused cancer in laboratory animals and may cause cancer in humans; there is no known threshold level below which there is no threat of cancer. The risk depends upon amount and duration of exposure (National Safety Council, United States).

76. Pressed wood products (i.e., particleboard, medium-density fibreboard, and hardwood plywood) are now considered the major sources of residential formaldehyde contamination (Godish, 1988; Etkin, 1996). Pressed wood products are bonded with UF resin; it is this adhesive portion that is responsible for the emission of formaldehyde into indoor air. The emission rate of formaldehyde is strongly influenced by the nature of the material. Generally, release of formaldehyde is highest from newly made wood products. Emissions then decrease over time, to very low rates, after a period of years (Godish, 1988; World Health Organization, 2002).

F. Legislation


77. The approach taken by the European Union to the limitation of volatile organic compounds (VOC) emissions from organic solvents is put forth in EU Council Directive 1999/13/EC (effective March 11, 1999). The Directive, which each Member State was required to bring into force within their respective jurisdictions by April 2001, aims to reduce emissions from solvents used in selected activities. The 20 activities targeted for control are, for the most part, consistent with ones identified in Canada and the United States as significant sources of VOC emissions (e.g., printing, surface coating, surface cleaning, vehicle coating, and the impregnation of wooden surfaces).

78. While the Directive lists target VOC emission limits for Member States, MSs may exempt most existing installations from compliance with emission limits if they implement a National Plan, which within the timescale leads to at least an equal reduction in emissions the limit values would have achieved, i.e., the Directive includes the option of complying through the establishment of flexible National Plans.

79. There is, therefore, no harmonized (Europe-wide) legislation for formaldehyde emission limits at this time. Consequently, Member States have introduced a number of pieces of legislation and regulations as appropriate. Consequently, acceptable emission levels vary across the European Union (ESA Fugitive Emissions Working Group).

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23 See Table 4. Emission ceilings for volatile organic compounds (thousands of tonnes of VOC per year) L 179/20 Official Journal of the European Union, 17.7.2003
2. Regulation in Member States

80. In 1980, the world’s first formaldehyde regulation for wood products was published in Germany. That guideline combined the formaldehyde steady state concentration, determined by a large chamber test, and the formaldehyde content, determined by the perforator method, classifying particleboards according to their formaldehyde release into three different emission classes, E1, E2, and E3 (Athanassiadou 2000).

81. While the test methods have evolved and improved over the years, these classifications are still referred to today; and in many developed countries, including several EU Member States, only E1 particleboard is accepted. In any case, formaldehyde concentration limits in most industrialized countries has been dramatically reduced over the last 20 years; and the combination of more stringent regulated levels24 combined with market forces25 have created an environment for a de facto E1 requirement in many markets.

3. Regulation in Brazil

82. Furniture for school children is regulated for such safety issues as the presence of toxic paint, mattress support, and resistance weight. There is, however, no regulation that limits formaldehyde emissions for furniture of any kind. A recent legislative proposal to establish low formaldehyde emissions levels was met with significant opposition from industry, small and medium-size enterprises who would be financially burdened by having to manufacture furniture using the more expensive (E1) particleboard.

83. In Brazil, where the climate is tropical in the summer and temperate in winter, most homes are not insulated and sealed as they are in colder climates (such as Northern Europe and North America); and open windows and open spaces make formaldehyde emissions less of an indoor pollutant issue. E2 particleboard, therefore, is the de facto acceptable material in the manufacture of furniture used in Brazil and that of its neighbouring trading partners.

G. Standards

84. Europe and North America pioneered in the development of test methods that would accurately measure formaldehyde emissions from panels and established emission guidelines. The European Standard(s) and the U.S. standard(s), however, take different approaches and measure slightly different emission characteristics. Studies are currently underway to compare standards from around the world, including the JIS R 3503 from Japan and the ISO standard that serves as the reference for the U.S. standard (Stout 2005).

85. For the present however, and for Brazil, the relevant test methods are EN 717 for Europe and ASTM E 1333 for North America.

H. The costs of particleboard and conformity assessment

86. Manufacturers (suppliers) of particleboard must have their products tested abroad. They base their prices on the amount of formaldehyde in the resin (less is more expensive), plus the cost of out-of-country testing. Both costs are passed on to the manufacturers of furniture, who then may have to have the finished (and sealed) product tested again, depending on the demands of the customer or state regulations.

24 Wood impregnation processes authorized in the UK have more stringent limits than are prescribed under the Directive (Entec UK Limited, 2000).

25 Many, if not most companies in Germany, for example, are producing particleboard of the E1 class (Athanassiadou).
87. Three companies interviewed for this case study were able to compare the costs of low emission particleboard (E1) used for export and higher emission particleboard (E2) for the domestic and neighbouring country markets: The first company estimated that E1 was 10-15% more expensive; the second company estimated that E1 was 30% more expensive; and the third company provided a calculated figure of 13.8% for the more expensive E1 particleboard.

88. The first company reported that sales to France, Germany, and the Netherlands were never concluded because testing in those countries was too expensive. It currently exports to Spain, Portugal, the United States, Canada, several countries in Central America, and South Africa.

89. The second company (whose estimate diverged significantly from those interviewed) is ISO 9001 certified and exports furniture made with E1 particleboard to France (where it has an authorized representative), E0 particleboard to Japan, and E2 to 35 other countries. It attributes its success in France and Japan, despite giving the highest cost-to-manufacture estimate (30%), to its ability to sell in a high volume to other countries.

90. The third company reported that the company has an internal quality program, but that its 370 employees has been reduced to 120 and that the number of export countries has been greatly reduced. The company exports 50% of its products, using E1 particleboard for France, the United States and Spain.

91. All other companies interviewed have either eschewed exporting to developed-country markets or have never attempted to export to those markets.

I. Outlook

1. The Instituto de Pesquisas Tecnologicas (IPT)

92. The technical division that deals with forest products (wood) of the Instituto de Pesquisas Tecnologicas (IPT), the research institute of the State of Sao Paulo, tests furniture to comply with Brazilian regulations for children’s furniture. IPT services SMEs and has over 100 years of experience of research and testing of wood products. Conversant with the requirements of foreign markets and the health hazards associated with formaldehyde emissions, IPT scientists are also aware of the challenges facing Brazilian exporters of furniture.

93. IPT technicians are competent to conduct testing to the European standard EN 717, as are other multidisciplinary teams in other laboratories in Brazil. What is necessary to conduct the testing, however, is equipment, which includes, among other things, a specially constructed chamber (a room).

94. IPT has presented a proposal to Fundo Nacional de Desenvolvimento Cientifico e Technologico, under Financiadora de Estudos e Projetos (FINEP), the government agency that finances scientific and technological studies and is part of the Ministerio da Cienda e Technogia. The proposal is for funds in the amount of 471 000 RS (approx. USD 188 000) to be used for the purchase of the equipment required by EN 717. The amount includes the cost of accreditation by INMETRO.

95. If successful, IPT would become the first laboratory in Brazil to test particleboard for formaldehyde emissions required by the furniture industry’s prime export target, the European Union. Although it is not within the realm of this paper to attempt a projection of the additional income that Brazilian furniture exports to developed-country markets would generate, it is probably safe to say that the profits would exceed by far the cost of the equipment that domestic conformity assessment providers require.
Box 2. The key issues

1. The Brazilian furniture industry consists of 13,500 very small, small, and medium-size domestic companies.

2. Formaldehyde is a known health hazard and may be a carcinogenic. The trend in developed countries is to lower the limits of formaldehyde that escapes from resin used in the manufacture of particleboard, used in production of furniture. Particleboard used in these countries is classified as E1 or E0.

3. E2 particleboard (which emits more formaldehyde than E1) is the de facto acceptable material in the manufacture of furniture used in Brazil and that of its neighbouring trading partners. E1 particleboard is calculated to be anywhere from 10% to 30% more expensive than E2. Largely due to the financial pressure that would be placed on its SMEs, Brazil has enacted no legislation that limits formaldehyde emissions for furniture.

4. The European Union is the most desired export market for many Brazilian furniture manufacturers, and for all of the companies interviewed for this case study. Of 12 companies interviewed, only 2 are currently exporting to EU countries and complying with EU conformity assessment requirements.

5. The EU test method, EN 717, calls for the use of specific equipment, the main component being a specially constructed chamber. There are no laboratories in Brazil that have such a chamber, although the Research Institute in the State of Sao Paulo (and others throughout Brazil) has scientists trained in the European method. Consequently, manufacturers who export to the EU must have particleboard tested in European laboratories.

6. In addition, some EU Member States have regulations that permit only E1 particleboard.

7. The costs of having particleboard tested abroad plus more stringent legal requirements for particleboard with lower emission levels, has made exporting to countries within the European Union (and other developed countries) a financial impossibility for Brazilian manufacturers of furniture.

2. **The Competition**

96. Brazil’s furniture sector is a growth sector. In 2005, from January to May alone, Brazil totalled US$ 404 million in sales to foreign markets (Abimovel). Yet, the companies interviewed have expressed the concern that increased exports from China into their targeted future market, the European Union, will pre-empt their entry.

3. **Private-sector initiatives**

97. There have been a series of gains in productivity, technology and design achieved by the Brazilian furniture industry (Abimovel). The winner of Brazil’s design award for 2005 does not export his company’s products, but is aware of the formaldehyde problem, and expressed his desire for legislation and the infrastructure to bring Brazilian’s furniture industry into line with international requirements. In general, however, the companies interviewed for this case study voiced considerable concern with the economic pressures of exporting; and while neighbouring countries and other developing countries still provide a market for Brazilian manufacturers of furniture, it is doubtful that, without the added conformity assessment infrastructure, the country will move to lower emission levels by legislation.

98. The one chemical company interviewed for this case study reported that it is trying to build a laboratory in Brazil in which to research and test a “safer” formaldehyde resin.

4. **Information**

99. INMETRO’s “Alerta Exportador” is an electronic tool designed to assist national companies in handling technical barriers to trade. *Alerta Exportador* is an early warning system that focuses on
Brazilian exporters. It aims at disseminating information related to technical regulations and conformity assessment procedures proposed by WTO members.

100. *Denuncie Barreiras Tecnicas* is an online service that acts as a channel between exporters and the Brazilian TBT Enquiry Point to denounce technical barriers identified on an exportation process. *Solicite Textos Completos* is a service to order full texts related to technical regulation proposals. *Coments as Notificacoes* is a service to receive comments on the proposals notified to WTO.

101. *Consulta as Norificacoes* is a database available to public consultation and *Solicite Informacoes* is a service where the exporter can present consultations related to exportation, more specifically related to technical barriers to trade. This service provides information on the mandatory requirements established by trading partners. *Paises e Produtos* is an online service that offers documents on mandatory requirements in several countries.

102. All of these services are free. Despite this sophisticated system, the companies interviewed relied on representatives or contacts in European Member States for information regarding formaldehyde emission limits, and a significant number of those companies interviewed seemed unaware of the health hazards associated with formaldehyde emissions and the trend in many markets to lower acceptable levels.

5. **Trends**

103. The consensus among many scientists is that the E1 emission level is low enough to avoid any danger. But it is also considered important that not only particleboard, but veneering and carpenter’s glue resins, lacquers and varnishes and other sources of formaldehyde used in the manufacture of furniture are under control; and technology is expanding in the area of decreasing the amount of free formaldehyde in resin while maintaining the required resin performance.

104. New and more stringent regulations for formaldehyde emissions are now under discussion in Germany, and the wood adhesives industry is developing new highly sophisticated aminoplastic resin systems which allow the production of wood-based panels with formaldehyde emission rates as low as natural wood itself. Furthermore, recent developments in technology have shown that it is possible to meet the new demands for E-zero (as in Japan) from composite panels products with the use of properly formulated aminoplastic resins systems (Athanassiadou 2000).
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the joint sponsorship of the United Nations Environment Programme, the International Labour Organization, and the World Health Organization, and produced within the framework of the Inter-

Interviews were conducted with:

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Figuiredo, Reinaldo, ANSI
Franco, Nilson, IPT
Haataja, David, Underwriters Laboratories, Sao Paulo, Brazil
Mitzhof, Sergio, Synteko
Nahuz, Marcio Augusto Rabelo, IPT
Poffo, Oswaldo, IPT
Spaki, Roberto Cezar, Synteko
Stout, Charlie, Composite Panel Association
ANNEX IV

THE CASE OF THE SHRIMP INDUSTRY IN NIGERIA

A. The shrimp industry in Nigeria

105. Nigeria is a maritime country where fishing plays an important role in the national economy, providing employment, food, income and foreign exchange earnings. The wild capture shrimp industry is significant to the economy, generating USD 57 million per annum in foreign exchange. Shrimp and/or prawn aquaculture technology is currently unavailable and unproven in Nigeria.

106. There are approximately 36 trawler companies with about 300 motor fishing vessels, all based in Lagos, with the exception of one company in Port Harcourt and another one in Calabar. In 1999, 187 vessels were licensed for inshore shrimp fishing. The major companies with large fleets are joint ventures. All are grouped within the Nigerian Trawler Owners' Association (NITOA) (Ogbonna, undated).

B. The wild capture process

107. On board vessels, after the trawl net is hauled, its codend is opened and washing/sorting/grading of products into various categories quickly takes place. The sorted fish are sealed in 20-kg bags and placed in the refrigerated fish hold at about -25°C. Similarly, the shrimps are packaged in 2.2 kg packets and quickly frozen in batches in the plate freezers on the deck at -30°C within four hours before being stowed in the fish hold in master cartons. Those earmarked for peeling are bagged. (Ogbonna, undated)

108. Nigerian trawlers are freezer vessels packing on board. The Nigerian laws oblige them to come back to port before exporting. The frozen products usually wait in cold stores. In addition, four shore-based establishments produce the peeled and deveined (PUD) shrimps, which cannot be processed on board (European Commission 1998).

C. Conformity assessment infrastructure and legislation

109. The Federal Department of Fisheries (FDF), which incorporates an official laboratory, is designated as the competent authority in Nigeria, but practical supervision had, in the interim, been devolved to the other official laboratory, the National Agency for Food and Drug Administration and Control (NAFDAC), which had been deemed as better equipped for the role. If it has not already happened, this situation will have needed resolution – processing plants and freezer trawlers have been given both FDF and NAFDAC certification numbers. (European Commission, 1998). A third laboratory is contained in the Nigerian Oceanographic Marine Research Institute NIOMR.

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26 The author would like to express her thanks to Dr. Otto Loesener of UNIDO and Dr. John Akanya, Director General of the Standards Organization of Nigeria, for their invaluable assistance in identifying the product sector and their contributions to the development of this study.
110. As of 1998, there were also two private laboratories working for the industry, but no official control was carried out on them. The same can be said for the in-plant laboratories (European Commission, 1998).

111. In 1998, the European Commission found that the inspection of NAFDAC as a laboratory (not as an inspection body) revealed that it had an experienced and trained staff, good documentary management, well-established sampling procedures and was well equipped for microbiology, heavy metals, radioactive compounds and physical-chemical tests. However, after NAFDAC sustained heavy damage, the Standards Organization of Nigeria (SON) laboratories established by UNIDO took over responsibility for testing and issuing certificates for exporters of wild capture shrimp. SON laboratories are continuing to upgrade with new equipment, thus improving the overall CA infrastructure of the country (Loesener, 2005).27


D. The U.S. market

113. After Japan, the United States is the world’s second largest importer of fisheries products. Developing countries are the major seafood suppliers to the United States. For the five consecutive years from 1996 to 2000, edible fishery product imports from developing economies were valued at approximately 2.5 times those from developed economies (Sun and Caswell 2002). Major suppliers are Mexico, Ecuador and China for white shrimp and Thailand, India, Vietnam and Indonesia for black tiger (USAID 2002). Nigeria however exports mainly to Europe.29

114. The Food, Drug, and Cosmetic Act, Section 801, is the legislative power that governs the safety of seafood. It empowers the U.S. Food and Drug Administration30 to detain seafood products that appear to be unsafe for human consumption.

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27 The Standards Organization of Nigeria (SON) was created in 1971 under the auspices of the Ministry on Industry with a mandate for standards elaboration, specifications, and quality assurance system of commodities, manufactured industrial and imported products and services generally, including metrology and was restructured in 1984 to confer SON with autonomy. SON is an active member of African Regional Organisation for Standardisation (ARSO), Codex Alimentarius Commission, which is the Food Standardisation Organ of the United Nations Food and Agriculture Organisation (FAO) and is also a member of the International Organisation for Standardisation. The Food & Chemical Laboratory functions as a general-purpose laboratory. And is principally involved in carrying out third party conformity assessment of products (goods) using statutory approved quality control standards-such as pre-qualification tests which form the basis for the Nigerian Industrial Standards award.


29 OECD trade data provides an alternative measure – some 6,800 tons were imported into Europe in 1998 (which takes the great bulk of Nigerian shrimp) (USAID 2002). Almost all Nigerian exports of fishery products are intended for EC countries, and mainly to Portugal, France, Belgium, The Netherlands and Spain (European Commission Report 1998).

30 One of FDA’s most important controls on imported seafood is port of entry examinations and product testing. The importer, or his/her representative, must file an entry notice and acquire a bond to cover his/her goods for release from the U.S. Customs Service. FDA is notified by Customs of the entry and
E. The Hazard Analysis Critical Control Point (HACCP) system

115. The Hazard Analysis Critical Control Point (HACCP) system is a widely recognized system for assuring food safety. It has been endorsed by many national and international scientific groups, companies, government agencies and academic organizations (see Box 3).

116. Hazard analysis takes place when the processor conducts, or has conducted, an analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards (U.S. Code of Federal Regulations, Title 21, Volume 2, Revised April 1, 2002).

117. The HACCP system requires the processor to have and implement a written plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. A HACCP plan must be specific to (1) Each location where fish and fishery products are processed by that processor; and (2) Each kind of fish and fishery product processed by the processor. (U.S. Code of Federal Regulations, Title 21, Volume 2, Revised April 1, 2002).

118. A HACCP written plan must include a list of procedures that will be used to monitor critical control points, corrective action plans, a list of verification procedures, and a recordkeeping system.

1. HACCP in Nigeria

119. The Nigerian legislation makes the implementation of HACCP mandatory for each vessel or establishment where fishery products are produced, processed and packaged, as well as for each kind of fishery products.

120. Nigeria established this system in 1998 and has been rewarded by inclusion on the EU “Decision 2001/635/EC -Part 1” list of countries – so is able to export freely to the European Union (and thus, in effect, the OECD) (USAID 2002).

2. HACCP in the United States

121. In the United States, the Hazard Analysis Critical Control Points (HACCP) system is now in place for many food industries, including the seafood industry. The final rule on HACCP for seafood was issued in December 1995 and was required to be implemented by December 1997.

3. HACCP in the European Union


decides the article’s admissibility. If FDA does not wish to examine the entry, the product is allowed to enter the United States. If FDA wishes to examine the entry, it will be sampled from the shipment and analyzed in FDA’s laboratory. If the analysis shows the product is in compliance, the shipment is released into United States commerce. However, if there is a violation, the product is refused entry (Sun and Caswell 2002).

31 Food hazards are listed as the following: (i) Natural toxins; (ii) Microbiological contamination; (iii) Chemical contamination; (iv) Pesticides; (v) Drug residues; (vi) Decomposition (viii) Unapproved use of direct or indirect food or colour additives; and (ix) Physical hazards.

Box 3. A brief history of HACCP

HACCP is defined as a systematic approach to be used in food production as a means to assure food safety. The HACCP concept is to prevent food safety problems before they occur. These food safety problems include biological, chemical and physical hazards.

HACCP started in 1959 with the Pillsbury Company’s manufacture of food products for the NASA space program. The US Army’s “Modes of Failure” concept to predict what could go wrong and to select key points in the process to monitor (the forerunner of modern process control) was evaluated and adopted. From this evolved the concepts of Critical Control Points (CCPs) and prevention, thereby laying the foundation for the development of the HACCP system. (Pierson 1995)

In the 30 years since its conception, the Hazard Analysis Critical Control Point system (HACCP) has grown to become the universally recognized and accepted method for food safety assurance. The recent and growing concern about food safety from public health authorities, food industry and consumers worldwide has been the major impetus in the application of the HACCP system. This concern has been substantiated by a significant increase in the incidence of food borne diseases in many countries during recent years.

WHO has recognized the importance of the HACCP system for prevention of food borne diseases for over 20 years and has played an important role in its development and promotion. One of the highlights in the history of the HACCP system was in 1993 when the Codes Guidelines for the Application of HACCP system were adopted by the FAO/WHO Codex Alimentarius Commission.

The Codes Guidelines play a crucial role in the international harmonization of the application of the Codex system. Following the successful conclusion of the GATT Uruguay Round of Multilateral Trade Negotiations in April 1994, Codex standards, guidelines (including the Guidelines for the Application of HACCP system) and recommendations constitute the reference for food safety requirements in international trade.

F. The cost of conformity assessment

123. While no data were found on the costs of implementing HACCP in Nigeria, implementation costs have been the subject of studies in the United States. Tables 1 and 2 show costs of implementing the U.S. Food and Drug Administration HACCP regulation and meeting the regulation requirements for one year by company average annual sales.

124. In another study, cost data were collected in personal interviews with quality control personnel using detailed interview protocols and survey instruments. 33 The results show that cost estimates vary greatly depending on how the cost of HACCP is defined (see also Box 4).

125. For the surveyed firms, the average first-year total cost of implementing HACCP was USD 113 505. This expenditure varied very much within the sample. The average first-year cost for sample companies of implementing only the FDA minimum requirements was USD 34 323. This shows that companies generally implemented much tougher and more expensive HACCP plans than required and often included non-safety related CCPs within their plans. The cost of implementing only the minimum FDA requirements was 30% of the actual costs companies incurred. Though implementing HACCP can be expensive, the results show that the incremental cost attributable to the FDA regulation, at USD 23 993, represents only about 20% of total costs.

Table 1. Total average costs of implementing the FDA HACCP regulation and meeting the regulation requirements for one year by company average annual sales *

<table>
<thead>
<tr>
<th>Average Annual Sales</th>
<th>HACCP Plan Development</th>
<th>HACCP Training</th>
<th>Investment for HACCP Requirements</th>
<th>Investment for Sanitation Requirements</th>
<th>Annual Cost of Routine Requirements</th>
<th>Total Cost</th>
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<td>$547</td>
<td>$ 4 847</td>
<td>$ 3 650</td>
<td>$ 7 935</td>
<td>$17 495</td>
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<tr>
<td>$500K-$1 Million</td>
<td>$ 930</td>
<td>$481</td>
<td>$ 7 590</td>
<td>$ 7 754</td>
<td>$ 9 738</td>
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<td>$1 to $3 Million</td>
<td>$1 042</td>
<td>$493</td>
<td>$12 012</td>
<td>$ 7 852</td>
<td>$ 9 886</td>
<td>$31 285</td>
</tr>
<tr>
<td>$3 to $5 Million</td>
<td>$1 333</td>
<td>$527</td>
<td>$12 250</td>
<td>$10 634</td>
<td>$13 236</td>
<td>$37 980</td>
</tr>
<tr>
<td>$5 to $10 Million</td>
<td>$1 832</td>
<td>$561</td>
<td>$35 562</td>
<td>$26 690</td>
<td>$16 791</td>
<td>$81 436</td>
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<td>$10 - $20 Million</td>
<td>$3 347</td>
<td>$588</td>
<td>$21 395</td>
<td>$16 805</td>
<td>$18 174</td>
<td>$60 309</td>
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<tr>
<td>&gt; $20 Million</td>
<td>$3 313</td>
<td>$847</td>
<td>$22 783</td>
<td>$14 346</td>
<td>$52 141</td>
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Table 2. Total average costs of implementing the FDA HACCP regulation and meeting the regulation requirements for one year *

<table>
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<th></th>
<th>HACCP Plan Development</th>
<th>HACCP Training</th>
<th>Equipment Investment for HACCP Requirements</th>
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<th>Annual Cost of Routine Requirements</th>
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<td>$15 077</td>
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<td>$14 174</td>
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</table>

* Tables 1 and 2 were prepared by Ken Gall, Seafood Specialist, and taken from the National Seafood Industry HACCP Implementation Survey Report, National Seafood HACCP Alliance for Training and Education, April 2000.

126. While no data was found to show the actual costs of implementing HACCP for Nigerian trawler owners, one is invited to consider that costs borne by companies such as those in the United States range from 20.0% of total costs while those of a developing country such as Bangladesh may represent 1.26% of export sales (see Box 4).

127. It should also be noted that governments of developing countries bear much, and sometimes all, of the costs of HACCP. In the case of Nigeria, the certified laboratories are government institutions. On the other hand, assuming costs for conformity assessment programs such as HACCP may place burdens on the governments of developing countries who may have to bear the labour costs as well as the cost of developing and maintaining facilities (Caswell 1998).

Box 4. Other cost data

Other data include that of the Food and Agriculture Organization of the United Nations and concerns a developing country, Bangladesh. The FAO has invested US$72,000 in Bangladesh training programs to prepare Bangladesh industry and government to use HACCP in the seafood industry. Across industry, government and externally funded training costs, the total investment to date in Bangladesh to upgrade shrimp plants to minimum standards represents 9.4 percent of export sales for one year. The annual cost to maintain a HACCP program represents 1.26 percent of export sales for one year (Cato and Lima dos Santos 1998).
G. Outlook

128. Shrimp is a relatively low risk product, especially as it is packed on-board freezer vessels that have implemented their HACCP programs (Otwell, 2005). Nigeria is benefiting from the fact that most shrimp is frozen at sea, thus removing much of the health risk. The processing plant visited (Banarly/Olokun) was impressive and reinforced the impression that Nigeria can provide more than adequate processing capacity for a sizable export-oriented shrimp culture industry (USAID, 2002).

129. However, the Nigerian coastal waters are most probably over-exploited with regard to shrimp resources; the breeding grounds/nurseries of commercially important fish/shell fish species are affected; and large quantities of juvenile fish are caught (Ogbonna).

130. To exploit its market opportunities, Nigeria needs to increase its shrimp and prawn production to meet both domestic and export demand through aquaculture (USAID, 2002). The USAID Mission to Nigeria and the Shell Petroleum Development Company signed a five-year, USD 20 million MOU to jointly pursue the goal of promoting prosperity and democracy in Nigeria, which will include support for the shrimp industry. The U.S. interest and investment in establishing a shrimp aquaculture in Nigeria portends well for its ability to export to the United States.

131. Regarding the conformity assessment capabilities of the Nigerian shrimp industry, it has earned the certification required to export to the European Union. In terms of conformity assessment, however, Nigeria’s ability to satisfy the CA requirements for entry into the European Union must be considered a success story (See Box 5).

132. The consensus from a number of qualified sources is that there is nothing to prevent Nigeria from exporting shrimp not only to the United States, but to other markets around the globe as well.

133. HACCP is an example of how harmonized standards and regulations work to facilitate international trade, and in particular, how they have benefited this developing country. While there are certainly differences in the implementation of HACCP regulations between the United States and the European Union and other countries, in theory, Nigeria, having qualified in one instance, is qualified for other regimes that subscribe to HACCP principles.

134. From all observations, the reasons for not exporting to the U.S. market are not related to conformity assessment, but to other issues, such as consumer preferences which affect pricing, a rapid increase in farmed shrimp from Asia and South America, which also contributed to lower prices in the

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34 Virtually all the world’s major stocks of wild shrimp are either fully or over-exploited and wild shrimp capture has hovered around 2 million tons per annum (p.a.) since the early 1980’s. This stagnating growth rate, in the face of growing demand, has boosted shrimp aquaculture, as producers search for ways to increase supply. Shrimp farms have developed rapidly during the past 20 years; global production multiplied from 80,000 tons in the early 1990’s to 800,000 tons in 2000. Today more than one quarter of shrimp consumed are produced by aquaculture, and this proportion is predicted to rise to 50% in the next couple of years (USAID 2002).

35 Shell will contribute $15 million and USAID will contribute $5 million.

36 The Spanish whole shrimp market (which gets premium prices) favours white shrimp. This is now countered by a French preference for whole darker shrimp, i.e. black tiger, or darker strains of P vannamei. A unique feature of the U.S. market is that there is demand for shrimp of all sizes. Shrimp imports have, however, been dominated by headless (lower cost) as well as peeled and deveined shrimp (Chemonics International, Inc., 2002).
United States, and distance to transport. It should also be noted that Nigeria does not export to Japan, the largest exporter of shrimp in the world.

135. Prospects could be especially promising regarding the U.S. market, as generally speaking U.S. imports from Sub-Saharan African countries increased in 2003, including large increases in imports from Nigeria of other products than shrimp. Moreover, the U.S. Department of State in 2001 certified Nigeria as one of the 43 nations authorized to export all categories of shrimp to the United States, with provisos to protect endangered sea turtle species through the use of Turtle Excluder Devices (TEDs).

136. The future of Nigeria’s shrimp supplies and exports and its expansion into international markets may well depend on the development of a viable aquaculture industry.

<table>
<thead>
<tr>
<th>Box 5. The key issues</th>
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<tr>
<td>1. Nigeria is a maritime country where fishing plays an important role in the national economy, providing employment, food, income and foreign exchange earnings.</td>
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<td>2. The significant Nigerian wild capture shrimp industry generates USD 57 million per annum in foreign exchange.</td>
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<td>3. Nigeria has in place a competent conformity assessment authority, The Federal Department of Fisheries (FDF), which incorporates an official laboratory, plus a second official laboratory, the National Agency for Food and Drug Administration and Control (NAFDAC), which, with the FDF, certifies shrimp processing plants and freezer trawlers. A third laboratory is contained in the Nigerian Oceanographic Marine Research Institute (NIOMR).</td>
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<tr>
<td>4. Nigerian legislation makes the implementation of HACCP mandatory for each vessel or establishment where fishery products are produced, processed and packaged, as well as for each kind of fishery products. The Hazard Analysis Critical Control Point (HACCP) system is a widely recognized system for assuring food safety that has been endorsed by many national and international scientific groups, corporations, government agencies, and academic organizations (See Box 1). HACCP principles are incorporated into the regulations of Nigeria, the European Union, and the United States. Nigeria was qualified by the European Commission to export shrimp into the European Union.</td>
</tr>
<tr>
<td>5. HACCP is an example of how harmonized standards and regulations work to facilitate international trade, and in particular, how they have benefited this developing country. While there are certainly differences in the implementation of HACCP regulations between the U.S. and the EU and other countries, in theory, Nigeria, having qualified for one, is qualified for other regimes that subscribe to HACCP principles.</td>
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<tr>
<td>6. Nigeria, however does not export to the United States. From all observations, the reasons for not exporting to the U.S. are not related to conformity assessment, but to other issues, such as consumer preferences which affect pricing, a rapid increase in farmed shrimp from Asia and South America, which also contributed to lower prices in the U.S., and distance to transport. It should also be noted that Nigeria does not export to Japan, the largest exporter of shrimp in the world.</td>
</tr>
<tr>
<td>7. In terms of conformity assessment, however, Nigeria’s ability to satisfy the CA requirements for entry into the European Union must be considered a success story. Furthermore, the U.S. interest and investment in establishing a shrimp aquaculture in Nigeria portends well for its ability to export to the U.S. as well.</td>
</tr>
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</table>
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Cluster, Jane, Dr., Office of Seafood, USFDA
Loesener, Otto, Dr., UNIDO
Otwell, Steve, Dr., Aquatic Food Products Laboratory, University of Florida
Suarez, Angel, Office of Compliance, USFDA
Zorn, David Dr., Office of Regulations and Policy, USFDA

37 Several other potential sources of information in Nigeria were approached but did not respond.