UNCTAD/DITC/COM/34
3 December 2001

ENGLISH ONLY

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT

FOOD QUALITY STANDARDS:
Definitions and role in international trade

Report by the UNCTAD secretariat

CONTENTS

Page

INTRODUCTION 1

WHY DOES QUALITY MATTER? 2-5

I. Quality system definitions 5-14

1.1. ISO 9000/9000:2000 ..... 5- 9
1.2. ISO 14000 9-11
1.3. HACCP 11-14

II. Integrated management system certification 15-16

2.1. How to integrate HACCP with ISO 9000? 15
2.2. How to integrate ISO 9000 with 14000? 16

III. WTO, quality standards and world trade 16-21

3.1. Agreement on Technical Barriers to Trade (TBT) 16-17
3.2. Contribution of international standards 17
3.3. Geographical distribution of ISO 9000 and ISO 14000 certificates 18-21

IV. How to improve the link between international standards and regulation? 21-23

4.1. Pressure from the WTO 21-22
4.2. Content of the OECD work: how diverse is the field? 22
4.3. Elements of effective linkages 22-23

V. CONCLUSIONS 23

APPENDIX 1 24

APPENDIX 2 26

INTRODUCTION

Trade liberalization and globalization in the world economy has intensified international competitiveness in the production of goods and services. The World Trade Organization's rules (WTO) for governing international trade brought into sharp focus the increasing importance of international standards and conformity assessment procedures in removing technical barriers. Most developing countries are signatories of the WTO Agreements and are parties to the Agreement on Technical Barriers to Trade (TBT). Many have also accepted the Code of Good Practice for the preparation, adoption and application of standards. That is to say that establishing national standards and their harmonization with international standards are now necessary conditions for the development of the economy of any country and its trade with foreign countries.

However, many developing countries, at varying stages of development, are lacking adequate standards infrastructure. Most of them have not had many years of systematic integrated standardization measures in place. Now the international trading environment calls for equal treatment and a move towards removal of former concessional trading arrangements for products such as sugar, rum and bananas, which are foreign exchange earnings. In addition, the use of international standards as a basis for international trade, including those which govern trading policies such as the tying of trade to environmental protection, plays a crucial role for gaining access to markets.

Being ill-equipped to face such a challenge, developing countries need continued technical assistance in the critical areas of standards infrastructure and metrology. The fact of underdevelopment is expected to be taken into account, as there is a growing concern among enemies of globalization that technical requirements are increasing and posing new barriers to market entry, even as tariff-related barriers are falling around the world.

Consequently, the special and differential treatment requested for smaller economies should be expanded and should not be seen as an excuse for backing out from the "state of the art" in standards activities, but as a demand for developing countries to be exempted in the short term from the implementation of requirements. Also requested is a flexibility in the bilateral arrangements, including the needed assistance for a fair trading partners for a win-win result.

In all these aspects, questioning techniques related to the adoption and the application of these standards need to be known by anyone whose activity is impacted by quality management. In most developing countries, only few people in the industry know what kind of information about voluntary standards and mandatory technical regulations is available, and where to look for it. In this respect, it is the aim of this paper to contribute to a better understanding of the debate around the internationally recognized standard for quality – International Sugar Organization (ISO) 9000/9000:2000/14000 – and Hazards Analysis Control Critical Points (HACCP). In light of this, Part I attempts to provide a definition of each of the above mentioned standards. Part II raises the issue of the integrated management system certification between HACCP and ISO 9000; ISO 9000 and 14000. The linkages between WTO (with the Agreement on TBT), quality standards and world trade are highlighted in Part III, while Part IV seeks how to improve the link between international standards and regulation.

Why does quality mater?

Confidence in food quality has been challenged in recent years by scares and health concerns linked to such incidents as salmonella in poultry and eggs, and the probable link between bovine spongiform encephalopathy (BSE) in cattle and new variant Creutzfeldt Jakob disease (CJD) in humans. For these reasons, consumers have lost confidence in the Governments' ability to ensure food safety, and attention is now focusing on producers, the food-industry and retailers. Moreover, consumers are demanding, in particular, more transparency, traceability and assurance in the food chain. There is every indication that these requirements will increase in the future especially in relation to food containing genetically modified organisms (GMO).

As a result, international trade relationships are affected by the interpretation of what quality is. Defined under various legislative instruments, the term "quality assurance"[1] is primarily being sought in relation to health and safety issues, and addressed to all who are involved in food production, processing, distribution and retail to observe "due diligence" to ensure food safety. In practice, the suppliers must demonstrate that they have a quality assurance and an appropriate control system. In order to demonstrate "due diligence" many firms have developed private quality standards which are promoted by trade organizations or are self-regulated, whilst others are independently certified (the certification process involving the setting up of product quality standards and establishing monitoring by parties outside the company). Consequently, such quality standards can be difficult to amend. Detailed agreements between a large number of regulatory authorities are frequently difficult to obtain: being cumbersome and burdened with details, these regulations tend not to achieve full consensus. Finally, they may result in the opposite of what was intended, due to confusion over what is being assured, and on what basis. Thus, what is considered safe is still contested, as can be seen in the case of beef produced using artificial growth hormones. The latter, for instance, is an acceptable practice in the United States and Canada, whilst it is not in the European Union. Furthermore, the interpretation of WTO rules in this respect give rise to disputes over trading practices. What may be considered by some to be product differentiation on food safety grounds, may be considered by competitors to be another form of trade barriers and market protection.

In this context, companies are more and more inclined to reassure customers by using quality standards as they open routes to adding value to products, especially in the food sector, and increase sales. To compete in the international market, the supplier offers not just a product, but also a range of services, which includes approved quality systems, a degree of assurance about continuity of supply and the capacity to bring new products and product presentations to the market rapidly. This means that the exigencies of consumers give little room for amateurism in today's international market place. For developing countries which are signatories of the Sanitary and Phytosanitary (SPS) Agreement and are parties to the Technicals Barriers to Trade (TBT) Agreement (many have also accepted the Code of Good Practice for the preparation, adoption and application of quality standards), there is a need for continued technical assistance in the critical area of standards infrastructure and metrology. The fact of underdevelopment should be taken into account as technical requirements are increasing and posing new barriers to market entry. For example, developing countries entering the soluble coffee business find themselves competing directly against two of the largest food companies. In order to make good returns, developing countries need to compete against both the technical efficiency of these firms and also their political and market power.

[1] Juran, J.M. (1989), *Leadership for Quality: An Executive Handbook*, Free Press, New York, USA. Juran included the consumer in his concept of product quality. His definition "quality is fitness for use" means "quality is to meet the expectations of the consumer".

In all these aspects, questioning techniques related to the adoption and the application of these quality standards need to be known by anyone whose activity is impacted by quality management. This is because food safety and quality assurance not only appear to be consumers' exigencies, but are also a part of the product process enabling the provision of greater returns to developing countries. The examples are numerous. They include the speciality vegetables, such as mangetout and babycorn, new fruit varieties (of which kiwi fruit is the best-known example, papaya, mango), gourmet coffee and partially dried fruit. But because there is no global approach that covers in a coherent manner the specific practices of national, regional and international markets functioning under such quality standards, companies are inclined to adopt the ISO 9000 and ISO 14000 series of standards or Hazard Analysis Critical Control Points (HACCP), which provide guidelines for the implementation of quality systems in the food chain and are accepted internationally. Companies know that commitment to quality can help them to achieve competitiveness and business excellence, and greater returns.

However, the investments needed to bring a company up to the standards of ISO 9000 and ISO14000 or an HACCP plan are substantial, and many enterprises, especially in developing countries, are unable to face such costs. At the same time, these enterprises feel that the implementation of such new regulations on food products is de facto a non-tariff measure against value-added products originating from developing countries. This raises a number of questions: how do WTO negotiations affect food production, will environmental protection be linked to primary food supply, will environmental payments be increased or be seen by some competitors as another form of market support? One approach[2] would be to integrate the requirements for food quality and environmental assurance into one regulation systems based on the existing internationally recognized management standards such as ISO 9000, ISO 14000 and HACCP, which have already been adopted by the main importing countries such as the United States and the European Union. HACCP being based on hazards and risks analysis, this means it is at the core of the WTO Agreements, in particular the SPS and technical barriers to trade (TBT) Agreements. HACCP is not a new approach , as it has been incorporated in the Food and Agriculture Organization (FAO)/World Health Organization (WHO) Codex Alimentarius. With regard to ISO regulations and environmental protection, the two generic standards ISO 9001 (control process) and ISO 14001 (the environmental management standard - EQM) are considered more applicable as the basis for food assurance[3].Therefore, quality implementation in the food industry could be further simplified through the adoption of EQM/HACCP assurance by the major food distributors and / or retailers, as this would provide an umbrella for all of the food assurance schemes flowing up the food supply chain. Furthermore, the positioning of an EQM/HACCP assurance scheme along food supply chains may limit the requirement for schemes at all levels, thus minimizing the costs of implementation and certification.

Product differentiation may be considered, therefore, as companies' strategies to tap opportunities offered by the changes in food habits, especially in developed countries. High income consumers tend to be less price sensitive, and more willing to pay for higher quality, variety and convenience. They expect quality control and products with specific characteristics to be available when desired. Products are differentiated based on what they do not contain as well as what they

[2] This refers to a model for environmental and food quality assurance outlined by Baines & Davies, in *Quality Assurance in International Food Supply*, Royal Agricultural College, Gloucestershire.

[3] In their model for environmental and food quality assurance, Baines & Davies justified reasons that make EQM more applicable as the basis for food assurance. This includes : applicable to any type or size of organization; more adapted to interested parties (i.e. suppliers, customers, local community, regulatory and emergency agencies); aims to minimize direct and indirect impacts of the organization acting on environment (i.e. human health and safety, socio-economic factors, the natural environmental). Impacts are minimized through legislation compliance, pollution prevention, and a commitment to continuous improvement.

do. Consumers are also specifying how products are produced[4]. Examples include, *inter alia*, organic vegetables and other fair trade and ethical products. Moreover, the use of a brand continues to expand even if its success depend mostly on the belief in the product. Given the expected continued increase in quality standards of living (food safety and protection of environment) and increased ethnic diversity of markets, the trend toward product differentiation will continue. Total sales are generally higher when using product differentiation, but the costs may be greater[5].

Speciality and other niche products

Changes in consumer habits make the fresh fruit and vegetables (FFV) more attractive than many other food items such as meat containing fat and grease. For these reasons, niche markets for horticultural products originating from developing countries exist in major developed markets. Exports from ACP countries which are being stimulated by preferential treatment offered to them through the Cotonou Agreement 2000 (successor of the Lomé Convention) have registered some "success stories". That is the case for Kenya and Zimbabwe respectively for the export of fresh vegetables and mangetout in the UK's market. However, most of these (FFV) products are imported in the EU's market when they do not have the competition from the European consumer crops. Another case in point is the main South African products exported to Europe such as pears, abricots, peaches and pineapple. Organic markets also are seen as good. Organic products in general are growing rapidly in Western Europe, North America and Japan. Most consumers are linking food and beverage purchases to greater awareness of health and environmental issues, and responding to new aggressive organic food promotion campaigns for retailers. Uganda, the Africa's second largest producer for coffee after Ivory Coast, does not want to miss this great opportunity in the market and has taken the initiative through several projects[6]. One of these projects aims to provide an incentive to small coffee farmers to stimulate organic coffee production in biologically diverse agricultural, and at the same time to further enhance uganda's coffee image abroad and to attract high premiums on the international markets. Many other developing countries such as Ethiopia, Brazil, Panama, Costa Rica and Colombia are under way to have more coffee growers converting to organic practices, as high quality organic commands about a 10-15% premium above the same coffee's price if it were grown conventionally[7].

Other initiatives under way for the development and the expansion of niche products also include the concept of fair trading, which has been lobbied for effectively and gained ground in recent years in developed countries, especially for food and beverage items from tropical developing countries. With the establishment of the WTO, the debate about the impact of unrestricted world trade on developing countries has highlighted the absence from the trade agenda of « issue of sustainable resource management, the regulation of commodity markets, and poverty reduction strategies[8]. Such concerns, articulated by *Christian Aid*[9] in their *global Supermarket*

[4] See Michael Boehlje, Lee Schrader and Jay Akridge in *Obervations on Formation of Food Supply Chains*, Department of Agricultural Economics, Perdue University, 1998.

[5] See David Keetch in *"The South African Canned fruit and vegetable industry"*, paper presented at the workshop on "*Diversification and Development in the Horticultural Sector in Africa"*, Bamako, Mali, 13-15 February 2001. According to the author, the costs of product differentiation may be greater because: (i) modifying a product to meet different market segments usually involves some research and developpement (product modification costs); (ii) it is usually more expensive to produce 100 units of ten different products than 1000 units of one products; (iii) administrative cots (marketing plans for the separate segments of the market); (iv) inventory costs; and (v) promotional costs involve trying to reach different market segments with each segment requiring creative advertising campaigns.

[6] See Coffee & Cocoa International , May 2000. For the past four years, the Export Promotion of Organic Products from Africa (EPOPA) programme, executed by the Swedish International Development Agency (SIDA) has been involved in supporting several organic initiatives in the country.

[7] See Coffee & Cocoa International, op.cit.

[8] See Watkins, K. *"The Oxfam Poverty Report"*, Oxfam, Oxford, 1995.

[9] See Christian Aid, *" The global Supermarket"*, Christian Aid, London, 1996.

Report (1996), in the Oxfarm Report (Watkins, op. Cit), the *World Development Movement* in their *"People before profits"* campaign and more recently *Max Havelaar Foundation* have pushed forward the debate on ethical trading, which has now become a significant issue for business, particularly retail corporations marketing goods identifiable as *"Third World"* products.

As considerations of health aspects of food are is expanding in developed countries, calorie also counts on fish packs, dietary plans, nutritional plans and recipes. These can contribute to an useful addition to value-added products which will increase the presence of fishery products in supermarkets and other retail outlets. Some new value-added include battered calamari in a light lime-flavoured batter, battered tiger prawns with sweet chili deep, skinless and boneless salmon fillets in brine, just to mention some recent examples. With fish, many developing countries have been successful in entering in certain areas of value-added products, while others are still quite difficult to enter. A good example for value-added fish product from a developing country are breaded hake filets, produced in Argentina or Uruguay for the main European brands[10]. The plants were selected by the European distributor, the quality was checked on a continuous basis by the buying company, the producers were able to guarantee regular supply of container loads of products, and the product was entering the EU's market. For many producers in developing countries, it is difficult to follow this successful example, due to the fact that their supply is seasonal, and they often have problems to guarantee stable supply, and the tropical climate always makes it difficult to maintain the quality of the final product at the same standard.

In conclusion, export opportunities for developing countries in terms of niche markets to generate more value added exist, especially because of lower tariffs (ACP and LDCs), fewer environmental constraints (lack capital to buy fertilizers), low raw material prices, fair trade and ethical products. But on the other hand, there are problems with hygiene conditions in plants, tropical climate, lack of marketing knowledge, problems with packaging and presentation, seasonality of products and lack of storage space. To reverse this situation, companies should take care of hygienic conditions of plants by including the HACCP system, constant quality control, attractive packaging design, delivery efficiency, quality and supply guarantee and good commercial practices. In this respect, Governments should (i) give high priority to full implementation of the international standards (i.e. ISO 9000, ISO 14000 and HACCP); (ii) ensure that sanitation and hygiene procedures be in place; (iii) put in place the necessary accredited inspection bodies and laboratories; (iv) emphasize the need for constantly improving the efficiency and effectiveness of inspection and quality control operations; and (v) bring equivalency, harmonization and transparency to international trade in order to minimize any technical barriers to trade for national companies.

I. Quality system definitions

1.1. ISO 9000/9000:2000

(i) ISO 9000

The acronym "ISO" stands for "International Organization for Standardization". Its counterparts at the country level are national institutes from industrialized and developing countries worldwide. The primary objective of the ISO is to add value to all types of business activities, and contribute to making the development, manufacturing and supply of products and services safer and cleaner. Most ISO standards are confined to a specific or particular product, material or process. However, both ISO 9000 and 14000 are known as generic management

[10] See H. Josupeit, *"Value-added products in Europe"*, Globefish Research Products in Europe, vol.24, August 1998.

system standards. Generic here means that the same standards can be applied to any organization, large, medium or small whatever its product - independent of whether its "product" is actually a service - in any sector of activity, and whether it is a business enterprise, a public administration, or a government department (ISO, 2000).

ISO 9000 is primarily concerned with quality management. The definition of "quality" in ISO 9000 refers to “all those features of a product or a service, which are required by the customer”. Quality management means what the organization does to ensure that its products conform to the customer's requirements. ISO is not a product quality label or guarantee. When an organization has a management system certified to an ISO 9000 standard, this means that an independent auditor has checked that the process influencing quality (ISO 9000), or the process influencing the impact of the organization's activities, conforms to the relevant standard's requirements.

The ISO 9000 family of standards represents an international consensus on good management practice with the aim of ensuring that the organization can, time and time again deliver the product or services that meet the client's quality requirements. The standards give organizations guidelines on what constitutes an effective quality management system, and models against which this system can be audited to give the organization and its clients assurance that it is operating effectively.

In addition to this, it should be noted that the ISO 9000 family also includes three quality assurance models - ISO 9001, ISO 9002 and ISO 9003 - against which the quality system can be audited. The organization should carry out this auditing itself to verify that it is managing its processes effectively. In other words, the organization can invite its clients to audit the quality system in order to give them confidence in its capacity to deliver products or services that will meet their needs. Lastly, it is possible to request the services of an independent quality system certification body to obtain an ISO 9000 certificate of conformity. This option has proved extremely popular in the market place because of the perceived credibility of an independent assessment. Thus, it may avoid multiple audits by the organization's clients and reduce the frequency or duration of client audits. The certificate can also serve as a business reference between the organization and potential clients, especially when supplier and clients are new to each other, or far removed geographically, as in an export context.

(ii) ISO 9000:2000: The revision process

A revision process has been conducted by the ISO's Technical Committee TC-176, which adopted a project management approach in order to cope with the complexity of the task. Initial project specifications and goals were established after user surveys had been carried out to determine needs and expectations for the new revisions. In order to reflect modern management approaches and to improve organizational performance it has been found useful and necessary to introduce structural changes to the standards while maintaining the essential requirements of the current standards.

Specifically, the main reason for the year 2000 revision of the ISO 9000 standards is to give users the opportunity to add value to their activities and to improve their performance continually by focussing on the major processes within the organization. Extensive surveys have been performed on a worldwide basis in order to understand the needs of all users of the quality management system standards. The new revisions will take into account previous experience with quality management system standards (1987 and 1994 editions) and emerging insights into generic

management systems. They will result in a closer alignment of quality management systems with the needs of companies and/or organizations, and will better reflect the way companies/organizations run their business activities. ISO directives also specify that standards be periodically revised to ensure that those standards are current and satisfy the needs of the global community.

The major reasons for the year 2000 revisions of the standards include emphazing the need to monitor customer satisfaction, producing more user-friendly documents, ensuring consistency between quality management system requirements and guidelines, and promoting the use of generic quality management principles by companies/organizations. The revision of the ISO 9000 quality management standards will include a radical change to the structure of ISO 9001 and ISO 9004, which, whilst retaining the essence of the original requirements, will reposition the 20 elements of the current ISO 9001:1994 and the guidelines of ISO 9004:1994 into four mains points:

- Management responsibility;
- Resource management;
- Product and/or service realization;
- Measurement, analysis and improvement.

Box 1
Frequently asked questions
(FAQs)

1. Who is responsible for revising the standards?
The revision process is the responsibility of the ISO Technical Committee (TC) 176 and is conducted on the basis of a consensus among quality and industry experts nominated by ISO Member bodies, and representing all interested parties.

2. When will the revised standards be available?
The revised quality management system standards (ISO 9000, 9001, and 9004) are scheduled to be available in the fourth quarter of the year 2000.

3. Will the year 2000 revision affect my company's/organization's current quality system registration/certification?
Yes. The strategy adopted by your organization to meet the requirements of ISO 9001:2000 should include an appropriate timing for upgrading your organization's registration/certification. It is expected that the process of upgrading registration/certification will be a smooth transition that is incorporated into the applicable Registration or Certification Body's regular audit routine. The International Accreditation Forum (IAF) has already established a set of guidelines for Certification Bodies/Registrars to follow, and this includes a transition period of up to three years after the new standards are published. You are advised to contact your Registration/Certification Body to negotiate a suitable transition time frame for your own organization.

Note: For further information on the complete list of frequently asked questions, see appendix 1.
Source: http://www.bsi.org.uk/iso-sc2/FAQs-DIS.html

The current ISO 9000 family of standards contains over 20 standards and documents. This proliferation of standards has been a particular concern of ISO 9000 users and customers. To respond to this concern, the ISO Committee TC 176 has agreed that the year 2000 ISO 9000

quality management standards will consist of three primary standards supported by a number of technical reports. To the extent possible, the key points in the current 20 standards will be integrated into the three primary standards, and sector needs will be addressed while maintaining the generic nature of the standards. The three primary standards are:

- ISO 9000: Quality management systems – Fundamentals and vocabulary;
- ISO 9001: Quality management systems – Requirements;
- ISO 9004: Quality management systems – Guidance for performance improvement.

ISO 9001 and ISO 9004 are being developed together, with the same sequence and structure in order to form a "consistent pair" of standards, while ISO 9000 is being developed in parallel with ISO 9001 and ISO 9004, to achieve a coherent terminology in the ISO 9000 family, ISO 14000 family and other management standards.

In addition to these three core standards, ISO 10011, the auditing standards, is also in the process of revision, and will be consolidated with the ISO 14010, ISO 14011 and ISO 14012 environmental auditing standards.

The current ISO 9001, ISO 9002 and ISO 9003 standards will be consolidated into the single revised 9001 standards. Reduction of scope of the ISO 9001 requirements will be permitted to omit requirements that do not apply to a particular organization.

For further information on how the changes may affect your company, consult the list of "Frequently Asked Questions" on the website http://www.iso.ch/9000e/summary.htm.

The revised ISO 9001 and ISO 9004 standards are being developed as a consistent pair of standards. Whereas the revised ISO 9001 clearly addresses the quality management system requirements for a company to demonstrate its capability to meet customer needs, the revised ISO 9004 is intended to lead beyond ISO 9001 towards the development of a comprehensive quality management system, designed to address the needs of all interested parties.

Box 2

ISO 9000:2000 forecast to play important role in Singapore's new knowledge-based economy

"... ISO 9000 will continue to be important in our future knowledge-based economy but will need to progress beyond being a tool for systems and process improvement to become a powerful instrument to help organizations achieve business excellence and greater competitiveness ... Singapore would transform from an industrial to a knowledge-based economy, from a stable to a dynamic market, from national to global competition, from scarce physical resources to abundant knowledge resources, from diminishing to increasing returns, and from hierarchies to networks. However, in this new economy scenario, ISO 9000:2000 urged local companies to upgrade to the new standard. The year 2000 revisions are aimed at encouraging organizations to give greater emphasis to customer satisfaction, as organizations would be expected to demonstrate commitment to quality, customers, planning and improvement, all of which would boost their competitiveness. ISO 9000:2000 would allow integration with other management systems relating to health, safety and the environment, as well as systems in the pipeline such as information security management ...".

Source: Mr. Lim Boon Heng, Chairman of the Singapore Productivity and Standards Boards (PSB), speaking at the PSB Awards Dinner, June 2000.

The revision of ISO 9001 and 9004 has been based on eight quality management principles which reflect best management practices and have been prepared by international quality experts and endorsed by ISO/TC 176. The eight principles are:

- Customer focused organization;
- Leadership;
- Involvement of people;
- Process approach;
- System approach to management;
- Continual improvement;
- Factual approach to decision making;
- Mutually beneficial supplier relationship.

In the new revisions of the standards there will be a single Quality Management Requirements standard (ISO 9001) applicable to all companies and/or organizations, products and services, that will replace the current three standards (ISO 9001, 9002 and 9003) in the 1994 version. This will be used for the certification of Quality Management Systems and may also be the basis for contractual agreements.

1.2. ISO 14000

(i) ISO 14000 and the environment

The ISO 14000 family of international standards on environmental management is a relative newcomer to ISO's portfolio, but environment-related standardization is far from being a new departure for ISO. In fact, ISO has a two-pronged approach to meeting the needs of businesses, industries, Governments, non-governmental organizations and consumers in the field of the environment.

On the one hand, it offers a wide-ranging portfolio of standardized sampling, testing and analytical methods to deal with specific environmental challenges. It has developed more than 350 International Standards (out of a total of more than 12,000) for the monitoring of such aspects as the quality of air, water and soil. These standards are a means of providing businesses and Governments with scientifically valid data on the environmental effects of economic activity. They also serve in a number of countries as the technical basis for environmental regulations.

On the other hand, ISO is leading a strategic approach by developing environmental management system standards that can be implemented in any type of organization in either public or private sectors (companies, administrations, public utilities).

ISO's direct involvement in environmental management stemmed from an intensive consultation process, carried out within the framework of the *Strategic Advisory Group on Environment* (SAGE), set up in 1991, in which 20 countries, 11 international organizations and more than 100 environmental experts participated in defining the basic requirements of a new approach to environment-related standards. This pioneering work was consolidated with ISO's commitment to support the objective of "sustainable development" discussed at the United Nations Conference on Environment and Development in Rio de Janeiro in 1992.

Today, with the globalization process delegations of business and Government experts from 55 countries participate actively within the *Technical Committee* (TC) 207; and another 16 countries have observer status. These delegations are chosen by the national standards institute concerned and they are required to bring to TC 207 a national consensus on issues being addressed

by the Committee. This national consensus is derived from a process of consultation with interested parties. It should be recalled that from the beginning, it was recognized that ISO/TC 207 should have close cooperation with ISO/TC 176 (*Quality management and quality assurance),* in the areas of management systems, auditing and related terminology. Active efforts are under way to ensure compatibility of ISO environmental management and quality management standards, for the benefit of all organizations wishing to implement them.

(ii) The ISO 14000 family of standards in its entirety: two approaches to implementation

The series is made up of documents related to EMS - environment management systems (i.e. ISO 14001 and ISO 14004) and documents related to environmental management tools (i.e. all other ISO 14000 series documents). This approach takes the view that establishment and implementation of an organization's EMS is of central importance in determining the organization's environmental policy, objectives, and targets. For example:

- ISO 14001 requires the conduct of EMS audits, and guidance for the conduct of such audits can be found in ISO 14010, ISO 14011 and ISO 14012;

- ISO 14001 requires an organization to monitor and measure the environmental performance of its activities, products and services in order to continually improve such performance, and ISO 14031 provides guidance for this purpose;

- ISO 14001 requires that an organization considers the environmental aspects of its products and services.

The ISO 14040 standards assist an organization in the identification and analysis of environmental aspects of products and services. The ISO 14020 standards address guidance on providing information on the environmental aspects of products and services through labels and declarations.

Identifying environmental aspects of an organization's activities, products and services, and determining their relative significance are important elements of implementing an EMS or conducting an EPE (environmental performance evaluation) in an organization. ISO 14001, ISO 14004 and ISO 14031 provide guidance on identifying significant environmental aspects. Thus, ISO 14040 states in its introduction: "LCA (life cycle assessment) is a technique for assessing the environmental aspects and potential impacts associated (with products and services). LCA can assist in identifying opportunities to improve the environmental aspects of products and services at various points in their life cycle".

Regarding the application to organizations or application to products/services, the ISO 14000 family is made up of documents which are generally applied at the organizational level (documents for environmental management systems, environmental auditing and environmental performance evaluation) and documents which are generally applied to products and services (documents for environmental declarations and claims, and documents for the cycle assessment). Both above mentioned approaches are equally valid for considering the ISO 14000 family of standards and they are mutually supportive.

What are the business benefits of ISO 14000? Any manager will try to avoid pollution that could cost the company a fine for infringing environmental legislation. But better managers will

agree that doing only just enough to keep the company out of trouble with government inspectors is a rather reactive approach to business in today's increasingly environment-conscious world. The ISO 14000 standards are practical tools for the manager who is not satisfied with mere compliance with legislation - which may be perceived as a cost of doing business. They are for the proactive manager with the breadth of vision to understand that implementing a strategic approach can bring return on investment in environment-related measures.

Implementing an ISO 14000-based environmental management system, and using other tools from the ISO 14000 family, will give one far more than just confidence that one is complying with legislation. The ISO 14000 approach forces one to take a hard look at all areas where one's business has an environmental impact. And this systematic approach can lead to benefits like the following:

- Reduced cost of waste management;
- Savings in consumption of energy and materials;
- Lower distribution costs;
- Improved corporate image among regulators, customers and the public;
- Framework for continuous improvement of environmental performance;

1.3. HACCP

(i) History of HACCP

The HACCP concept has its origin in the United States. The chronology of its development is as follows: (i) 1958 - Foundation of the NASA (National Aerorautics and Space Administration), (ii) 1959 - Development of the HACCP concept to assure one hundred per cent safety of food to be used in space; (iii) 1971 - the HACCP system was published and documented in the United States; (iv) 1985 - the National Academy of Science (NAS) recommended the use of the system. Worlwide the system came to be used and the FAO/WHO Codex Alimentarius (Food and Agriculture Organization/World Health Organization) cited the system in the Codex; (v) 1993 - the European regulations 93/43 EG from 14.7.93, provides the use of the system for the production of food; and (vi) 1998 - with coming into force on the august the 8th of 1998 the Hygiene Verordnung (German Hygiene Rule) demands the use of the HACCP system in Germany.

(ii) Definitions

What is HACCP? Hazard Analysis and Critical Control Point (HACCP) is a systematic approach to the identification, evaluation, and control of food safety hazard based on the following seven principles:

- **Analyse hazards.** Potential hazards associated with a food and measures to control those hazards are identified. The hazard could be biological, such as a microbe, chemical, such as a toxin, or physical such as ground glass or metal fragments;
- **Identify critical control points (**These are points in a food's production - from its raw) state through processing and shipping to consumption by the consumer - at which the potential hazard can be controlled or eliminated. Examples are cooking, cooling, packaging, and metal detection;
- **Establish preventive measures with critical limits for each control points.** For a cooked food, for example, this might include setting the minimum cooking temperature and time required to ensure the elimination of any harmful microbes.

- **Establish procedures to monitor the critical control points.** Such procedures might include determining how, and by whom, cooking time and temperature should be monitored;
- **Establish corrective actions to be taken when monitoring shows that a critical limit has not been met –** (for example, reprocessing**)** or disposing of food if the minimum cooking temperature is not met;

- **Establish procedures to verify that the system is working properly** - for example, testing time-and-temperature recording devices to verify that a cooking unit is working properly;
- **Establish effective recordkeeping to document the HACCP system.** This would include records of hazards and their control methods, the monitoring of safety requirements and action taken to correct potential problems. Each of these principles must be backed by sound scientific knowledge - for example, published microbiological studies on time and temperature factors for controlling foodborne pathogens.

In addition to this, the HACCP principles contain some specific terms for which the definitions are as follow

Hazard:	A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control;
Hazard analysis:	The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan;
Control:	*(i)* To manage the conditions of an operation, maintain compliance with established criteria; *(ii)* The state where correct procedures are being followed and criteria are being met;

Critical control point: A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Detailed information can be obtained from the following website: http://vm.cfsan.fda.gov (See also Quality Management Programme of the Department of Commerce, United States - National Marine Fisheries Service).

(iii) Guidelines for application of HACCP principles

The production of safe food products requires that the HACCP be built upon a solid foundation of prerequisite programmes such as:

Facilities: The establishment should be located, constructed and maintained according to sanitary design principles. There should be linear product flow and traffic control to minimize cross-contamination from raw to cooked materials;

Supplier control: Each facility should assure that its suppliers have in place effective good manufacturing practices (GMP) and food safety programmes. These may be the subject of continuing supplier guarantee and supplier HACCP system verification;

Specifications: There should be written specifications for all ingredients, products and packaging materials;

Production equipment: All equipment should be constructed and installed according to sanitary design principles. Preventive maintenance and calibration schedules should be established and documented;

Cleaning and sanitation: All procedures for cleaning and sanitation of the equipment and the facility should be written and followed. A master sanitation schedule should be in place;

Personal hygiene: All employees and other persons who enter the manufacturing plant should follow the requirements for personal hygiene;

Training: All employees should receive documented training in personal hygiene, GMP, cleaning and sanitation procedures, personal safety, and their role in the HACCP programme;

Chemical control: Documented procedures must be in place to assure the segregation and proper use of non-food chemicals in the plant. These include cleaning chemicals, fumigants, and pesticides or baits used in, or around, the plant;

Receiving storage and shipping: All materials and product should be stored under sanitary conditions and the proper environmental conditions, such as temperature and humidity, to ensure their safety and wholesomeness;

Traceability and recall: All raw materials and products should be lot-coded and a recall system should be in place so that rapid and complete traces and recalls can be done when a product retrieval is necessary;

Pest control: Effective pest control programmes should be in place.

These above mentioned conditions and practices are now considered to be prerequisite to the development and implementation of effective HACCP plans. All these prerequisite programmes should be documented and regularly audited. For some companies, prerequisite programmes are established and managed separately from the HACCP plan. However, certain aspects of these conditions may be incorporated into an HACCP plan. For example, many food industries have preventive maintenance procedures for processing equipment to avoid unexpected equipment failure and loss of production.

The success of an HACCP plan depends, of course, on educating and training management and employees in the importance of their role in producing safe foods. This should also include information on the control of foodborne hazards related to all stages of the food chain. It is important to emphasize that employees must first understand what HACCP is and then learn the skills necessary to make it function properly. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring each critical control point (CCP).

(iv) Developing an HACCP plan

In the development of a HACCP plan, five preliminary tasks need to be accomplished before the application of the HACCP principles to a specific product and process. These five preliminary tasks are:

(a) Assemble the HACCP team: The first task is to assemble an HACCP team consisting of individuals who have specific knowledge and expertise appropriate to the product and process. It is

the team's responsibility to develop the HACCP plan. The team should be multidisciplinary and include individuals from areas such as engineering, production, sanitation, quality assurance, and food microbiology. The team should include local personnel who are involved in the operational activities. This foster a sense of ownership among those who must implement the plan. The HACCP team may need assistance from outside experts who are knowledgeable in the potential biological, chemical and/or physical hazards associated with the product and the process.

However, a plan which is developed totally by outside sources may be erroneous and incomplete, and lack support at the local level.

Due to the technical nature of the information required for hazard analysis, it is recommended that experts who are knowledgeable in the food process should either participate in, or verify the completeness of, the hazard analysis and the HACCP plan. Such individuals should have the knowledge and experience to correctly (i) conduct a hazard analysis; (ii) identify potential hazards; (iii) identify hazards which must be controlled; (iv) recommend controls, critical limits, and procedures for monitoring and verification; (v) recommend appropriate corrective actions when a deviation occurs; (vi) recommend research related to the HACCP plan if important information is not known; and (vii) validate the HACCP plan.

(b) Describe the food and its distribution: The HACCP team first describes the food. This consists of a general description of the food, ingredients and processing methods. The method of distribution should be described along with information on whether the food is to be distributed frozen, refrigerated or at ambient temperature.

(c) Describe the intended use and consumers of the food: Describe the normal expected use of the food. The intended consumers may be the general public or a particular segment of the population (e.g. infants, immunocomptromised individuals, the elderly, etc.).

(d) Develop a flow diagram which describes the process: The purpose of a flow diagram is to provide a clear, simple outline of the steps involved in the process. The scope of the flow diagram must cover all the steps in the process which are directly under the control of the establishment. In addition, the flow diagram can include steps in the food chain which happen before and after the processing that occurs in the establishment. The flow diagram need not be as complex as engineering drawings. Also, a simple schematic of the facility is often useful in understanding and evaluating product and process flow.

(e) Verify the flow diagram: The HACCP team should perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram. Modifications should be made to the flow diagram as necessary and documented.

After these five preliminary tasks have been completed, the seven principles of HACCP are applied. Upon completion of the HACCP plan, operator procedures, forms and procedures for monitoring and corrective action are developed. Often it is a good idea to develop a timeline for the activities involved in the initial implementation of the HACCP plan. Implementation of the HACCP system involves the continual application of monitoring, record keeping, corrective action procedures and other activities as described in the HACCP plan.

II. Integrated management system certification

2.1. How to integrate HACCP with ISO 9000?

HACCP may be integrated in the ISO 9000 Quality Assurance System which controls the characteristics of quality of the production covering all aspects of quality. As a result, the hybrid quality system obtained (HACCP and ISO 9000) provides dynamic hygiene conditions with the following components: cleaning, disinfection and maintenance of the building, hygienical handling of food.

In a broader definition, the building must be cleaned and disinfected properly. Maintenance of the building includes painting of walls and ceilings to avoid molds. Broken coverings of walls should be changed and all unnecessary holes should be closed. The handling through all phases of the production, from income control, production to storage and transportation should be controlled.

On the specific side of incoming control, raw products and ingredients should not be accepted when there is evidence for the presence of pest, pathogen microorganism or there is evidence that the products are spoiled. If necessary, the products must be moved to adequate containers, or moved from wood pallets over to plastic pallets. Moreover, all products should be labelled with the name of the producer, the date of delivery and the expiry date.

Regarding storage and handling of raw materials, the process should be done under well defined conditions, particularly in the food sector, as salmonellae are mainly transmitted by contaminated eggs, minced meat and related products. For example, food prepared with raw eggs for use such as desserts without heating have to be cooled down to +7°C. They have to be maintained at this temperature or below and to be eaten within 24 hours after production. They can also be deep frozen and consumed 24 hours after defrosting, their temperature not rising over +7°C.

In addition, the integration of HACCP with ISO 9000 offers supermarkets an exacting system of storage, distribution and selling of their goods. In some specific cases, where the responsibility of the producer and/or exporters can be commited, the HACCP concept can be considered as an extension of the ISO 9000. For example, in case of spoiled food, injured people have the rights of “recourse”. If the producer of the spoiled food has a valid HACCP concept with written results of his controls, the injured person must provide evidence that failure originated during handling and treatment of a specific producer. If the produce does not have the written results of his controls or the frequency of the controls are unsufficient, he has to prove that the failure has not originated under his responsibility.The HACCP system is therefore a practical instrument of protection against unjustified accusations. However, if the producer fails to prove that the failure could not have originated during his responsibility, he has to assume the liability.

Many hazards which may be present in food products are identical with those described above.

This means that all efforts concerning distribution, storage, handling and processing have to be related to cooling and freezing, to cleaning of the machines and ustensils, and to disinfection and hygiene of the personnel; further efforts must be made concerning pest control, good condition of the building, hand washing facilities, and it must be ensured that there is no direct access between toilets and the area where food is stored, handled or sold.

2.2. How to integrate ISO 9000 with ISO 14000?

Those familiar with ISO 9000 find it useful to relate ISO 14000 with the more well-known ISO 9000 series of quality management standards. The management system components of ISO 14001 were designed to be as consistent as possible with those of ISO 9000. Quality assurance is aimed at meeting customer requirements, the efficiency of the production process and continuous improvement. ISO 14001 is aimed at these, and more: "customer requirements" have expanded to include regulatory and other mandatory environmental requirements; and "continuous improvement" is driven not only by "customer" expectations but also by priorities and objectives generated internally by the organization. A company with an ISO 9000 registration has a good foundation for ISO 14001 and both can be part of an organization's overall management system. However, ISO 9000 is not a prerequisite for ISO 14001.

ISO 14001 uses the same fundamental systems as ISO 9000 such as documentation control, management system auditing, operational control, control of records, management policies, audits, training, statistical techniques, corrective and preventive action. An organization with an ISO 9000 registration will find that they are a long way towards an ISO 14001 registration from the outset. Even though there are differences, the management system is generally consistent in both standards. The approach to management common to ISO 14001 and ISO 9000 serve as a model to be adapted to meet the needs of the organization and integrate them into existing management systems.

III. WTO, quality standards and world trade

3.1. Agreement on Technical B rriers to Trade (TBT)

Article 12.5 of the TBT Agreement points out that "Members shall take all reasonable measures as may be available to them to ensure that international standardizing bodies and international systems for conformity assessment are organized and operated in a way which facilitates active and representative participation of relevant bodies in all Members, taking into account the special problems of developing country Members". As it is mentioned here, this Article does not include a definition of what can be considered as an international standard. Recently, WTO members agreed that there is a need to arrive at such a definition. The ISO - together with the International Electrotechnical Commission (IEC) and the International Telecommunication Union (ITU)- has built a strategic partnership with WTO. The political agreements reached within the framework of the WTO require underpinning by technical agreements. As the three principal organizations in international standardization, ISO, IEC and ITU have the complementary scopes, the framework, the expertise and the experience to provide this technical support for the growth of the global market.

The Agreement on TBT - sometimes referred as the Standards Code - aims to reduce impediments to trade resulting from differences between national regulations and standards. As far as international consensus-based standards are concemed, the Agreement invites the signatory Governments to ensure that the standardizing bodies in their countries accept and comply with a "Code of good practice for the Preparation, adoption and application of standards", embodied in Annex 2 to the Agreement and which is known as the WTO Code of Good Practice. The Agreement on TBT is one of the 29 individual legal texts of the WTO Agreement which forces Members to ensure that technical regulations, voluntary standards and conformity assessment procedures do not create unnecessary obstacles to trade. Annex 1 of the TBT Agreement is the Code of Good Practice for the Preparation, Adoption and Application of Standards. In accepting the TBT Agreement, WTO Members agree to ensure that their central government standardizing

bodies accept and comply with this Code of Good Practice and agree also to take reasonable measures to ensure that local government, non-governmental and regional standardizing bodies do the same. The Code is therefore open to acceptance by all such bodies.

3.2. Contribution of international standards

The TBT Agreement recognizes the important contribution that international standards and standardizing bodies constitute the Technical Management Board, and aim at reporting to and, when relevant, advising Council on all matters concerning the organization, coordination, strategic

planning, and programming of the technical work of the ISO. The Technical Management Board Members are AFNOR France (2002), ANSI USA (2000), BSI UK (2000), DIN Germany (2000), DSM Malaysia (2002), ICONTEC Colombia (2001), JISC Japan (2001), SABS South Africa (2002), SAI Australia (2002), SCC Canada (2002) SIS Sweden (2002) SNV Switzerland (2001)[11]. The figures in brackets show the year at the end of which the term of office expires conformity assessment systems can make to improving efficiency of production and facilitating international trade. Where international standards exist or their completion is imminent, the Code of Good Practice says that standardizing bodies should use them, or the relevant parts of them, as a basis for standards they develop. It also aims at the harmonization of standards on as wide a basis as possible, encouraging all standardizing bodies to play as full a part as resources allow in the preparation of international standards by the relevant international body, including the ISO and the IEC.

In the interest of transparency, the Code requires that standardizing bodies that have accepted its terms notify the ISO/IEC Information Centre located at the ISO Central Secretariat in Geneva, either directly or through the relevant national/international member of ISO-Net. At least once every six months, standardizing bodies having accepted the Code must publish their work programmes through the ISO/IEC Information Centre. Other important provisions relate to the preparation, adoption and application of standards. The WTO TBT Standards Code Directory 2000 lists all standardizing bodies that had notified acceptance of the WTO TBT Code of Good Practice for the Preparation and Application of Standards. An updated list of the standardizing bodies that had notified acceptance of the WTO TBT Code is published yearly[12].

The vast majority of ISO standards are highly specific to a particular product, material or process. The use of these two standards (ISO 9000 and ISO 14000) by enterprises and/or organizations points out the need of clarifying terms.

ISO 14000 is primarily concerned with environmental management. This means what the enterprise/organization does to eliminate harmful effects on the environment caused by its activities.

It is important to remember that ISO 9000 is not a product quality label or guarantee. ISO 14000 is not a "green" label for products. The ISO does not assess or audit quality of environmental management systems. When an organization has a management system certified to an ISO 9000 or ISO 14000 standard, this means that an independent auditor has checked that the process influencing quality (ISO 9000), or the process influencing the impact of the organization's activities on the environment (ISO 14000), conforms to the relevant standard's requirements.

[11] These acronyms are the technical management boards at the national levels.
[12] This list can be obtained on www.iso.ch/wtotbt.htm

3.3. Geographical distribution of ISO 9000 and ISO 14000 certificates

The success of the ISO 9000 family of standards is still growing, and the number of countries where ISO 9000 is being implemented has increased. Up to the end of December 1999 at least 343 643 ISO 9000 certificates had been awarded in 150 countries worldwide. This is an increase of 71796 ISO 9000 certificates (26.40 per cent) over the end of December 1998, when the total stood at 271 847 for 141 countries. However, looking at the different regions of the world, Europe, with 190 248 certificates awarded, is still increasing rapidly with over 23,900 more certificates than last year. With over 56 500 certificates awarded in 1999, the Far East confirms the

growing interest of the region's industries in the ISO 9000 certification process. North America shows an increase of 11,616 new certificates, representing an annual increase of 34.60 per cent.

Table 1: Number of ISO 9000 certificates by region (percentages)

	Cycle*1	Cycle 2	Cycle 3	Cycle 4	Cycle 5	Cycle 6	Cycle 7	Cycle 8	Cycle 9
Africa/Western Asia	3.42	2.73	2.64	2.75	2.65	3.79	3.88	4.47	5.04
Europe	83.02	81.12	78.73	75.61	72.72	67.58	64.34	61.16	55.36
Central and South America	0.10	0.30	0.68	0.77	0.96	1.05	1.34	1.92	2.61
North America	4.32	5.61	6.99	7.77	8.15	10.44	11.25	12.34	13.14
Far East Countries	2.46	3.40	4.39	6.29	7.26	11.31	13.38	13.95	16.48
Australia/ New Zealand	6.69	6.84	6.58	6.81	8.27	5.83	5.80	6.16	7.36

*The dates of ISO 9000 certification for cycle is as follow:

Cycle 1: 1993-01-31; Cycle 2: 1993-09-30; Cycle 3: 1994-06-30; Cycle 4: 1995-03-31; Cycle 5: 1995-12-31; Cycle 6: 1996 -12-31; Cycle 7: 1997-12-31; Cycle 8: 1998 -12-31; and Cycle 9: 1999-12-31.

Source: ISO Survey of ISO 9000 and ISO 14000 Certificates- ninth cycle, 2000.

With 8,663 and 8,067 new ISO 9000 certificates respectively, Australia and the United States show, however, the highest annual growth. China, with over 6,800 new certificates, comes in third position and Germany shows 6,095 new certificates, displaying very consistent growth. Table 2 shows the number of certificates by industrial sectors. With 229,846 certificates in 1998, the number of certificates had reached 274 040 in 1999. That is 44,194 more certificates than in 1998. The highest number of certificates by industrial sectors is in the electrical and optical equipment (40,035) followed by the basic metal and fabricated metal products (28,972), construction (25,273), machinery and equipment (19,827) and wholesale and retail trade (13,803).

Table 2: Number of certificates by industrial sectors

ISO 9000 by industrial sectors	1998	1999	ISO 9000 by industrial sectors	1998	1999
Agriculture, fishing	610	678	Aerospace	1,052	4,131
Mining & quarrying	1,052	1,791	Other transport equipment	3,040	7,656
Food products, beverages and tobacco	7,347	8,746	Manufacturing not elsewhere classified	2,106	4,844
Textiles & textile products	2,835	3,673	Recycling	1,001	1,765
Leather & leather products	2,313	2,093	Electricity supply	860	932
Wood & wood products	2,218	1,967	Gas supply	390	558
Pulp, paper & paper products	1,316	3,279	Water supply	505	799
Publishing companies	363	354	Construction	19,768	25,273
Manufacture of coke & refined petroleum products	1,009	1,669	Hotels & restaurants	865	1,794
Nuclear fuel	279	220	Transport, storage & communication	11,738	11,366
Chemicals, chemical products & fibres	11,803	12,615	Financial inteimediation, real estate, rental	4,690	3,218
Pharmaceuticals	1,160	1,105	Information technology	5,826	6,706
Rubber and plastic products	6,277	13,575	Engineering services	8,064	9,201
Non-metallic mineral products	2,328	3,571	Other services	13,088	12,150
Concrete, cement, tin, plaster	4,998	7,107	Public administration	689	2,086
Basic metal & fabricated metal products	28,885	28,972	Education	1,833	3,996
Machinery and equipment	20,275	19,827	Health and social work	1,250	2,871
Electrical & optical equipment	36,653	40,035	Other social services	1,250	2,871
Shipbuilding	398	4670			
TOTAL	---------	---------	**229,846**		**274,040**

Source: ISO Survey

Although the share of Africa increases slightly, it remains, however, very low compared to other regions. Table 3 shows the ISO 9000 certifications growth in Africa from 1995 to end 1999. As a result, the limited number of certified export companies may partly cause the lack of competitiveness of some African export products, particularly those which are perishable products such as fruits, vegetables, shrimps and/or fish, given that the primary objective of the international standards is to increase the level of consumer satisfaction with the delivery of products and services, and to enhance the consumer/provider relationship.

Table 3: Number of ISO 9000 certificates in Africa: growth from 1995 to end of 1999

Countries	March 1995	Dec. 1995	Dec. 1996	Dec. 1997	Dec. 1998	Dec. 1999
Algeria					2	4
Botswana			1	4	4	4
Cameroon			I	5	5	5
Congo			1	2	2	2
Côte d'Ivoire			3	4	8	8
Dem. Rep. of the Congo	1	1	1	1	1	1
Egypt	16	45	166	344	385	649
Gabon					2	3
Ghana	1	2	2	2	2	3
Guinea					1	2
Kenya	1	1	11	28	416	419
Libyan Arab Jamahiriya				1	1	1
Madagascar						1
Malawi					1	1
Mali			4	5	5	5
Mauritius	3	4	59	72	92	92
Morocco	6	9	34	60	71	77
Mozambique					1	3
Namibia	5	6	11	2	14	19
Nigeria	1	1	4	3	20	20
Senegal				1	1	4
Seychelles			1	2	2	5
Sierra Leone			1	1	1	1
South Africa	1369	1454	1882	1915	2166	3316
Sudan				I		1
Tunisia	3	13	25	51	70	163
United Republic of Tanzania					1	2
Zambia	1	3	3	3	4	4
Zimbabwe	12	23	44	49	60	112

Source: ISO Survey.

Regarding the ISO 14000, the number of certificates is less important than in the case of ISO 9000. However the certificates awarded at the end of 1999 numbered 14 106, compared to 7887 at the end of December 1998, showing a significant rise of 6,219, (i.e. 78.85 per cent). As noted in the case of ISO 9000, Europe and the Far East experienced a very significant growth in 1999, showing a total of 11,715 certificates, compared to the other regions where ISO 14000 appears to be slower in taking off. Table 4 contains these figures.

Table 4: Number of ISO 14000 certificates by region (per centages)

	Cycle 5 1995-12-31	Cycle 6 1996-12-31	Cycle 7 1997-12-31	Cycle 8 1998-12-31	Cycle 9 1999-12-31
Africa/West Asia	0.39	0.67	1.65	1.75	2.39
Europe	87.94	63.58	59.24	53.94	52.21
Central and South America	1.17	1.01	2.21	1.83	2.19
North America	0.39	2.88	2.64	5.50	6.91
Far East countries	9.73	28.10	30.59	32.10	30.84
Australia/New Zealand	0.39	3.76	3.68	4.88	5.46

Source: ISO Survey.

In addition, a growing expansion of ISO 14000 among countries may be also noted. For example, up to the end of 1999, 14,106 environmental certificates were held in 84 countries. During that period, ISO 14000 was implemented in 12 additional countries, in Africa ISO 14600 in 6 of these countries. However, Japan shows the highest increase with 1,473 new certificates awarded. The United Kingdom follows with an increase of 571 and Sweden comes in third position with an increase of 547 certificates.

IV. How to improve the link between international standards and regulations?

4.1. Pressure from the WTO

In 1997, trade ministers of a group of the world's major economies set themseves the goal of trying to improve the link between standards and regulation, through the OECD (Organisation for Economic Co-operation and Development) in Paris. The OECD has a long track record in the field of regulatory reform. Over two years, in 1998 and 1999, the OECD undertook research to reveal how the link between standards and regulations worked in practice. The World Trade Organization (WTO) illustrates that its TBT and SPS Agreements (see OECD's studies on "Regulatory Reform and International Standardisation: selected cases", available also on www.oecd.org/ech) emphasize the value of using International Standards, and state that their use in regulations is presumed to be a defence against any accusation of creating an unnecessary obstacle to trade. The OECD provided evidence to confirm the economic benefits of using International Standards, as meeting disparate national technical regulations is expensive. However, these benefits may be mitigated for a number of reasons:

- Many International Standards universally accepted under that name are developed as voluntary texts by bodies dominated by industry. While that gives clear benefits in the free market, regulators may lack confidence in them, either because they have not been involved in their preparation, or because they may have public policy objectives beyond those of industry. Indeed, the WTO allows Members to apply higher levels of protection for legitimate objectives such as health, safety and environmental protection, on condition that technical regulations are no more restrictive than necessary to meet those objectives. That opens the door to differences in national technical regulations;

- In some sectors, there simply are not enough International Standards from ISO to provide a base for regulation. Thus, at the start of the OECD study, the ISO had no base of standards in pressure equipment or mineral exploration equipment, and only limited principles of machinery safety. Yet in those sectors, international trade is large, and other standards are accepted both in the market and as a basis for regulation. Consequently, options should be taken to reach a consensus on which standards should be considered acceptable for use in regulation.

4.2. Content of the OECD work: how diverse is the field?

In the first phase of its work, the OECD dealt with two elementary questions: (i) how diverse is the body standards with wide international acceptance?; and (ii) which features of the standardization process do the players in standardization regard as most in need of attention if the link with regulation is to be improved?

The OECD work showed that sectors like pressure equipment are not unique. The ISO itself has for years maintained lists of standards bodies with international activities, and has a working partnership with some of them. Other examples where standards were identified, outside the ISO/ITU but with significant international acceptance, in regulation or in the market, include automative parts, chemicals, measuring instruments, pharmaceuticals, transport equipment, equipment for mineral exploration, electronic data transmission, digital audio and video. And the field grows all the time since the globalization process has intensified. One area which continues to record a high demand of international standards is the food sector in its broader sense (agro-industry products, fast food, etc.). The diversity of structure and methods of standards development, including other models in which standardization operates without any regulatory participation at all, or on the contrary with direct involvement of regulators in international programmes, led to the conclusion that ways of harnessing the strengths of a broader range of existing, widely used and respected international structures should be sought.

4.3. Elements of effective linkages

The desire to harness the strengths of existing systems led to know whether among so many diverse structures, the elements of effective linkages between standards and regulation can be identified? Research focused on identifying areas where improvement was felt to be needed. It did not try to second-guess the ISO to propose what was important in standardization activity. So, for example, the goal of technical clarity and accuracy in standards was identified, only to be quickly eliminated from this work for the simple reason that those aspects of standardization were felt to be under good control. Elimination of that and other criteria does not mean that they were felt to be unique. The work[4] led to a list of seven issues that justified attention:

- The detailed methods of involving regulators in international standards work or in their use: the issues they should address (product specifications and conformity assessment), the range of public policy issues they should consider, the method of regulatory intervention (in the development itself, or as interpreters and users), and the forum of international coordination (bilateral, multilateral and regional, or multilateral and global);

- The nature of the deliverables of standards bodies, for example, the potential value of high-levei umbrella standards alongside detailed standards, and the use of technical reports and guides, etc.;

[4] Reference is made to OECD's work on Standardization and Regulatory Reform, in ISO Bulletin, July 2000.

- The depth and scope of the standards, and in particulai the extent to which distinction is desirable between end-performance criteria such as safety; test criteria and methods; and other descriptive specifications;

- The inherent speed and simplicity of the standards development process, and the methods improving them, such as increased use of electronic data transmission or reduced formality in development procedures;

- The mechanisms for monitoring the follow-up and implementation of adopted standards;

- The ability of standards bodies to weed out texts which are obsolete or irrelevant;

- The relationships with industry-led consortia which do have the status of formal standards bodies.

Finally, there appears to be a consensus that improvements are needed to: link standards and regulation, but not yet any consensus on how the linkage should be organized or by whom, or on whether work should be organized multisectorally, or individually by sector. The issue of how to improve regulatory confidence in the output of industry-led standards bodies seems likely to attract major attention. International Standards bodies do not systematically absorb the function of setting regulatory requirements; although they are now beginning to think of defining umbrella performance standards in terms more likely to be acceptable to regulators, it is unclear whether further modification of their procedures to give them a formal role in the regulatory process would be efficient. An alternative is available: to require regulators to examine explicitly the potential regulatory impact of using international standards. The procedure is now widely known under the name of Regulatory Impact Analysis (RIA). By placing the burden on regulatory authorities for this work, International Standards bodies would continue to have enough flexibility on procedures to fulfi their present, primary goal of making International Standards relevant to the market.

V. CONCLUSIONS

To be able to make higher-quality products and to conquer international niche markets, developing countries need to master modern approaches. This should include the evaluation of the markets and consumers' requirements, product development and manufacture, and quality assessment. Although, international quality standards exist, they tend to be cumbersome and burdened by details. They have also proven to be difficult to prepare. Consequently, such standards can be difficult to amend. Detailed agreements between a large number of regulatory authorities are frequently difficult to obtain, and such regulations tend not to achieve full consensus. In this respect, it is desirable to harmonize these technical regulations with a view to limit obstacles to international trade and to facilitate market access. A regulatory framework shared by broad regulatory bodies may be easier to compile and may more easily find consensus. Established mechanisms of International Standardizing Bodies may provide a forum for all interested parties and ensure a degree of trust at the international level[5].

[5] These problems have been recognized by the United Nations/Economic Commission of Europe Working Party on Technical Harmonization and Standardization Policies (WP.6), which at its ninth session in 1999 commissioned a team of specialists to investigate the question.

The technical barriers that the emergence of these standards and technical regulations, of quality requirements including the procedures and technical mechanisms for the assessment of conformity to such referentials, may contribute to the marginalization of ill-equipped countries, especially least developed countries (LDCs). This gives rise to concerns, particularly in the specific practices of local and regional markets functioning under national legislations. It is, therefore, desirable to adopt a global approach that will cover the regulated sectors in a coherent manner. The use of the Internet, the development of electronic trade and sectoral portals for customer-supplier relations, the increasing constraints dictated by the environmental protection and food safety concerns, the emergence of social standards in the WTO agenda, are as many factors strengthening the actuality of adopting a harmonized system which should not be seen as trade-restrictive or discriminatory by all parties (governmental bodies, companies, suppliers, buyers and consumers). The nature of such harmonization may be limited to the definition of common regulatory objectives linked to existing international standards in order to establish new technical standards at national level with those countries which agreed on them.

APPENDIX 1: Frequently asked questions about standards[10]

A. What do standards have to do with competition?

Traditionally, standards have been thought of not as a natural priority, but as a tolerated requirement. Today that view is changing. With global economy being a reality, industries are waking up to the importance of standards, their use and misuse. Knowledge of the process by which standards are developed is also gaining importance. This is especially true of quality standards. Quality is one of few remaining fields where one can gain a distinct advantage over one's competition.

B. What other advantages are there?

By being active in the development of standards, one's industry will receive advance notice of new standards or changes to existing standards that may be vital to its success. One will also have the opportunity to contribute one's expertise. This earns one international and national recognition and prestige. One will learn first-hand the best way to correlate these standards through dialogue with other participants. One will also be in a position to note the trends in quality that correlate to the standards.

C. How does the voluntary standards system work for industry?

Standards are developed in a system that is considered voluntary. What that means is that, except in the case of government contracts where governmental bodies can require the use of a specific standard, the decision to use standards in industry is regulated by the market place. Why is this important? Because it provides certain advantages: it allows for the necessary flexibility to respond to changes in technology and market demand, and anyone with a vested interest in a proposed standard can participate in its development. This openness guarantees that the standards developed are the standards needed.

A system such as this requires oversight. That is why the American National Standards Institute (ANSI) was formed in 1918 by five professional/technical societies and three federal government agencies, prompted by a desire to eliminate conflict and duplication in the United States voluntary standards development process. Over the years, ANSI has become the overseer of the consensus method of developing standards in that country, as well as being the United States

[10] This can be found on the website address: http://www.asq.org/standard/faq.html.

member body of the International Organization for Standardization and the International Electrotechnical Commission (IEC). Today, ANSI guides the efforts of the more than 250 major standards developing organizations. The ISO is made up of approximately 180 Technical Committees. The results of ANSI and ISO technical works are published as International Standards.

D. How does the industry communicate with ISO?

The industry communicates with ISO via a Technical Advisory Group (TAG). A TAG is a group of experts in a particular field, whose primary purpose is to develop and transmit, via their member body, their nation's position on activities and ballots of the ISO or IEC technical committee for which the TAG has been established to ISO or IEC, TAGs are actively involved in the creation of international standards. Participation in a TAG is vital if the link between national industries and the international standards community is to be maintained. Participation in a TAG is an opportunity for a country's industry to help shape the international standards that will influence the way it does business globally.

E. How does the Series work?

ISO 9000 provides the user with guidelines for selection and use of ISO 9001, 9002, 9003 and 9004. ISO 9001, 9002, and 9003 are quality system models for external quality assurance.

These three models are actually successive subsets of each other. ISO 9001 is the most comprehensive covering design, manufacturing, installation and servicing systems. ISO 9002 covers only final product inspection and test. These three models were developed for use in contractual situations such as those between a customer and a supplier. ISO 9004 provides guidelines for internal use by a producer developing its own quality system to meet business needs and take advantage of opportunities. The choice of which model to implement depends on the scope of one’s operation. For example, if one only manufactures, one may wish to consider ISO 9002. Finally, if one neither designs nor manufactures, one may wish to consider ISO 9003.

F. If a company is not registered as complying with international quality system standards, does it mean that it will not be able to sell its products globally?

International quality standards are not a legal requirement for access to foreign markets, but it can be beneficial. For example, in the European Union, ISO 9000 registration is for many regulated products an alternative for product certification, not an absolute requirement. In fact, as cited in most European Union legislation, quality system registration is not mandatory, nor is it a stand-alone procedure. Manufacturers interested in the European markets need to review relevant European Union product safety directives available from the United States Department of Commerce for specifics applicable to their product area. In some sensitive sectors such as the food industries, companies from developed countries (European Union, United States, etc.) may require suppliers to attest that they have approved the quality system in place as a condition for purchase. In other words, if two suppliers are competing for the same contract, the one with ISO 9000 registration may have a competitive edge with some buyers. Therefore, international quality system standards may be a competitive factor in product areas where safety is a concern.

APPENDIX 2: Code of Good Practice for the Preparation, Adoption and Application of Standards

General Provisions

A. This Code is open to acceptance by any standardizing body within the territory of a Member of the WTO, whether a central government body, a local government body or a non-governmental body; to any governmental regional standardizing body one or more members of which are Members of the WTO; and to any non-governmental regional standardizing body, one or more members of which are situated within the territory of a Member of the WTO (referred to in this Code collectively as "standardizing bodies" and individually as "the standardizing body").

B. Standardizing bodies that have accepted or withdrawn from this Code shall notify the ISO/IEC Information Centre in Geneva. The notification shall include the name and address of the body concerned and the scope of its current and expected standardization activities. The notification may be sent either directly to the ISO/IEC Information Centre, or through the national member body of ISO/IEC or, preferably, through the relevant national member of international affiliate of ISONET, as appropriate.

Substantive Provisions

C. In respect of standards, the standardizing body shall accord treatment to products originating in the territory of any member of the WTO no less favourably that treatment accorded to similar products of national origin and to similar products originating in any other country.

D. The standardizing body shall ensure that standards are not prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to international trade.

E. Where international standards exist or their completion is imminent, the standardizing body shall use them, or the relevant parts of them, as a basis for the standards it develops, except where such international standards or relevant parts would be ineffective or inappropriate, for instance, because of an insufficient level of protection, or fundamental climatic or geographical factors, or fundamental technological problems.

F. With a view to harmonizing standards on as wide a basis as possible, the standardizing body shall, in an appropriate way, play a full part, within the limits of its resources, in the preparation by relevant international standardizing bodies of international standards regarding subject matter for which it either has adopted, or expects to adopt, standards. For standardizing bodies within the territory of a Member, participation in a particular international standardization activity shall, whenever possible, take place through one delegation representing all standardization bodies in the territory that has adopted, or expect to adopt, standards for the subject matter to which the international standardization activity relates.

G. The standardizing body within the territory of a Member shall make every effort to avoid duplication of, or overlap with, the work of other standardizing bodies in the national territory or with the work of relevant international or regional standardizing bodies. They shall also make every effort to achieve a national consensus on the standards they develop. Likewise the regional standardizing body shall make every effort to avoid duplication of; or overlap with, the work of relevant international standardizing bodies.

H. Whenever appropriate, the standardizing body shall specify standards based on product requirements in terms of performance rather than design or descriptive characteristics.

I. At least once every six months, the standardizing body shall publish a work programme containing its name and address, the standards it is currently preparing and the standards which it has adopted in the preceding period. A standard is under preparation from the moment a decision has been made to develop a standard until that standard has been adopted. The titles of specific draft standards shall, upon request, be provided in English, French, Spanish. A notice of the existence of the work programme shall be published in a national or, as the case may be, regional publication of standardization activities.

The work programme shall for each standard indicate, in accordance with any ISONET rules, the classification relevant to the subject matter, the stage attained in the standards development, and the references of any international standards taken as a basis. No later than at the time of publication of its work programme, the standardizing body shall notify the existence thereof to the ISO/IEC Information Centre in Geneva.

The notification shall contain the name and address of the standardizing body, the name and issue of the publication in which the work programme is published, the period to which the work programme applies, its price (if any), and how and where it can be obtained. The notification may be sent directly to the ISO/IEC Information Centre, or, preferably, through the relevant national member or international affiliate of ISONET, as appropriate.

J. The national member of ISO/IEC shall make every effort to become a member of ISONET, or to appoint another body to become a member, as well as to acquire the most advanced membership type possible for the ISONET member. Other standardizing bodies shall make every effort to associate themselves with the ISONET member.

K. Before adopting a standard, the standardizing body shall allow a period of at least 60 days for the submission of comments on the draft standard by interested parties within the territory of a member of the WTO. This period may, however, be threaten to arise. No later than at the start of the comment period, the standardizing body shall publish a notice announcing the period for commenting in the publication referred to in paragraph I. Such notification shall include, as far as practicable, whether the draft standard deviates from relevant international standards.

L. On the request of any interested party within the territory of a Member of the WTO, the standardizing body shall promptly provide, or arrange to provide, a copy of a draft standard which it has submitted for comments. Any fees charged for this service shall, apart from the real cost of delivery, be the same for foreign and domestic parties.

M. The standardizing body shall take into account, in the further processing of the standard, the comments received during the period for commenting. Comments received through standardizing bodies that have accepted this Code of Good Practice shall, if so requested, be replied to as promptly as possible. The reply shall include an explanation of why a deviation from relevant international standards is necessary.

N. Once the standard has been adopted, it shall be promptly published.

O. On the request of any interested party within the territory of a Member of the WTO, the standardizing body shall promptly provide, or arrange to provide, a copy of its most recent work programme or of a standard which it produced. Any fees charged for this service shall, apart from the real cost of delivery, be the same for foreign and domestic parties.

P. The standardizing body shall afford sympathetic consideration to, and adequate opportunity for, consultation regarding representations with respect to the operation of this Code presented by standardizing bodies that have accepted this Code of Good Practice. It shall make an objective effort to solve any complaints.

REFERENCES

B & D (1998), *Quality insurance in international food supply*, Royal Agriculture College, Gloucestershire.

JURAN, JM, (1989), *Leadership for quality – an executive handbook*, The Free Press, New York.

ISO (2000), *The ISO Survey of ISO 9000 and ISO 14000 Certificates, ninth cycle*, Geneva.

OECD (2000), *Hygiene Rules 93/43/EWG in the production line of food in Europe*, Paris

OECD (2000), Regulatory Reform and International Standardization: selected cases (available also in www.oecd.org/ech): in *ISO Bulle*tin, July.

Websites consulted:

- http://www.iso.ch/wtotbt.htm

- http://www.iso.ch/9000e/summary.htm

- http://www.vm.cfsan.fda.gov

- http://www.asq.org/stancert/faq.htm