



International Inspection and Certifications Systems

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Introduction

Trade is the crucial driver for economic growth in developing countries. The massive increase in trade over the past several decades has been driven by a diverse set of factors, including falling legal trade barriers and plummeting transportation costs, which have permitted companies to seek place manufacturing facilities where the best and least expensive mix of technology, labor, and capital are available. Aiding this process has been the rise of international standards and methods for ensuring that such standards are met that have given buyers in one country confidence that goods produced elsewhere will perform as expected. It is in this light that countries with foresight view their inspection and conformity assessment systems: as key features of trade infrastructure that make an economy more competitive. This report looks at how different countries systems have been developed and in particular how they are applied to imported goods.

In seeking to expand international trade, it is virtually impossible to underestimate the importance of adopting and implementing international practices in the area of metrology, accreditation, standardization and certification (MAS-Q) --- activities associated with inspection of consumer, industrial and food commodities. These activities provide a vital link to global trade, market access and export competitiveness as they contribute to consumer confidence in product safety, quality and adherence to health and environmental standards. In view of the ever increasing globalization of trade and investment via multilateral institutions such as the World Trade Organization (WTO) as well as through regional and bilateral trade agreements that promulgate rules governing non-tariff trade barriers, adopting and implementing similar or equivalent MAS-Q procedures has become a central political task as well as an enormous challenge for many countries.

More specifically, one of the main challenges facing countries participating in the international trading system is the diverse inspection and certification practices and standards used in different countries. Unless trading partners adhere to similar or equivalent procedures and requirements, and recognize each other's certification and inspections results, then the costly problem of discriminatory, non-transparent and unnecessary obstacles to trade will persist.

This purpose of the report is to provide a basis for discussion on international best practices in inspection. Some of the information contained here-in was taken from parts of previously published documents, guides, standards, etc. produced by numerous international MAS-Q organizations such as ISO, WTO, the World Bank, NIST, CSA, ILAC, IAF and others. The report is divided into several sections:

Section One provides a general overview and introduction to international inspection and certification. It will define what is meant by inspection and introduce other activities that are intimately intertwined with the inspection activities.

Section Two focuses on the differences between inspection and certification, and the various types of methods used to establish conformity.

Section Three addresses food inspections systems. Inspection of food and agricultural products differ dramatically from industrial and commercial products. This section takes a close look at the basic principles for food import and export inspection and certification and food safety management systems.

Section Four looks at what can be considered Best Practices in Inspection and Certification. There is no one national inspection system that is considered to be the best practice, but there are significant similarities in many of the systems which are all based on a common set of principles aimed at facilitating trade. This section looks at those similar practices.

Section Five contains examples of National and Regional Inspection and Certification Systems – a brief overview of both systems utilized in industrialized and developing countries.

Section Six concludes with a brief summary and comments with regard to possible next steps to be considered by Egypt.

An Overview of International Inspection and Certification

In describing the importance of inspection, testing and certification in the global economy, ISO's Standard 17011: "Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies" states:

"In the regulatory sector, government authorities implement laws covering the approval of products and services for reasons of safety, health, environmental protection, fraud prevention or market fairness. In the voluntary sector, many lines of industry have within an economy as well as globally, set up systems for conformity assessment and approval, aimed at achieving a minimum technical level, enabling comparability, and also ensuring competition on equal terms.

A prerequisite for trade on equal terms is that any product or service, accepted formally in one economy, must also be free to circulate in other economies without having to undergo extensive re-testing, re-inspection, re-certification, etc. This should be the case regardless of whether the product or service falls wholly or partly under the regulatory sector."

Although, this report primarily focuses on inspection and certification, it is important that the reader understand the general principles of conformity assessment. The US National Institute of Standards and Technology, the International Organization for Standardization and other authoritative bodies state that conformity assessment includes

"all activities concerned with determining directly or indirectly that relevant requirements in standards or regulations are fulfilled. Conformity assessment procedures provide a means of ensuring that the products, services, or systems produced or operated have the required characteristics, and that these characteristics are consistent from product to product, service to service, or system to system. Conformity assessment includes: sampling and testing; inspection; certification; quality management system assessment (including HACCP and food safety management) and certification; and accreditation of the competence of those activities and recognition of an accreditation program's capability. A specific conformity assessment process may include one or more of these conformity assessment activities. While each of these activities is a distinct operation, they are closely interrelated. In addition, standards are interwoven into all aspects of these activities and can have a major impact on the outcome of a conformity assessment process. Conformity assessment activities form a vital link between standards (which define necessary characteristics or requirements for products) and the products themselves."

The Standards Council of Canada in its "National Conformity Assessment Principles for Canada" provides a more readily accessible description of conformity assessment"

"Examples of conformity assessment are all around us, every day, making our lives a little better, providing assurance that the products we use won't harm us, that their components will work and that manufacturers are effectively managing the impact of their activities on health, safety and the environment, and that services are being delivered in a consistent fashion. In essence, conformity assessment is the practice of determining whether a product, service or system meets the requirements of a particular standard.

The “*standard*” being the document that describes the important features of that product, service or system and, the essential requirements that it must meet.

[Internationally,] conformity assessment serves to reassure users and provide them with confidence in the integrity of products, services or systems. Conformity assessment helps ensure that products, services and systems meet the requirements of standards for consistency, compatibility, effectiveness, and safety. It is thus that standards and conformity assessment go hand-in-hand. Together they affect virtually every aspect of society and are vital to preserving and enhancing our quality of life.

Despite the simplicity of the definitions provided above, there are actually many facets and diverse activities that make up a national conformity assessment system. These activities include verifying the capabilities of those organizations that offer conformity assessment services, interacting with relevant international bodies, contributing to the reduction of potential barriers to trade and participating in the promotion of public health and safety.”

Who is qualified to perform inspection and/or certification that will be accepted internationally without redundant inspection and certification?

Certification and inspection bodies that have been accredited by an accreditation body¹ are qualified to perform internationally accepted inspection and certification. Another option for recognizing certification and inspection bodies is through bilateral trade agreements. Accreditation is granted to the certification and/or inspection body as recognition that it meets and continues to meet international accepted criteria. These criteria cover integrity and technical competence and the capability of the staff to assess products or manufacturers in specific areas to a consistent level of quality. Certificates and inspection and test reports are internationally recognized and accepted if the organization that performed the certification has been accredited by an accreditation body. Accreditation and certification require one hundred percent compliance to the appropriate international standard and full compliance to rules and procedures established by the International Accreditation governing bodies, (ie, the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC)

If accompanied with the proper documentation, products should not be subjected to redundant testing, inspection or certification procedures when they are exported to other markets.

What is the purpose of inspection?

Inspection can take many forms. In its simplest form, it is a verification of the quantity and/or weight of traded goods, or if it occurs at a border, verification can consist of

¹ The accreditation body must be a signatory to one of the international mutual recognition agreements. For example, the International Accreditation Forum, which is the governing body on inspection and certification.

examining import/export documents with a visual check of the cargo. However, when inspection for safety and/or quality is a requirement, the process becomes more technical and testing and/or certification may be required.

Inspection is carried out on behalf of clients and/or official authorities with the objective of providing important information relative to a product's or manufacturer's conformity to regulations, standards, or specifications. Inspection parameters may include matters of quality, quantity, safety, fitness for use, and continued safety compliance of a supplier's process. Inspection of goods may typically take place within the domestic market or at the border before goods enter a country as follows:

- At the manufacturer's /supplier's premises during the production process or on the finished product, which can be carried out by the manufacturer through self declaration, by the customer or by a third party to an agreed level established between the customer and the supplier;
- Prior to export, also known as pre-shipment inspection, this is normally conducted by a third party to check and certify that shipments are complete, accurate and undamaged at the time of shipment thus guaranteeing against spurious damage and shortage claims when the goods arrive at final destination;
- Through market surveillance, which is usually carried out by official authorities to ensure compliance to mandatory health and safety technical regulations and consumer protection (see section on market surveillance for additional information);
or
- Upon port of entry, either by the importer or a third party, to check and authenticate shipments, to inspect and verify quality standards, and to ensure that contracted goods are supplied in the correct quantities and the right condition. In addition, official authorities (e.g., Customs Authority or Ministry of Agriculture) may also inspect imported goods at the port of entry to ensure compliance to mandatory health and safety technical regulations.

Differences between Inspection and Certification

There are two major International Organization for Standardization (ISO) documents that impact all conformity assessment bodies: 1) ISO/IEC 17000:2004 – Conformity Assessment – Vocabulary and General Principles, and 2) ISO/IEC Guide 2:2004 – Standardization and Related Activities – General Activities. These two documents define the international vocabulary, terminology, definitions, general rules and procedures that all conformity assessment bodies are obligated to follow.

ISO/IEC 17000:2004 defines inspection as follows:

“Examination of a product design, product process or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements. NOTE Inspection of a process may include inspection of persons, facilities, technology and methodology.”

ISO/IEC Guide 2:1994 defines certification as follow:

“Certification is a procedure by which a third party gives written assurance that a product, process or service conforms to specified requirements.”

How does inspection relate to other forms of conformity assessment and what is its place in international trade?

From an historical point of view, inspection is probably the most generic of terms, as it encompasses elements of testing, measurement and certification. However, it is usually thought of as relating to visual examination of products, services and installations; the use of simple instruments, tools and gauges; and the examination and categorization of bulk commodities taking into account other evidence of conformity such as results. Because it relies to a large extent on visual examination, the outcome of inspection is often more subjective than the result of a more scientific examination. Inspection standards are therefore less precisely defined than standards for testing.

At the technical level, inspection is often associated with more than conformity assessment. It is also linked with verification of quantities, classification or grading of products and services, assessment of the adequacy of documentation and other administrative matters. While it is perhaps the oldest form of conformity assessment, inspection is the latest to be covered by accreditation. This is largely due to its close links to government regulation and enforcement where the inspector is deemed by law to be competent. As some governments seek to reduce their direct involvement with these matters, some functions formally undertaken by government are being contracted to the

private sector. Accreditation is seen as one way of reassuring people that these functions are being carried out by competent organizations and individuals.

To provide a better understanding on the nature and operation of an inspection body and a certification body, the following illustrates the common and different elements of the two independent, yet similar and related activities.

- An **inspection body** is an entity which performs the examination of a product design, product, service, process or plant, and subsequently makes the determination of their conformity with specific requirements. An inspection report or inspection certificate may be used in the judgment to issue product certification. An inspection body may be either government or private sector operated. For the inspection report or certificate to be accepted and recognized, the inspection body should be accredited by an internationally recognized accreditation body.
- A **certification body** confirms the conformity of products, services and processes to specified requirements. The certification body should be accredited by an internationally recognized accreditation body, and operates within their "Scope of Accreditation" which clearly establishes and identifies what the certification body is accredited (authorized and technically qualified) to perform. The certification body cannot undertake any certifications that they are not accredited to perform.

It should be noted that there are three methods of verifying conformity that are recognized and accepted internationally. These are generally known as first, second and third party assessment.

- **First party assessment.** Usually in the form of a supplier's self declaration of conformity, this is widely used in commercial transactions. Integrity and reliability of the conformity assessment process is ensured mainly through a supplier's need to defend their brand reputation in competitive markets; liability legislation and provisions against false advertising etc. may impose additional disciplines. The procedures generally prove time and cost efficient and do not require a producer to disclose information that may be considered commercially sensitive.
- **Second party assessment.** Usually carried out within a manufacturer's premises through inspectors commissioned by customers. This tends to provide a more reliable indication, in particular in technically complex areas, of a product being manufactured in accordance with specified requirements.
- **Third party assessment.** Conducted by independent persons or bodies, this is generally considered the strictest approach to conformity assessment. Third parties may be involved at all stages of insuring compliance, individually or combined, of the verification process.

With the growth of world trade and increasing trade liberalization as well as the rapid development of new manufacturing and distribution technologies, hundreds of third-party national and multinational inspection bodies have been created. These organizations examine a huge range of products, materials, installations, plants, processes, work procedures and services, in the private as well as the public sector, and report on such parameters as quality, fitness for use and continuing safety in operation.

The tables below provide an overview of functions and/or responsibilities related to different conformity bodies that provide accredited inspection, and certification services

Primary International Standards Used by the Conformity Assessment Body

Inspection body	ISO/IEC 17020 : General criteria for the operation of various types of bodies performing inspection
Product certification body	ISO/IEC Guide 65: General requirements for bodies operating products certification systems
Accreditation Body	ISO/IEC TR 1710: General Requirements for bodies providing accreditation of inspection bodies

There are two additional ISO documents that impact all conformity assessment bodies:

ISO/IEC 17000:2004 - Conformity assessment — Vocabulary and general principles

ISO/IEC Guide 2:2004 - Standardization and related activities — General vocabulary

Comment: These two documents define the international vocabulary, terminology, definitions, general rules and procedures that all conformity assessment bodies are obligated to follow.

Primary Function of the Conformity Assessment Body

Testing laboratory	<ul style="list-style-type: none"> ✓ Testing of products as received <i>e.g. testing of packaging and food additives in canned sardines</i> ✓ Not necessarily operated by third party. Testing can be carried out by the first party or the second party. Reporting the test results as received.
Inspection body	<ul style="list-style-type: none"> ✓ Inspection of products according to the requirements <i>e.g. inspection of contaminants in canned sardines (tin shall not be more than 150 mg/kg and mercury not more than 0.2 mg/kg)</i> or In-service inspection <i>e.g. inspection of boilers</i> ✓ Not necessarily operated by third party. Inspection can be carried out by the first party or the second party. Reporting or certifying the inspection results according to the requirements on the basis of professional judgment.
Product Certification Body	<ul style="list-style-type: none"> ✓ Certifying compliance of products according to the standards <i>e.g. certifying that all lots of canned sardines comply with CODEX</i> ✓ Normally operated by third party
Accreditation Body	<ul style="list-style-type: none"> ✓ Authoritative body that performs accreditation. This is third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks <p>NOTE The authority of an accreditation body is generally derived from government.</p>

Certificate, Report, Licenses Issued by the Conformity Assessment Body

Testing laboratory	The laboratory issues a test report stating their findings as to compliance to conformity, (ie: the product meets or does not meet the minimum requirements) certificates are not normally provided.
Inspection body	The inspection report and or inspection certificate can be issued, they shall include all the results of examinations and the determination of conformity made from these results as well as all information needed to understand and interpret them.
Product Certification Body	<p>The certification body will issue to the supplier of the product formal certification documents such as a letter or certificate signed by an officer who has been assigned such responsibility. The documents shall contain the following:</p> <p>The name and address of the supplier whose products are subject to certification;</p> <p>The scope of the certification granting, including as appropriate,</p> <ul style="list-style-type: none"> ✓ The products certified, which may be identified by type or range of products, ✓ The product standards or other normative documents to which the product or product type is certified, ✓ The applicable certification system; <p>The effective date of certification, and the term of the certification if applicable.</p>
Accreditation Body	The accreditation body will issue a certificate to the laboratory or the certification body that has meet all the requirements of the appropriate standard. As part of the certificate, a “Scope of Accreditation” (SoA) is supplied. This SoA clearly defines what functions the laboratory or certification body is accredited to perform. The laboratory or certification body cannot claim that they are accredited to perform any activities that are not listed on the SoA.

Name, logo or Mark of the conformity Assessment Body

Testing laboratory	The name, logo or mark of the testing laboratory is shown on the test report or certificate.
Inspection body	The name, logo or mark of the inspection body is shown on the inspection report or inspection certificate. Marking to show that the products have passed the inspection can be put on the lot which has been subject to inspection only.
Product certification body	A legally registered certification mark should be applied or issued under the procedures of a 3 rd party certification system for a product or service which is in conformity with specific standards or other technical specifications. Ie; CE, UL, CSA etc.
Accreditation Body	The name and or logo of the accreditation body is shown on the accreditation report.

Note: Product conformity plays a major role in consumer safety and international trade. Before 1990, product conformity was fundamentally concerned with consumer safety. Products that display an authorized conformity mark label indicated that they have passed certain safety, health and environmental standards. Officials and consumers considered the mark a sign that the product was safe to use and that the interests of the consumer are protected.

Market Surveillance

The purpose of market surveillance is to ensure that the products in the domestic marketplace are safe and comply with the provisions of applicable standards and technical regulations. Market surveillance is important for and in the interest of consumers and regulators, because it helps to eliminate unfair competition and potentially hazardous products.

Market surveillance is usually the responsibility of public authorities to guarantee the impartiality of market surveillance operations. Market surveillance authorities should have the necessary resources and powers to conduct their surveillance activities, i.e., to monitor products placed on the market and, in cases of non-compliance, to take appropriate action. As regards personnel resources, authorities need to have, or have access to, a sufficient number of suitably qualified and experienced staff, with the necessary professional integrity. To guarantee the quality of the test data, the testing facility used by a market surveillance authority should comply with the relevant criteria of international accreditation and certification standards and procedures. For example, the authority should be independent and carry out its operations in an impartial and non-discriminatory way. Further, the authority should carry out market surveillance respecting the principle of proportionality, for example, action must be in accordance with the degree of risk or noncompliance and the impact on the free circulation of products may not be more than is necessary for achieving the objectives of market surveillance. The surveillance authority may subcontract technical tasks (such as testing or inspection) to another body, provided that it retains the responsibility for its decisions, and provided there is no conflict of interest between the other body's conformity assessment activities and its surveillance tasks. In doing so the authority should exercise great care to ensure that the impartiality of the advice it receives is beyond reproach. Responsibility for any decision to be taken on the basis of such advice shall reside in the surveillance authority.

For market surveillance to be efficient, resources should be concentrated where risks are likely to be higher or non-compliance more frequent, or where a particular interest can be identified. Statistics and risk assessment procedures can be used for this purpose.

Monitoring of products placed on the market may be divided between several authorities at the national level, for example, functionally or geographically. Where the same products are subject to control by more than one authority (for example, customs and a sector authority like a Ministry of Agriculture, or local authorities), coordination between authorities is necessary.

Under market surveillance, inspection of weights and measures (or legal metrology as it is formally known) in the market is of vital concern. In simple terms, is the consumer getting what he/she is paying for? Almost everything that is bought is sold by weight, volume, length, count or measure; for example, a kilogram of vegetables, a liter of gasoline, a meter of cloth, a dozen eggs, and the amount of electricity or natural gas used in a home. Package labeling and marking of consumer goods is also considered a weights and measure function. The inspection function for weights and measures is the responsibility of public authorities. In most countries weights and measures officials work in ministries of agriculture, health, consumer protection and energy.

Third Party Certification and Inspection

Many developing countries and transitional economies do not have the financial and/or technical resources to provide inspection, certification and testing services needed to implement a fully functional system. Some of these countries, economies and many industrial nations utilize the services of a third party inspection service, certification body and/or testing laboratories. Conformity assessment by a third-party is widely accepted in Europe, the United States, and the Middle East, although there is no precedent in Japan at this time for this type of activity.

As stated earlier, some governments seek to reduce their direct involvement with these matters; some functions formally undertaken by government are being contracted to the private sector. There are hundreds of multinational (private sector) companies throughout the world that offer this type of service; some are industry sector specific, while others offer a broad range of services. Accreditation is seen as one way of reassuring people that these functions are being carried out by competent organizations and individuals.

The governmental authority responsible for insuring conformity may subcontract technical tasks (such as testing or inspection or certification) to another body, provided that it retains the responsibility for its decisions, and provided there is no conflict of interest between the other body's conformity assessment activities and its surveillance tasks. In doing so the authority should exercise great care to ensure that the impartiality of the advice it receives is beyond reproach. There are hundreds of private sector bodies worldwide that

offer such services. Many are sector specific, e.g., automotive industry, food industry, or construction. In the United States, there are over 150 companies. The vast majority of third party inspection and certification bodies are accredited by an internationally recognized accreditation body. Those that are not accredited by an internationally recognized accreditation body are sometimes authorized by their government to perform inspection and or certification on their behalf. Note: This practice is common in former eastern block countries and Soviet Republics. The primary reason for this is that many of these countries do not have an accreditation infrastructure that follows international rules and guides.

The International Accreditation Forum, Inc. (IAF)² is the world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programs of conformity assessment. Its primary function is to develop a single worldwide program of conformity assessment which reduces risk for business and its customers by assuring them that accredited certificates may be relied upon. Accreditation assures users of the competence and impartiality of the body accredited. IAF members accredit certification or registration bodies that issue certificates attesting that an organization's management, products or personnel comply with a specified standard (called conformity assessment).

Example - Exporting to Russia and some CIS countries.

Depending on the nature of the goods, importers will need to comply with one or more certification requirements. There are 19 mandatory certification systems regulated by Laws of the Russian Federation (GOST R) and over 300 voluntary ones. Today, the GOST R Certificate of Conformity is the most common permitted document in Russia

² Additional information is available on the IAF Web Site < www.IAF.nu > Achieving Mutual recognition of accreditation and certification procedures is the best approach toward reducing duplication of re-testing and re-certification thus reducing cost and eliminating non-tariff barriers to trade and market access delays.

Food Inspection Systems

As distinct from commercial and industrial products, inspection systems related to food and agricultural products often require very specific and diligent systems due to the importance of keeping the food supply safe. The World Health Organization through the *Codex Alimentarius Commission* has developed and adopted a set of fundamental “*Principles for Food Import and Export Inspection and Certification*”.³

“Official and officially recognized inspection and certification systems are fundamentally important and very widely used means of food control. The confidence of consumers in the quality (including safety) of their food supply depends in part on their perception as to the effectiveness of food control measures. A substantial part of the worldwide trade in food, for example in meat and meat products, depends upon the use of inspection and certification systems. However, inspection and certification requirements may significantly impede international trade in foodstuffs. Consequently it is desirable that the design and application of these systems should reflect appropriate principles.

Inspection of food may occur at any stage in the production and distribution process. For some foods, inspection oversight of harvesting, processing, storage, transport, and other handling of product may be the most appropriate means of ensuring food safety. According to the methods of preservation used, it may be necessary to maintain inspection oversight on a continuous basis up to the time of retail sale. Inspection systems may be focused on the foodstuffs themselves, on the procedures and facilities employed in the production and distribution chain, on the substance and materials which can be incorporated into or contaminate foodstuffs.

Inspection should be carried out at the most appropriate stages (e.g. control of refrigeration at every stage of the cold chain). For some requirements, i.e., those pertaining to product description, it may be possible to limit inspection to the distribution process and prior to final sale.

In both design and use, food inspection and certification systems should be governed by a number of principles which will ensure an optimal outcome consistent with consumer protection and facilitation of trade.”

Food Safety Management Systems

Different countries, and even regions, markets, industries and retailers often implement their own standards and requirements for food safety. However, these standards might not address some key issues, such as traceability or lack of interactive communication across the supply chain, well. A certified food safety management system meeting the requirements of the new international standard (ISO 22000) can be well integrated with existing food quality and safety management systems and is a solid base for customer confidence.

³ See Annex 1 for full text of “Principles for Food Import and Export Inspection and Certification.

Increasing consumer demand for safe food has led many companies to develop both food quality and safety management systems based on the Hazard Analysis and Critical Control Point (HACCP) which was first used by NASA in 1959 and first published and implemented in 1973 by the Pillsbury Corporation in the USA. Over the years HACCP has been considered the most effective system of food safety assurance. Implementing principles of HACCP became a legal requirement for most food premises within the EU and USA and many other countries. Note: Compliance to HACCP is verified by certification, it is not an inspection activity.

Until recently, HACCP was a widely accepted food safety management system used to assure the safety of food. It is a systematic approach to the identification, assessment of risk and severity, and control of the biological, chemical and physical hazards associated with a particular food production process or practice. HACCP advantages included enhanced public health control over the occurrence of potential hazards in the food supply and increased consumer confidence in the safety of the food supply. The short coming of HACCP was that it was a set of principles and not a standard, thus implementation of HACCP principles took different forms and were interpreted differently. All certifications were not necessarily equal.

In 2001, ISO started the development on an auditable standard, which further defines HACCP's role in food safety management systems and eventually culminated in the newly formed ISO 22000. ISO 22000 is the international standard that defines food safety management requirements that companies need to meet or exceed. It is the one standard that encompasses all the consumer and market needs. It speeds and simplifies processes without compromising other quality or safety management systems. It can be used by all organizations in the supply chain, from farmers to food services, to processing, transportation, storage, retail and packaging. ISO 22000 also creates a harmonized safety standard that is accepted world wide. By integrating multiple principals, methodologies and applications, ISO 22000 is easier to understand, apply and recognize, which makes it more efficient and effective as an entry-to-market tool than previous combinations of national standards.

ISO 22000 specifies the requirements for a food safety management system that combines well-recognized key elements to ensure food safety along the food chain, up to the point of final consumption, including

1. Providing interactive communication, internationally and across the supply chain;
2. Complying with the HACCP principles: hazard analysis, identify Critical Control Points (CCP's), establish critical links, monitor CCP's, establish corrective action, record keeping, and verification;

3. Harmonizing the voluntary and prerequisite standards;
4. Creating a structure that's aligned with ISO 9001:2000;
5. Creating system management; and
6. Ensuring process control (i.e., any stage in the production and or distribution process).

Best Practices in Inspection and Certification (Conformity Assessment)

There is no one national inspection or certification system that is considered the best practice, but there are significant similarities in many national systems of conformity assessment which are based on a common set of principles aimed at facilitating trade. Beyond the trade sphere, standards and conformity assessment contribute to the basic infrastructure that underpins society. The health and safety of a nations citizens, environmental protection and good regulatory practice, are all supported by conformity assessment activities.

The following appear to be some of the basic principles that are utilized in many countries

- ✓ Conformity Assessment contributes to safeguarding public health, the environment.
- ✓ Conformity Assessment is based on international standards, agreements and protocols without undue national bias.
- ✓ Conformity Assessment upholds the WTO Agreement on Technical Barriers to Trade (TBT) and, avoids creating unnecessary obstacles to trade.
- ✓ Information regarding Conformity Assessment (CA) requirements, accreditation procedures and results are made publicly available. Activities are conducted with due regard to confidentiality while ensuring full disclosure of CA results to regulatory authorities as required.
- ✓ Conformity Assessment is inherently voluntary. However, marketplace demands and/or government regulation may mandate specific CA requirements
- ✓ Conformity Assessment operates in an explicit, credible, and transparent manner and is accessible, equitable and fair in its treatment of all users.

The following are some of the major inspection, certification and conformity assessment similarities used in many countries:

- **Using qualified inspectors and auditors.** Technical competence, qualifications and integrity of inspectors and auditors is a major requirement of implementing all successful inspection, market surveillance or certification systems. Most inspectors and auditors have special training, experience and international recognized credentials. The International Register of Certificated Auditors (IRCA)⁴ is the world's original and largest international certification body for auditors/inspectors. Located in the UK in the center of London, IRCA certifies more than 11,500 auditors/inspectors in over 105 countries. IRCA offers certification programs that recognize the competence of auditors/inspectors who audit quality, environmental, occupational health and safety, software development, information security and food safety management systems. IRCA also offers a wide range of training courses.
- **WTO and EU Compliance.** Economies that have officially stated their intention to accede to the World Trade Organization (WTO) or the European Union (EU), and those who have already completed the accession process, have had to develop new

⁴ Additional information is available on their web site , <www.irac.org >

or revise laws governing mandatory inspection and certification to bring them into compliance with the with the WTO Agreement on Technical Barriers to Trade (TBT Agreement) and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).⁵

These Agreements seek to ensure that technical regulations, standards and procedures for assessment of conformity (with technical regulations and standards) as may be used in international trade, do not create unnecessary obstacles to such trade. Technical regulations and standards refer to characteristics for products or related processes and production methods (PPMs) and may include or deal exclusively with terminology, symbols, marks, packaging or labeling requirements as they apply to a product. The difference between technical regulations and standards is that compliance to technical regulations is mandatory and compliance to standards is voluntary.

- **Standards and Technical Regulations.** All WTO members are required to a comply with the WTO/ISO “TBT Code of Good Practice”. The TBT Agreement - sometimes referred to as the Standards Code - is one of the legal texts of the WTO Agreement which obliges WTO Members to ensure that technical regulations, voluntary standards and conformity assessment procedures do not create unnecessary obstacles to trade. Annex 3 of the TBT Agreement is the *Code of Good Practice for the Preparation, Adoption and Application of Standards*, which is known as the WTO Code of Good Practice. 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 also agree to take reasonable measures to ensure that local government, non-governmental and regional standardizing bodies do the same. The TBT Agreement recognizes the important contribution that international standards and 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 IEC.

As of 15 July 2006, a total of 161 standardizing bodies from 121 countries have formally accepted the Code, including Egypt.

- **Inspection and certification bodies** use harmonized international standards, procedures and guides. The most commonly used standard for inspection bodies is ISO/IEC 17020 “General criteria for the operation of various types of bodies performing inspection”.
- **Laboratory Testing Activities.** In order to ensure acceptability of test results performed by testing and calibration laboratories internationally, it is essential that the international standard determining the competence of the laboratories, i.e., ISO: 17025, is implemented. Many countries have formally adopted this standard as a national standard, e.g., USA, Canada, Mexico, and EU members.
- **Authoritative Agencies.** The government agency normally responsibility for inspection and enforcement of conformity is determined by a mutual agreement

⁵ The SPS Agreement governs the *Application* of SPS measures are mandatory technical requirements adopted by countries to protect the health and lives of humans, animals, and plants from risks associated with disease, pests, contamination of foodstuffs, and to prevent damage caused by the establishment or spread of pests. Sanitary measures relate to human or animal health, while phytosanitary measures relate to plant health.

between agencies and is usually based on the agencies primary responsibility. For example, agricultural products would be the responsibility of the Ministry of Agriculture; medical devices and drugs would be under the Ministry of Health; and aircraft, automobiles, etc. would be under the Ministry of Transportation. There are instances where there appears to be overlapping authority, and in these few cases, it is important that the agencies resolve who has the ultimate and sole authority.

- **Harmonized Procedures – A New Approach to Lawmaking.** The formation of the single market in Europe, one in which there is a free flow of goods, has as one of its objectives, the elimination of barriers to trade between the Member State countries. Differences between national laws, standards, and conformity assessment procedures made trade between the countries difficult, contentious, and expensive. In order to eliminate these barriers, a new legislative technique and strategy was instituted. The new approach was designed to envelop, or "harmonize," the health, safety, and environmental requirements of Member States into one European-wide legislative package. The result of this new approach to lawmaking, or "harmonization," was a new set of laws that emanated from the European Commission in Brussels, Belgium. They are called the New Approach Directives. In each case, one law replaced fifteen. Member States were required to adopt the new harmonized laws.

"New Approach" Directives (or Community Law) set out the essential requirements, on safety for example, written in general terms which must be met before products may be sold in the UK or anywhere else in the European Community. European harmonized standards provide the detailed technical information enabling manufacturers to meet the essential requirements. The directives also explain how manufacturers are able to demonstrate conformity with the essential requirements. Products which meet the essential requirements are to display the CE marking, as described in the particular directive, which means that the products can be sold anywhere in the Community.

Note: Many countries outside of the EU have started to adopt and implement the New Approach Directives as national Technical Regulations. This concept eliminates the need for developing countries to create new technical regulations and standards as well as simplifies trade facilitation between the developing country and EU members.

- **Adopting International Standards and Procedures.** There is a major trend for developing countries and those translational economies to adopt international standards (ISO, IEC, CODEX, etc.) without change or modification. In the past many developing countries would claim compliance to an international standard, in relativity, they modified the standard to suite their outdated system. In the Former Soviet Republics, this was a common practice.

Examples of National and Regional Inspection and Certification Systems⁶

Inspection and certifications systems are based on international and/or regional standards and regulations; there is no one model that is considered the best practice. The European Union system is made up of several national systems of member countries, each complying with the regional requirements in their own way. The Sistema Interamericano de Metrología, Normalización, Acreditación y Calidad has the Interamerican Metrology System (SIM), or the regional organization for metrology and conformity assessment in the Americas. It is comprised of the national metrology institutes from the 34 member nations represented at the Organization of the American States, (OAS), which acts as its Executive Secretariat.

The following is a brief overview of the some of the national practices on standards, inspection, technical regulations and conformity assessment in the Western Hemisphere, followed by other regional and national systems.

Western Hemisphere⁷

Bahamas

There are two government agencies involved with inspections and testing. However, the activities are limited to the food sector. There are presently no accreditation systems in place, nor any certification programs for laboratories or inspection program. The government is the operator of the inspection and testing programs. Testing and inspection performed in other economies are generally accepted.

Bolivia

At present a process is under way to adopt new legislation to create the Bolivian System for Standardization, Metrology, Accreditation, and Certification. This system will be based on the actions of three main entities: the National Standardization Organization (now IBNORCA); the Bolivian Metrology Institute, which administers the National Metrological Service; and the Bolivian Accreditation Agency (currently a mixed commission made up of IBNORCA and the Secretariat for Industry and Commerce), which will accredit, among others, inspection and certification offices, testing laboratories, and calibration laboratories. This system will introduce present-day criteria

⁶ The material in this section is drawn either from country web sites or the NIST web site that provides information on conformity assessment systems in various countries.

⁷ The information in the Western Hemisphere” section is drawn from “Inventory of National Practices on Standards, Technical Regulations and Conformity Assessment in the Western Hemisphere” at http://www.ftaa-alca.org/WGroups/WGSTBT/Npract/english/tbt_6a.asp

for accreditation and certification and seek to guarantee the principles of transparency, technical suitability, and action by third parties.

Brazil

The National System of Metrology, Standardization and Industrial Quality (SINMETRO) set up in 1973, it has as one of its objectives to provide the country with an infrastructure of technological services for quality and productivity, consisting of basically, a system of generating standards and technical regulations, of networks of calibration and testing laboratories and also a system of certification of conformity. Brazil has a comprehensive network of inspection and testing bodies and authorities which have the capability of carrying out most work required by business and government. There are bodies in the private sector and public sector both in the areas of health care, agriculture, environment, labor, etc.

Colombia

Decree 2269/93 created the National System for Standardization, Certification and Metrology. As a result of this decree some regulatory provisions have been issued, such as: - Resolution 140/94 of the Superintendency of Industry and Commerce which lays down provisions on accreditation, certification, and conformity assessment, regulating the conditions that must be met by certification and inspection organizations and testing laboratories to receive accreditation. - Decree 300/95, signed by the Ministers of Finance and Public Credit, Economic Development and External Trade, which establishes the procedures to be followed by importers in order to show conformity of their products with the Mandatory Official Colombian Technical Standards. - Decree 1112/96, which creates the National System of Information on Standardization's Measures and Procedures for Conformity's Evaluation, and establishes the general criteria for the issuance of technical regulations. Signed by all Ministers related to the issuance of technical regulations. - Resolution 547/96, of the Superintendency of Industry and Commerce, which establishes the compulsory registration of producers and importers of goods and services which are subject to fulfill mandatory technical standards or technical regulations.- Resolution 343 of the Superintendency of Industry and Commerce which defines the modalities of certification to demonstrate the fulfillment of the mandatory official Colombian technical standards and technical regulations. The Testing Laboratories are accredited by the Superintendency of Industry and Commerce and form the National Network of Accredited Laboratories, which currently has more than 24 properly accredited testing laboratories in different areas.

The National Institute for Supervision of Drugs and Food (INVIMA) and the Colombian Agricultural Institute (ICA) have special responsibility for establishing the conditions that must be met by the agencies that wish to be accredited as certification agencies, inspection agencies, and testing laboratories to certify conformity in terms of food, rugs and cosmetics, plant and animal health. For the development of such activities, the ICA and the INVIMA advance work in those areas under the advice of the Superintendency of Industry and Commerce, establish the minimal requirements for the accreditation of the bodies and laboratories under their area of capacity, and recognize the Superintendency of Industry and Commerce as the only body of accreditation. The Superintendency of Industry and Commerce, the ICA and the INVIMA are national in scope and financed by the Government. The agencies for certification, and for inspection, and the testing laboratories may be public or private, but are always supervised by the entities that accredit them. Under Decision 376 of the Commission of the Cartagena Agreement, at the Andean level, work is under way to create the Andean Network of Accreditation Agencies, to win multilateral acceptance of certificates of conformity.

Costa Rica

In Costa Rica the system for accreditation of testing, inspecting, and calibrating laboratories is governed by the National Accreditation Entity (ENA), whose technical secretariat is in the National Office of Standards and Units of Measure (ONNUM). According to its charter, the ENA has as its purposes to guarantee and support the technical competence and credibility of the entities that operate in the system, and in particular to ensure the availability and enhancement of the services offered by the various entities operating in the system.

Ecuador

The testing laboratories are in public and private organizations and at the centers of higher education. The work of these laboratories is normally not directed to quality certification, but rather involves verification. There are testing laboratories that provide services to third persons; the laboratories are not, at this time, grouped into networks or associations of laboratories for product certification. The Ecuadorian government is working to organize the project known as SINLA (National System of Accredited Laboratories), national in scope, and following international practice. The SINLA network will begin to operate in the second half of 1996. The inspection agencies and enterprises have testing laboratories with very limited infrastructure.

Guatemala

The process of assessing conformity with technical regulations is compulsory and is performed through different government offices, based on their area of competence, namely: - Control and Registry of Foods entrusted to the Department of Registration and Control of Foods, Division of Registration and Control of Drugs and Foods, General Health Services, under the Ministry of Public Health and Social Assistance. - Control and Registry of Drugs under the responsibility of the Department of Registration and Control of Foods, Division of Registration and Control of Drugs and Foods, General Health Services, under the Ministry of Public Health and Social Assistance. - Control and oversight of fuels, entrusted to the General Bureau on Hydrocarbons, under the Ministry of Energy and Mines. - Registry of agricultural pesticides and related substances (raw materials, chemical fertilizers, natural fertilizers) under the Technical Bureau for Plant Health of the General Farm Services Bureau, Ministry of Agriculture, Livestock, and Food. - Registry of Food Products for animals and veterinary medicines, under the Department of Control of Veterinary Products, Technical Bureau for Animal Health, Ministry of Agriculture, Livestock, and Food. Guatemala has conformity assessment entities that publish results for a registry of products: - LUCAM (Unified Laboratory for Food and Drug Control) under the Ministry of Public Health and Social Assistance; - DIGESEPE (General Animal Services Bureau), under the Ministry of Agriculture, Livestock, and Food; - General Bureau of Hydrocarbons and Bureau of Nuclear Energy, both under the Ministry of Energy and Mines.

Jamaica

The Jamaican Bureau of Standards has a range of laboratories to support its standards development activities and offers testing services to industry in areas such as engineering, textiles, paints, microbiology, chemicals, food, metallurgy, paper, furniture and packaging. Inspection and testing of imported and exported foods products which are susceptible to pest infestation is handled by the Storage and Prevention of Infestation Department. The Ministry of Health tests and inspects pharmaceuticals, and provides testing inspection under the Veterinary Public Health Departments.

Mexico

The Federal Bureau of Consumer Protection (PROFECO) is responsible for overseeing compliance with Official Mexican Standards. In the case of imported merchandise subject to compliance with Mexican Official Standards at the point of entry of the merchandise into the country, the inspection is carried out by the Department of

Economy and Public Credit (SHCP). The tests are carried out by the different laboratories of SECOFI's General Bureau of Standards and the laboratories it accredits through the National System of Accreditation for Testing Laboratories.

Peru

Peru has testing laboratories (public, private, and university) that provide services in different areas of testing and product areas. These laboratories are accredited before the Commission of Technical and Trade Regulations (CNM) of the INDECOPI in order to demonstrate their technical competence and suitability for undertaking the accredited tests. The program for accreditation of laboratories and inspection agencies is voluntary; once obtained, it confers the status of official testing laboratory.

United States

The United States has a comprehensive network of inspection and testing bodies and authorities which have the capability of carrying out most work required by business and government. Most of these bodies are in the private sector, and public sector facilities may operate on a commercial basis. The Federal Communications Commission (FCC), for example, generally relies on private sector labs to do the conformance testing required to receive the necessary equipment authorization to market, manufacture, or import devices that generate radio frequency energy. The FCC does its own compliance testing, both before and subsequent to issuing equipment authorizations, on a spot check basis. The United States maintains a comprehensive voluntary product certification system beyond manufacturer's inspection which includes supplier's declaration of conformance to standards, industry association verification programs and third party inspection and testing programs. These programs are basically self-policing with little or no involvement by government regulatory officials.

Laboratory accreditation is one method by which the quality and accuracy of test data is ensured. For example, the Federal Communications Commission (FCC) does not accredit laboratories to do FCC tests, but the laboratories must file information with the FCC to demonstrate that they are capable of making the necessary compliance measurements. The National Institute of Standards and Technology (NIST) has a voluntary accreditation program (NVLAP) to accredit test labs that do electromagnetic compatibility (EMC) testing. The Environmental Protection Agency (EPA) has a formal program for certifying the competence of laboratories analyzing drinking water for compliance with drinking water standards. The Federal Drug Administration (FDA), in contrast, relies on its own labs to do compliance testing on foods and medical products, although private labs often provide analytical data to support a sponsor's claim that its

products comply with FDA requirements. FDA does not accredit such labs, but does inspect them and audit their data for accuracy. Most U.S. laboratory accreditation programs have been designed to meet particular governmental or private sector needs. These programs, consequently, take distinctive forms and use different sets of procedures to assure that a laboratory has sufficient competence to perform the specified testing. Laboratory accreditation programs are operated by all levels of government and by the private sector as well. There is no centralized government coordinating body.

Venezuela

The Autonomous Service, Bureau for Standardization and Quality Certification (SENORCA), established by Presidential Decree No. 2801 of February 4, 1993, under the Ministry of Development, operates a program to accredit testing laboratories and certification and inspection entities that is open to all types and sizes of laboratories, covering all areas of product and materials testing. SENORCA performs evaluations for testing laboratories that wish to become accredited, and audits already-accredited ones to ensure compliance with the terms of their accreditation. Inspections and tests are also performed by the various Ministries on a compulsory basis (per the Organic Law of the Central Administration) that act in the field of health, hygiene and safety, environment, farming, and stock-raising.

The European Union

Within the EC, there are active national and regional conformity assessment bodies and standards organization. With the introduction of the "New Approach Directives" Europe established a common set of technical regulations that governs trade within the community as well as for countries that wish to import their products into the EC. Not all products are governed by New Approach Directives. There are essentially three regulatory levels. Technical requirements differ for each of them. There are the "old approach" regulations, which have technical specifications integrated into the annexes. Some of these products are regulated on a product-by-product basis. The New Approach Directives make references to harmonized standards. In the third level, products are unregulated at the EU level, but the products may be regulated at the national level and are governed by Member State laws.

The "New Approach", defined in a Council Resolution of May 1985, represents an innovative way of technical harmonization. It introduces, among other things, a clear separation of responsibilities between the EC legislator and the European standards

bodies CEN, CENELEC and ETSI in the legal framework allowing for the free movement of goods.

- EC directives define the "essential requirements", e.g., protection of health and safety that goods must meet when they are placed on the market.
- The European standards bodies have the task of drawing up the corresponding technical specifications meeting the essential requirements of the directives, compliance with which will provide a presumption of conformity with the essential requirements. Such specifications are referred to as "harmonized standards".

"Harmonized standards" are European standards, adopted by CEN, CENELEC or ETSI, following a mandate issued by the European Commission after consultation of Member States. They are developed through an open and transparent process, built on consensus between all interested parties. Compliance with harmonized standards, of which the reference numbers have been published in the Official Journal and which have been transposed into national standards, provides presumption of conformity to the corresponding essential requirements of the EC directives. Compliance with harmonized standards remains voluntary, and manufacturers are free to choose any other technical solution that provides compliance with the essential requirements. In a number of cases compliance with harmonized standards also increases the options for conformity assessment procedures.

Where the Commission or the Member States consider that harmonized standards present shortcomings with respect to the essential requirements, the publication of the reference in the Official Journal can, in conformity with the procedures laid down in the directives, be withdrawn by the Commission. In such cases, the harmonized standard will cease to provide a presumption of conformity.

It must be remembered that the European Union is the newest economic region in the industrialized world and as such, is still a work in progress. Non-EU members soon realized that complying with the new approach was not easy as it was promoted. Obtaining regulations and procedures was complex, and there was no central point that would speak for all member countries. In addition EC members had their own TBT enquiry points, this also posed a problem, and there was an uncoordinated approach. The EC commission soon realized the shortcomings of their system.

Regulating and harmonizing laws for every product with specific, highly technical requirements for each proved to be an impossible task. The new, more practical approach, the New Approach, was to govern families of products. Regulation of these products took on a more generic format, and was limited to "[Essential Health and Safety Requirements.](#)" Today, because these laws have replaced old national laws, products meeting these essential health and safety requirements can be placed on the market in any country within the European Economic Area (EEA) Union and move freely throughout all member countries.

Essential health and safety requirements are at the heart of the New Approach Directives. They are mandatory, legally binding obligations, and they are enforced. The aim of most essential requirements is the elimination of risks of accident to the extent possible. All manufacturers, domestic or foreign, are obliged to meet all the essential requirements pertaining to their product. The law does not distinguish between European manufacturers and manufacturers of other countries.

Conformity assessment in Europe, therefore, is the process by which compliance with essential requirements is determined. This process can be carried out with or without the use of standards. This last principle is important to manufacturers of new or innovative products for which standards do not yet exist, and ensures that standards annexed to New Approach Directives (which are voluntary) do not become obligatory.

In Europe, the point of the New Approach Directives was to eliminate differences between national laws, thereby eliminating barriers to trade between the Member States. But differences in national standards and testing and certification procedures were the root causes of barriers to trade, and it followed that a new, integrated scheme for technical harmonization had to be implemented as well. The new scheme was embodied in two Decisions: (1) the Module Decision, and (2) the regulation on CE Marking. The policy was called the Global Approach. It incorporated conformity assessment procedures directly into the New Approach Directives.

A European Communities' enquiry point has been set up within the Commission to manage the notification procedure. This is known as the EC-TBT Enquiry Point. There is also a service responsible for the TBT notification procedure in each Member State. The EC-TBT Enquiry Point ensures the European Communities' participation in the information and notification system for technical regulations and conformity assessment procedures established by the Agreement. In particular it is responsible for sending the WTO Secretariat notifications of proposed Community acts falling within the scope of the Agreement, for following up comments received by the European Communities and for responding to

requests for information made by the enquiry points of third countries on announced proposals. In liaison with enterprises, it also analyses proposals announced by third countries and coordinates the comments of the European Communities on these texts. The Community enquiry point also exchanges information with its counterparts in Member States. To this end, a group bringing together the national services responsible for notifications has been created. Chaired by the Community enquiry point, it meets regularly to discuss issues linked to the Agreement's application. This group has recently been enlarged to include the services responsible for notifications in the new Member States of the European Union. The activities of the Community enquiry point are mainly aimed at increasing the participation of Member States and European enterprises in the notification procedure established by the Agreement and at encouraging, by monitoring the measures announced by third countries, the integration of European enterprises within the world economy. In order to understand the practical operation of the notification procedure at Community level, the following three scenarios should be analyzed: notification of proposed Community acts, notifications of proposals elaborated by Member States of the European Union and notifications of third countries.

Examples of European National Procedures

France

The French Standards Association (AFNOR) heads the AFNOR Group. AFNOR was founded in 1926 and is a state-approved organization under the administrative supervision of the Ministry for Industry. It has a membership of approximately 3000 companies. Under the decree of 26 January 1984, AFNOR controls the central standardization system consisting of 31 sector-based standardization offices, public authorities and 20,000 experts. AFNOR is the French member of CEN and ISO and responsible for all the tasks assigned to France in this respect. The AFNOR Group consists of an association, a pivotal company and three commercial subsidiaries:

The pivotal company, AFAQ-AFNOR, whose capital is entirely owned by AFNOR, holds all the securities of the commercial subsidiaries. It incorporates the support resources that may be required to work with all the Group's operational and subsidiary entities. This company is responsible for the strategic and operational management and control of its subsidiaries and helps to ensure that they run smoothly.

Commercial subsidiaries:

AFAQ AFNOR Certification is the Certification Center responsible for the certification activities that were previously dealt with by the AFAQ Association and AFNOR Certification and are now combined within one subsidiary company;

Activities

Within a context of trade globalization and the pursuit of competitiveness, the Group, which brings together the activities of both AFAQ and AFNOR, is the preferred partner of most socio-economic players. The Group has demonstrated its expertise in four complementary activities.

Standardization: AFNOR develops the reference systems required by economic players to promote their strategic and commercial development. As European and International standardization represents more than 80% of its work, AFNOR is influential in representing French interests within these standardization authorities.

Publication and distribution of information products: AFNOR helps players to access reference systems by providing them with international reference standards and information and assisting companies with setting up documentary databases tailored to their needs.

Training: CAP AFNOR, a subsidiary of the Group, helps economic players to apply the reference systems and prepare applications for standardization, certification and progress initiatives through its wide range of inter/intra company training and information days.

Certification: AFAQ AFNOR Certification is now the Group's certification body. It offers a wide range of certifications for management systems, products, services and persons.

A dedicated international centre has been set up within the new Group to contribute to an ambitious development program in the certification, technical cooperation and training fields. It is supported by AFAQ's subsidiaries, partners and counterparts outside France and AFNOR's standardization and international technical cooperation network.

Greece

Hellenic Standardization (ELOT) is the Greek national body, standardization, is one of the main objectives of ELOT which is realized through the elaboration and publication of Hellenic Standards and the promotion of their implementation. Hellenic Standards, according to the International guides, are documents that provide for common and repeated use of specifications, rules, guidelines, activities' characteristics or their results, aiming at the achievement of the optimum degree of order in a given context. Hellenic standards support the development of national economy in general. They refer to products, processes and services as well as to quality systems.

Systems & Products Certification

By law ELOT is responsible for the development of Certification activities, procedures and systems (e.g.: ISO certification systems). In the context, ELOT grants Conformity Marks and

Certificates of Conformity, which denote the conformity of products, processes, activities, organizations, systems and personnel to the requirements of normative documents, and which are called ELOT Conformity Marks/ Certificates of Conformity. Conformity marks are granted to products in conformity with the requirements of Hellenic Standards, European Standards (EN), Experimental European Standards (CEN), harmonization Documents (HD), as well as European telecommunication Standards (ETSI), Experimental European Telecommunication Standards (I-ETS), issued by ELOT, CEN or CENELEC or ETSI , are defined as Hellenic Marks of Conformity. ELOT is the unique certification organization, authorized for the granting of these marks.

ELOT also undertakes sampling, testing, inspections, assessment of procedures and systems using its own facilities and staff or in cooperation with other approved interested parties. The assessment and certification procedures are based on the requirements of standards Greek and European guidelines for the implementation of bodies conducting certification of Quality management and environmental management systems, (ISO 9001, ISO 14000). ELOT is also involved in the implementation of EEC Directives in cooperation with the concerned public authorities.

Product Certification

Product Certification schemes are carried out to the General Rules for Product Certification, as well as the Specific Rules for Product Certification, for each product category, which are based on the relevant ISO/IEC Guides as well as the EN 45000 series of standards. ELOT has developed and implements certification schemes for: electric household appliances, electric cables, steel for reinforced steel, asbestos- cement, ceramic tiles, sanitary appliances, ready mixed concrete, switches etc.

Inspections and Testing

ELOT carries out sampling and inspections for certification purposes. They undertake inspections on behalf of foreign certification bodies and organizations such as UL, VDE, KEMA, CEBC, BSI, AFNOR etc. The tests required for the operation of the ELOT certification schemes are carried out either in the ELOT testing Laboratories either in approved subcontracted laboratories. ELOT carries out testing in the following fields, using its own testing facilities: electric household appliances, electric cables, toys, plastic pipes while in the other field uses subcontracted laboratories.

Health and Safety Management System Certification

ELOT also developed and operates a scheme for the certification of Health & Safety Management Systems, according to the requirements of standard OHSAS 18001 and granted the first certificate in 1999.

HACCP System Certification

ELOT also developed and operates a scheme for the certification of HACCP Management Systems, according to the requirements of standard ELOT 1416.

Finland

METROLOGY

The national measuring system, or the measurement standard system, gives the necessary preconditions for the accuracy and reliability of physical and chemical measurements. All accurate and reliable measurements in industry, research, health care, trade, etc., are based on a measurement standard system in accordance with the international SI-unit system. The national measurement standard laboratories and accredited calibration laboratories are responsible for the national calibration service in Finland. The Centre for Metrology and Accreditation (MIKES) is the national measurement standard system implementer in Finland, while the Safety Technology Authority (TUKES) is responsible for the statutory measurements (calibration).

TESTING, CERTIFICATION AND INSPECTION

The conformity of products and services is verified with testing, inspection and certification. Testing also plays an important role in industrial R&D activities. Internationalizing markets and production systems increase the importance of these services, because reliable proofs for the market access of products and services are required more and more often. It is essential for the free movement of goods and services that the mutual recognition of testing, inspection and certification results is as wide as possible. Accreditation is a central means to ensure realization of mutual recognition. Some testing, inspection and certification institutes also perform assessments under legislation. The competent ministries, together with the surveillance authorities, are responsible for the accreditation and supervision of these institutes. The Ministry of Trade and Industry is responsible for the general operating rules of the assessment bodies within its safety sectors. The Safety Technology Authority (TUKES) has some tasks related to the approval and supervision of the assessment bodies within the scope of national regulations.

STANDARDIZATION

The Ministry of Trade and Industry participates in the general development of national, European and international standardization activities. The Ministry is responsible, under the Standardization Act, for the general regulation of national standardization and financing of the infrastructure. The standardization bodies, which are usually organizations outside administration, are responsible for the actual standardization work.

The Czech Republic

The Czech Office for Standards, Metrology and Testing (COSMT) was established by the Czech National Council in 1993. The Organization is the State Administration in the Field of Standards, Metrology and Testing. As the state administration body responsible for such activities. COSMT is a budgetary organization subordinated to the Ministry of Industry and Trade. The COSMT's mission is to perform tasks set out in Czech legislation on technical standardization, metrology and testing and tasks related to the harmonization of Czech technical regulations and standards with the technical regulations of the European Community.

Technical harmonization is one of the essential elements of the system of the single internal EC market in the field of free movement of goods; it includes the complex of activities and areas relating to the preparation and implementation of technical regulations, standards and conformity assessment procedures. The pre-accession strategy of the technical harmonization was based on obligations flowing from the Europe Agreement, especially Article 75, namely the goal to achieve full conformity of the Czech system and EC technical regulations, European standardization and procedures of conformity assessment. The proceeding preparations of the Czech Republic for the accession to the EU accentuate this effort. The harmonization of Czech technical regulations with the EC law, including the build-up of the corresponding infrastructure, is the basic prerequisite of the integration. The plan and the course of the transposition were closely watched in the Timetables of legislative steps to ensure transposition of EC technical regulations into Czech legislation. The plan was adopted in March, 2004 by a Government Resolution.

Denmark

Danish Standards is a private, non-profit organization, which has been approved as a technological service institute (GTS institute). The mission of Danish Standards is to strengthen the Danish society through the provision of our core services: standardization, certification and the communication of knowledge and thereby to create value for stakeholders, customers, employees and the society in general. Danish Standards is Denmark's national standardization body and one of the leading certification enterprises in

Denmark. In addition, Danish Standards has been designated as the National Enquiry Point for the World Trade Organization. The WTO Enquiry Point is the official information center for international standards, certification schemes and regulations in Denmark. As a non-profit organization, it is important that we are of use to trade and industry as well as to society as such. Our joint mission is to: contribute to increasing Danish influence on European and international standards, further matters of importance to society, such as health, safety, environmental, and consumer protection matters, through the inclusion of these themes in standardization and certification work, develop, establish and administer certification, marking and control schemes, and to ensure that Danish enterprises have easy access to information about standards and certification.

South East Asia

Within South East Asia is the “Association of South East Asian nations”(ASEAN)

Member countries include: Brunei Darussalam, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Viet Nam.

Recognizing the contribution of standards and conformity assessment to facilitate and liberalize trade and investment in the region, ASEAN through the ASEAN Consultative Committee on Standards and Quality (ACCSQ) has endeavored to harmonize national standards with international standards and implement mutual recognition arrangements on conformity assessment to achieve its end-goal of “One Standard, One Test, and Accepted Everywhere”.

All Member Countries have accomplished the harmonization of standards for the 20 priority products and 81 standards for Safety and EMC. New areas for harmonization are currently being identified. Priority for harmonization will be given to those standards used in technical regulations in Member Countries.

Work on Mutual Recognition Arrangements (MRAs) has been accelerated. Mutual Recognition Arrangement for Electrical and Electronic was signed by the ASEAN Economic Ministers on 5 April 2002 in Bangkok, Thailand. To date, ten member countries have notified their participation either in acceptance of test report and/or product certification. Member countries have also agreed to work toward harmonization of regulatory regimes in electrical and electronic sector by 2010. The Agreement on ASEAN Harmonized Cosmetic Regulatory Scheme was signed by the ASEAN Economic Ministers on 2 September 2003 in Phnom Penh. The first part of the Agreement is an MRA under which signatories are to recognize the product registration approval of any signatory in accordance with agreed rules and procedures. The second part is the ASEAN Cosmetic Directive, which lays down the requirements for cosmetic products to comply with all signatory countries.

As part of the ASEAN program, SIRIM QAS Sdn. Bhd. (India) was established in March 1997 as a wholly owned subsidiary of SIRIM Berhad. The company took over the certification, inspection and testing activities that were previously carried out by SIRIM Berhad. As the leading certification, inspection and testing body in Malaysia, SIRIM QAS Sdn. Bhd. has gained wide recognition nationally and internationally. It provides a very comprehensive range of certification, inspection and testing services that conform to national and international standards and guides.

The certification activities of SIRIM QAS include Product Certification, Quality Management Systems Certification, Forest Management Systems Certification, Chain of Custody Certification, Occupational Health and Safety Management Systems Certification, Electromagnetic Compatibility Certification and Certification of Communication Equipment.

Testing is conducted to national and international standards using up-to-date testing facilities operated by highly competent staff. As a company fully owned by the Malaysian government, SIRIM QAS fulfils its role in assisting not only the Malaysian industries in enhancing their quality and competitiveness in the global marketplace but also the regulatory authorities in enforcing regulations relating to public health and safety and the preservation of the environment.

In this respect, the Malaysian regulatory bodies have imposed mandatory certifications and testing for several products like household appliances, motorcyclist helmets, motor vehicle seat belts, fire extinguishers, fire resistant door set and specific communication equipment. Therefore, the Product Certification Marks (MS and S Mark) and Communication Equipment Certification Mark (CM Mark) are used in the mandatory certification to denote that the products meet the requirements of specific standards and certification requirements.

Apart from the mandatory certification mentioned above, the certification, inspection and testing services are generally voluntary in nature. Nevertheless, these activities are widely accepted and recognized by customers not only in Malaysia but overseas as a means of providing third party assurance of quality, reliability and safety and effectively instilling confidence without the need for additional testing and further proof.

Thailand

The Thai Industrial Standards Institute has as its mission the administration of the standardization work of the country through the promotion, supporting and development of domestic products to achieve acceptable quality, so as to increase the competitiveness of the Thai industry in the global market, safeguard the environment,

and protect the consumers ensuring fair treatment, and safety of life and properties, and thereby have the authorities and duties as follows:

- ✓ To recommend policies, guidelines and measures for the promotion and development of the standardization work of the country;
- ✓ To implement the Thai Industrial Standards law and other relevant laws;
- ✓ To cooperate and coordinate with relevant local, foreign and international organizations and agencies on standardization, including entry into relevant technical cooperative agreements;
- ✓ To undertake matters relevant to the certification of standards related systems, and accreditation of the competence of testing and calibration laboratories, and registration of personnel, training courses and training course providers;
- ✓ To undertake matters relevant to standardization data and information of the country;
- ✓ To promote and undertake organization and personnel development in both the public and private sectors through standardization;
- ✓ To operate any other tasks as mandated by law or entrusted by the Ministry or the Cabinet.

Armenia

Overview of certification and conformity assessment system

1. Regulatory Agencies and their functions

According to the law the National Institute of Standards Closed Joint Stock Company (SARM) operating within the Ministry of Trade and Economic Development is primarily responsible for all issues related to standardization and certification. The National Institute of Standards maintains the National Fund of Standards of the Republic of Armenia which contains International (ISO), Interstate (GOST), Regional (EN), Armenian (AST) and other state standards. The company has been accredited for products, services and quality management systems (ISO 9000) certification body, as well a products certification body within the system of the Russian Federation, carries out conformity assessment works in the mentioned fields and testing of large number of items.

The following entities operating with the Ministry of Trade and Economic Development are also involved in standardization and certification process:

- ✓ Metrolog a Closed Joint Stock Company provides control of metering devices, which are subject to inspection and or certification.
- ✓ The Quality Control Inspectorate assesses the compliance of the products with claimed quality standards.
- ✓ Accreditation Agency provides accreditation of certification laboratories and other private and public legal entities involved in the certification process.

- ✓ According to the Government decrees in addition to the Ministry of Trade and Economic Development the following government bodies are engaged in the provision of certificates of conformity:
- ✓ Ministry of Agriculture Armenian Drug and
- ✓ Medical Technology Agency (pharmaceutical products)

2 .Current Legislation

The legislation regulating the certification and conformity assessment system includes the Law on Standardization, the Law on the Conformity Assessment of Products and Services to Normative Requirements, the Law on Unified Metering, and several Government decrees.

3. Mandatory Certification vs. Voluntary Declaration of Conformity

Based on the Law on the Conformity Assessment of Products and Services to Normative Requirements the Government of Armenia established the list of the products and services subject to the compulsory conformity assessment in the Republic of Armenia.

4 .Voluntary assessment

Public and private entities that choose to certify their products and services not included in the above-mentioned list may apply to the National Institute of Standards (SARM) or certification laboratories accredited by SARM. Their products' conformity assessment is carried out in compliance with the applicant's announced normative and technical requirements.

The certificates issued by Rostest (Russian Federation) are also accepted by local certification and customs authorities, but still subject to additional certification albeit in this case the procedure is much shorter. At the same time the Article 4 of the Law on the Conformity Assessment of Products and Services to Normative Requirements says: " should the international treaties of the Republic of Armenia stipulate otherwise rules than the product conformity assessment legislation of the Republic of Armenia, the provisions of international treaties shall prevail".

5. Brief overview of Standardization and Accreditation Systems as relates to Certification and Conformity Assessment processes

Certification and Conformity Assessment processes are described in the Law on the Conformity Assessment of Products and Services to Normative Requirements. Accreditation Agency under the Ministry of Trade and Economic Development and the interagency accreditation board authorized by the Government of Armenia implement accreditation of legal entities as certification bodies or testing laboratories. The board, based on positive outcomes of accreditation officially recognizes the competence of legal entity in certain

sphere, as well as officially recognizes independence of the legal entity on product manufacturer (seller, buyer) or service provider.

Bulgaria

The 1964 Law on Standardization and Metrology, amended in 2002, together with the Regulation for Implementation of the Law, sets forth the legal requirements for product standards and quality control in Bulgaria. Bulgaria has its standardization, conformity assessment, and accreditation and product certification bodies. In certain areas, such as processed foods, beverages and pharmaceutical products, sector-specific standards and certificates are issued by individual ministries or agencies.

Bulgaria is making an effort to harmonize its national standards with international standards. Bulgaria is a participant in the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) and International Technical Union (ITU). Bulgaria is in the process of harmonizing 1,757 of its standards to European standards, in anticipation of joining the European Union. As of September 2000, all domestic standards on safety, on protection of human life and health and on consumer and environmental protection are no longer mandatory.

The major requirements for the safety of products are regulated in ordinances to be issued by the separate ministries and will comply with the respective EU directives. The standards developing, conformity assessment, product certification and accreditation bodies in Bulgaria are:

The **Ministry of Economy** through its department on Euro Integration, is responsible for harmonizing the Bulgarian legislation with the EU legislation including everything related to putting the whole metrology, standardization, certification and testing, verification and accreditation process in compliance with the EU requirements. The web site includes list of all Bulgarian legal documents which have been harmonized with the EU legislation by groups, including: vehicles, food products, chemicals, pharmaceutical products, cosmetic products, legislative metrology and prepackaging, electrical-shock risk and electrical appliances, toys, telecommunication equipment and a group incorporating mechanical appliances, liquid gas appliances, equipment under pressure, construction, leisure sailing vessels, textiles, shoes, crystal glass and lumber.

The **Ministry of Agriculture and Forestry** The Bulgarian Ministry of Agriculture and Forestry is the authority responsible for agriculture and food products' testing & certification, registration of technical documentation (former national standards BDS) for product certification; assessment of conformity and establishing the national policy as to MRA's with international standardization institutions. It is responsible for the in-country and border control health and sanitary policy. The Ministry is performing its functions related to standards, certification, verification and conformity assessment through its National Services, which are listed on its web site the most important one being the State Agency National Veterinary Service through its Directorate State Veterinary Sanitary Control. The Executive Agency Bulgarian

Accreditation Service has accredited a Central Laboratory for Veterinary, Sanitary Expertise and Ecology to perform laboratory testing, inspection, certification, auditing and verification of Phyto and veterinary products.

Conformity assessment body

The State Agency for Metrology and Technical Surveillance (SAMTS) The Agency is performing fundamental metrology, metrological control, monitoring and supervision; conformity assessment; technical inspection of high-risk equipment; market surveillance and quality control of liquid fuels. A list of Bulgarian standards implementing the EU standards supporting Ordinances for the essential requirements on conformity assessment could be found in the official bulletin of SAMTS (accessed through the main menu of SAMTS web site) and the Journal “Standardization, Metrology, Certification”. SAMTS is member of many international metrological organizations such as OIML (International Organization for Legal Metrology), WELMEC (EU organization for cooperation in legal metrology), BIPM (the international Convention on Metre) etc. SAMTS has signed MRA-s with Ukraine, Russia, Kazakhstan, Azerbaidzhan, Armenia, Croatia, Serbia and Montenegro, Macedonia, Moldova and the Czech Republic.

Product certification

The Executive Agency for Certification and Testing (<http://exact.e-gov.bg>) The Agency performs testing and certification of electrical appliances, toys; electrical-magnetic compliance, tobacco & tobacco products; chemicals; cosmetics; foodstuffs; sugar & sugar products; dried fruits & vegetables; meat and processed-meat products through a number of laboratories around Bulgaria. There is a procedure for mutual recognition of international certificates issued by international certification bodies such as TUV, SGS etc.

Canada

In Canada, a single national accreditation body— the Standards Council of Canada (SCC), coordinates conformity assessment activities. Considered one of the most comprehensive and well-coordinated national accreditation infrastructures in the world, the Canadian network of conformity assessment participants are interconnected by the SCC through our National Standards System (NSS). The Canadian public, individuals and organizations who produce, market, import and export products, regulators and other authorities with jurisdiction, conformity assessment performers and their clients, as well as local, provincial/territorial and federal governments—are all implicated in this National System. Having a National System based on a shared set of principles enables the entire country to benefit from the knowledge,

experience and financial resources of the many dedicated stakeholders who voluntarily contribute to it. As a result of our collective efforts, the Canadian Conformity Assessment system is strong. This strength comes from a solid foundation, the underlying international guides, standards and protocols upon which it is built and, the key leadership role that the SCC plays both at home and in the international arena.

The underlying principles of Conformity Assessment (CA) in Canada, are that:

- ✓ Conformity Assessment contributes to safeguarding public health, the environment and
- ✓ Conformity Assessment is based on international standards, agreements and protocols without undue national bias.
- ✓ Conformity Assessment upholds the WTO Agreement on Technical Barriers to Trade (TBT) and, avoids creating unnecessary obstacles to trade.
- ✓ Conformity Assessment operates in an explicit, credible, and transparent manner, and is accessible, equitable and fair treatment of all users.
- ✓ Conformity Assessment services are delivered in a timely and professional manner, in accordance with an accepted code of ethics.
- ✓ Information regarding Conformity Assessment requirements, accreditation procedures and results made publicly available. Activities are conducted with due regard to confidentiality while ensuring full disclosure of CA results to regulatory authorities, as required.
- ✓ Conformity Assessment is inherently voluntary. However, marketplace demands and or government regulation may mandate specific CA requirements.
- ✓ Multi-stakeholder input and involvement is solicited on Conformity Assessment topics as appropriate. These discussions and exchanges are consensus –based, foster a cooperative spirit and are considerate of the unique contributions of affected stakeholders

Public Health and Safety

Beyond the trade sphere, standards and conformity assessment contribute to the basic infrastructure that underpins society. The health and safety of our citizens, environmental protection, sustainability and good regulatory practice, are all supported by Conformity Assessment activities. In Canada, the responsibility to safeguard public health, the environment and public safety is shared by local, provincial and federal jurisdictions. Product/systems/ services requirements are specifically designed to address these responsibilities.

Some product requirements may result in lawful TBTs that take precedence over international trade agreements. The regulation of electrical, fire, building, gas, plumbing and pressure vessel safety, for example, is the responsibility of Canada's provinces. The six model safety codes developed may contain unique Canadian requirements that address Canada's provinces may contain unique Canadian requirements that address special needs of the regulators.

The responsibility for public health, health of animals, food safety and food quality rests with the Canadian federal government. The import and export of agricultural products are subject to many safety-related TBTs invoked by Canada and by Canada's trading partners.

Summary and Conclusions

As stated earlier in this report, there is no single best practice for inspection as well as all conformity assessment activities, but there are many national and regional systems that satisfy the needs of the country, i.e., protect safety, health, the environment and that are trade facilitation friendly.

Egypt became a member of the WTO in June, 1995 and has officially notified the WTO and ISO of their acceptance of the “Code of Good Practice” for the Preparation, Adoption and Application of Standards. Within Egypt there are two National accreditation bodies. Both established in 1996, they are the Egyptian Accreditation Council (EGAC) which is under the Ministry of Trade and Industry and the National Laboratory Accreditation Bureau (NLAB). In principle, NLAB accredits laboratories and EGAC accredits certification bodies. In practice, there is an overlap between the two agencies. NLAB is a full member and signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement, (MRA), while EGAC is an Associate Member and not a signatory to the MRA. This means that accreditations performed by NLAB are recognized in some 49 countries while accreditations performed by EGAC are not. EGAC is also an associate member of the International Accreditation Forum (IAF) although EGAC has not yet met the requirements for full membership in either organization.

It is recommended that in the second phase of this consultancy, attention and consideration to providing assistance to help EGAC achieve full membership to both MRA's. This will facilitate acceptance of accreditation and certification activities performed in Egypt internationally; and accreditation and certifications results performed in other member countries to be officially recognized in Egypt without redundant testing, inspection and certification of imported goods.

Annex 1

THE U.S. CERTIFICATION SYSTEM FROM A GOVERNMENTAL PERSPECTIVE

The following report was written by Dr. Maureen A. Breitenberg of the Office of Standards Services of the US National Institute of Standards and Technology, Gaithersburg, MD

INTRODUCTION

After declaring independence from England and prior to the formation of the United States of America, authority to regulate products and to conduct such product assessments as were deemed necessary rested with the individual states. With the signing of the U.S. Constitution, states gave to the federal government the authority to "regulate Commerce with foreign Nations, and among the several States, and with the Indian However, in the first ten amendments to the Constitution, also known as the "Bill of Rights," the States spelled out that the "...Powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." As a result, authority in the United States to regulate products (and to assess the conformity of products to mandatory requirements) is split between the federal and state governments. Conformity assessment is defined in ISO/IEC(1) Guide 2: 1996 as: "any activity concerned with determining directly or indirectly that relevant requirements are fulfilled." Conformity assessment procedures provide a means of ensuring that the products, services, or systems produced or operated have the required characteristics, and that these characteristics are consistent from product to product, service to service, or system to system. Conformity assessment includes: sampling and testing inspection; certification(2) (of both products and personnel); and quality and environmental system assessment and registration.(3) Conformity assessment also includes accreditation of the competence of those activities by a third party and recognition (usually by a government agency) of an accreditation program's capability. It should be recognized that product certification, the type of conformity assessment discussed in this paper, is only one type of conformity assessment.

At the federal level, one of the first instances of major regulatory involvement in product certification occurred approximately 60 years ago. At that time U.S. drug manufacturers could produce and sell drugs without testing them on either animals or humans and without any kind of governmental approval. Governmental action could be taken only against drugs which were misbranded or adulterated. In 1937, physicians in Tulsa, Oklahoma reported to the American Medical Association (AMA) the deaths of six patients from a liquefied version of the then wonder drug sulfa. This drug ultimately killed 107 people, mostly children, before doctors realized what was happening and the drug was recalled. This tragedy led to the enactment of the 1938 Food, Drug and Cosmetic Act, which requires that drugs be tested and approved by the Food and Drug Administration (FDA) before marketing. From such early beginnings, the federal involvement in certification has grown both in extent and complexity.

The U.S. REGULATORY PHILOSOPHY

It might be useful to know something about the United States' regulatory philosophy to understand when federal or state government agencies are likely to become involved in conformity assessment, especially product certification. The United States' regulatory philosophy relies heavily on a manufacturer's declaration of conformity (or self-certification) wherever possible. Manufacturers' declaration of conformity is one of the oldest and simplest forms of certification. The vast majority of U.S. marketplace transactions involve only the buyer and the seller – without intervention by any third party, whether government or the private sector. There are a number of reasons why this approach is successful in the United States. These include: (1) the sometimes severe penalties imposed by the U.S. legal and judicial system on products proven to be defective or hazardous to the public safety or

environment; (2) the increasing access that the U.S. consumer has to information about poor quality or hazardous and defective products through various news and publications media; (3) the size of the U.S. marketplace and the ability of the U.S. consumer to switch to a competing product if dissatisfied; and (4) U.S. laws and regulations regarding truth in labeling and advertising. The last three serve to increase consumer protection by enabling U.S. consumers to make better informed decisions regarding the products they purchase and to switch to brands if dissatisfied.

FALSE AND MISLEADING ADVERTISING PROHIBITIONS

As noted above, one reason why the U.S. system works is that there are a number of federal and state laws and regulations(4) that prohibit the use of false or misleading labeling or advertising of products or services sold in the United States. In some cases, U.S. laws and regulations not only prohibit false or misleading labeling or advertising, but also mandate that information regarding certain characteristics of a product or service be disclosed to buyers. At the federal level, one of most important laws in this area, which is enforced by the Federal Trade Commission (FTC), is The Fair Packaging and Labeling Act. This Act requires consumer commodities to be accurately labeled regarding the description of the product's identity and net quantity. The Textile, Wool, and Fur Acts, also enforced by the FTC, protect consumers against misleading or false advertising and invoicing of textile, wool, and fur products. On the other hand, the Appliance Labeling Rule, a joint FTC/US Department of Energy (DOE) regulation, is an example of a regulation that requires the disclosure of information to buyers, namely specific information on the energy costs or efficiencies of major home appliances. While the FTC is not authorized to resolve individual consumer complaints (though most states have established offices for this purpose), letters from consumers can trigger investigations of an industry or of a specific company. If, during an investigation, the FTC staff find reason to believe that a company has violated the law, and if the case is not settled by a formal agreement with the company (a consent order), the Commission can decide to sue the company. Depending on circumstances, the case may be tried before an administrative law judge or in federal court. The FTC may seek a cease and desist order, a preliminary or permanent injunction against the sale of the product, consumer redress, or other appropriate relief.

INDUSTRY SELF-POLICING EFFORTS

When a manufacturer's declaration of conformity combined with federal and state prohibitions on the use of false or misleading labeling or advertising, does not afford sufficient marketplace protection, the government will frequently rely on self-policing efforts by the affected industry. A number of private sector industry or trade associations conduct conformity assessment programs, especially product certification programs, to:

- (1) enhance the reputation of their industry;
 - (2) provide manufacturers with some assurance regarding product quality, safety, environmental impact, or compliance with mandatory requirements;
 - (3) level the playing field, that is, establish a minimum level of quality or safety for products produced by their industry and provide consumers with a means to identify products which meet those minimum requirements;
- and
- (4) avoid the need for government regulation.

GOVERNMENT INVOLVEMENT

Although the U.S. Government relies to a large extent on manufacturers' d declarations of conformity to both mandatory and voluntary product requirements, as well as on industry's self- policing efforts, if a product fails to meet mandatory requirements, the federal agency with jurisdiction over that product has the authority to take enforcement action against the

producer, supplier or distributor of the product. Governmental reliance on a manufacturer's or supplier's declaration of conformity does not preclude the federal government from taking whatever action it deems necessary against a manufacturer or supplier if the government determines that a product is not in compliance with regulatory requirements. In addition, when manufacturer's self-declarations or industry self-policing efforts are not effective or adequate, government agencies may become more directly involved in the assessment of compliance with mandatory product requirements. If the problem with a specific product or service is a local one, states and local government agencies are likely to be the responsible authorities. If a serious problem exists, which is national in scope and which cannot be adequately or economically addressed at the state and local levels, then the federal government is likely to get involved.

FEDERAL INVOLVEMENT

Federal government involvement generally occurs when Congress passes a law giving a specific federal agency the statutory authority required to address such a problem at the national level. Federal agencies then develop regulations to implement that law. As required by the Administrative Procedures Act, such regulations go through an extensive public review and comment process before they become final -- a process discussed in more detail later. In addition to regulatory programs, federal agencies also conduct a number of other types of certification programs. In general, federal government certification programs can be classified into several general categories

- Programs to certify products which directly affect the health or safety of the user or the general public.
- Programs to test products to avoid the necessity for retesting at local levels or prior to each procurement.
- Programs to provide a uniform basis for trade by assessing the quality and condition of products offered for sale.

Examples of the first type of certification program include the evaluation and approval by the Food and Drug Administration (FDA), U.S. Department of Health and Human Services, of new animal and human drugs, medical devices, biological, and other products; the certification by the Federal Aviation Administration (FAA), U.S. Department of Transportation, of airplanes and major airplane components; respirators and other breathing apparatus by the National Institute for Occupational Safety and Health; and the certification by the Mine Safety and Health Administration (MSHA), Department of Labor, of electrical and other potentially hazardous equipment used in mines. An example of the second type of program is the Department of Defense's (DOD) Qualified Products Listing (QPL) Program for parts, materials and components used in military systems. This program reduces retesting prior to each government purchase by testing products and placing those approved on appropriate QPL's. An extension of this concept also underlies the DOD Qualified Manufacturing Lists (QML's) Program, in which a manufacturer's process controls and manufacturing capabilities are evaluated and approved for an entire range of products.

An example of the third type of program is the U.S. Department of Agriculture's (USDA) program to grade and certify meat and meat products (on a voluntary basis) using uniform grading standards for the buying and selling of such products. The USDA also certifies dairy products, fresh and processed fruits, vegetables, nuts and related products. The National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce, likewise inspects and grades processed fish and shellfish at a seafood processor's request. The complexity of such programs and the procedures used by each can vary extensively depending on purpose, the nature of the product or service, as well as the extent to which private sector programs are available and effective and can be used to supplement federal efforts. More complex and comprehensive programs tend to be more effective, but they also tend to be more costly. The federal government is obligated (by law in the regulatory area) to consider both effectiveness and cost and to weigh the two when establishing a new program.

FEDERAL GOVERNMENT INVOLVEMENT IN CERTIFICATION PROGRAM ACCREDITATION

The U.S. accreditation system for certification programs is less complex than other U.S. conformity assessment areas, primarily because the United States only has a few major programs. The most prominent government program of this type is operated by Occupational Safety and Health Administration (OSHA) within the U.S. Department of Labor (DOL). OSHA's program covers electrical equipment/materials used in the work place. By law, all electrical products used in the work place must be tested and listed or labeled by a certifier (known as a Nationally Recognized Testing Laboratory, or NRTL) which is recognized/approved by OSHA. NRTLs are private sector certifiers, and participation in the OSHA program is voluntary. However, if certifiers wish to test such products, they must be recognized/approved by OSHA. (5) NRTLs are subject to review at least once every 5 years. Applicants for OSHA recognition as an NRTL must have adequate administrative and technical capability to be able to certify products in the areas for which they seek approval/recognition. They must also be able to inspect factory production runs as part of a product's evaluation and to conduct field inspections to ensure proper use of the certifier's identifying mark or label on the product. The program is open to all U.S. certifiers and to foreign certifiers if the countries of those foreign certifiers are open to U.S. certifiers. The National Institute of Standards and Technology can also accredit certifiers under its National Voluntary Conformity Assessment Evaluation (NVCASE) Program. The program is intended to enable the Department of Commerce, acting through NIST, to evaluate and recognize competently conducted U.S. conformity assessment activities, including certification, which are capable of meeting regulatory requirements of another country with which the United States has an applicable mutual recognition agreement. The program supplements the programs of other federal agencies and is generally initiated upon NIST's receipt of a request for assistance from the appropriate U.S. regulatory agency. The results of NIST evaluations provide a basis for the U.S. Government to assure foreign governments that qualified U.S. conformity assessment bodies are competent and can satisfy foreign regulatory requirements. NIST will conduct evaluations using publicly developed requirements based to the maximum extent possible on international guides and standards for the acceptance of conformity assessment activities. The program operates on a fee-for-service basis. NIST provides a certificate of recognition to a body meeting the requirements and maintain lists of all qualified conformity assessment bodies.

CERTIFICATION MARKS

The federal government is also concerned with the registration of marks used in certification programs due to the increasing international use and importance of these marks in the marketplace. One of the most interesting things NIST learned during the latest revision

of NIST SP 774, the Directory of Private Sector Product Certification Programs, was that while many, but not all, of the marks used in certification programs are registered with the U.S. Patent and Trademark Office (PTO), many of these registered marks are not "certification marks" as defined by U.S. law. To explain this situation, it may be helpful to quote selectively from the definitions for the various types of registered marks and related definitions contained in Section 1127, "Construction and Definitions," of the Trademark Act of 1946 ("Lanham Act") as amended. "The term 'person' and any other word used to designate the applicant or other entitled to a benefit or privilege or rendered liable under the provisions of this Act ... includes a juristic person as well as a natural person. The term 'juristic person' includes a firm, corporation, union, association, or other organization capable of suing and being sued in a court of law." "The term 'person' ... includes any State, instrumentality of a State and any officer or employee of a State or instrumentality of a State acting in his or her official capacity. Any State, and any such instrumentality, officer or employee, shall be subject to the provisions of this Act in the same manner and to the same extent as any nongovernmental entity." "The terms 'applicant' and 'registrant' embrace the

legal representatives, predecessors, successors and assigns of such applicant or registrant." "The term 'related company' means any person whose use of a mark is controlled by the owner of the mark with respect to the nature and quality of the goods and services on or in connection with which the mark is used." "The terms 'trade name' and 'commercial name' mean any name used by a person to identify his or her business or vocation." "The term 'trademark' includes any word, name, symbol, or device or any combination thereof --

(1) used by a person; or

(2) which a person has a bona fide intention to use in commerce and applies to register on the principal register established by this Act, to identify and distinguish his or her goods, including a unique product, from those manufactured or sold by others and to indicate the source of goods, even if that source is unknown." "The term 'service mark' means any word, name, symbol, or device or any combination thereof --

(1) used by a person, or

(2) which a person has a bona fide intention to use in commerce and applies to register on the principal register established by this Act, to identify and distinguish the services of one person, including a unique service, from the services of others and to indicate the source of the services, even if that source is unknown. Titles, character names, and other distinctive features of radio or television programs may be registered as service marks notwithstanding that they, or the programs, may advertise the goods of the sponsor." "The term 'certification mark' means any word, name, symbol, or device or any combination thereof --

(1) used by a person other than its owner, or

(2) which its owner has a bona fide intention to permit a person other than the owner to use in commerce and files an application to register on the principal register established by this Act, to certify regional or other origin, material, mode of manufacture, quality, accuracy, or other characteristics of such person's goods or services or that the work or labor on the goods or services was performed by members of a union or other organization." "The term 'collective mark' means a trademark or service mark --

(1) used by members of a cooperative, an association or other collective group or organization, or

(2) which such cooperative, association, or other collective group or organization has a bona fide intention to use in commerce and applies to register on the principal register established by this Act, and includes marks indicating membership in a union, an association or other organization." "The term 'used in commerce' means the bona fide use of a mark in the ordinary course of trade, and not made merely to reserve a right in a mark." "The term 'mark' includes any trademark, service mark, collective mark, or certification mark." U.S. certification programs use ALL of these types of registration marks defined in the Trademark Act. In fact, only a few programs use federally-registered certification marks as defined by the Trademark Act. In addition, unregistered marks (often initializations/acronyms and/or symbols/logos used on letterheads and reports to identify the organizations that provide product certification) are also used in U.S. certification programs. The type of mark used by a particular program is based on the type of organization which runs the program (e.g., an independent laboratory or a trade association); existing ownership of a well recognized trademark, service mark, or collective mark; familiarity on the part of the certifier with the different categories of marks; and the cost and perceived need for a registered mark. In drafting certification-related regulations, several government agencies have already learned that the terminology used in connection with marking requirements can have a major impact on the number and types of organizations eligible to participate in the conformity assessment program. For example, requiring certification programs to have a certification mark (as distinct from some other type of mark) can eliminate many U.S. certification programs from participation. Some agencies also own certification marks which are registered with the U.S. Patent and Trademark Office and which are used in their product approval/certification programs. Examples include the Department of Transportation mark in its program for tanks used in the transport of

hazardous materials. The U.S. Department of Agriculture owns and uses several marks in connection with its poultry and meat grading programs, and the Environmental Protection Agency uses its Energy Star mark in programs designed to promote the manufacture and use of more energy efficient products.

STATE/LOCAL GOVERNMENT INVOLVEMENT

As noted above, federal agencies are not the only U.S. governmental agencies with authority regarding certification. States administer many different types of certification programs covering a diversity of products. In some cases, states inspect or test products under authority delegated by the federal government. For example, many states inspect meat and meat products, certifying those that meet standards established by the USDA. These states then authorize the use of the appropriate USDA marks. Many states also inspect and issue certificates of conformity for manufactured homes under authority delegated by the U.S. Department of Housing and Urban Development (HUD). Most state and local jurisdictions also have responsibility for water quality testing under authority delegated to them by the U.S. Environmental Protection Agency (EPA). States may also impose additional state requirements and simultaneously check for conformity to both state and federal requirements. States regulate products under their own authority for health and safety reasons, including amusement rides and thermal insulation, depending on each state's perception of the health and safety impact of such products on its population. Products may be inspected and/or tested directly by the states themselves, or indirectly through a requirement that such products be inspected and/or tested and certified by an approved body, such as a nationally recognized laboratory. An example of the latter is the regulation of electrical building products by imposing a state requirement that they be tested/inspected and bear the mark of a "nationally recognized testing laboratory." The term "nationally recognized laboratory" is currently defined by each state and/or municipality. States regulate products of direct or indirect economic importance. Florida and California, for example, inspect products important to their citrus fruit industry. Nebraska, with a considerable agricultural industry, regulates tractors through a testing program at the University of Nebraska and issues certificates of conformity for approved models. California, with its air pollution problem, stringently regulates auto emissions equipment. States inspect, test, and/or certify materials, products, systems and services they procure, such as materials for the construction of state roads and bridges. In yet other cases, the states establish standards, but leave enforcement (testing, inspection, etc.) to local authorities. This is sometimes true for building and construction materials. Again, the complexity of such state and local programs and the procedures used can differ greatly just as they can at the federal level, depending on the purpose of the program, the nature of the product or service, and the extent to which private sector programs are available and effective.

TRANSPARENCY IN THE DEVELOPMENT OF U.S. REGULATIONS

As mentioned earlier in this paper, the federal government develops regulations, including those with conformity assessment requirements, only after an extensive public review and comment process. The Administrative Procedures Act (APA) establishes general procedures for rulemaking which must be followed by U.S. federal government agencies (5U.S.C. section 551 et seq.). At a minimum, the APA requires that for the issuance of a substantive rule (as distinguished from a procedural rule or statement of policy), an agency must:

(1) Publish a notice of proposed rulemaking in the Federal Register. This notice must set forth the text or the substance of the proposed rule, the legal authority for the rulemaking proceeding, and applicable times and places for public participation.

(2) Provide all interested parties -- national and non-national alike -- an adequate opportunity for submission of written comments on the proposed rule. This public comment process serves a number of purposes; including giving interested persons the opportunity to provide the agency with information that will enhance the agency's knowledge of the subject matter of the rulemaking. The public comment process also provides interested persons with

the opportunity to challenge the factual assumptions on which the agency is proceeding, and to show in what respect such assumptions are in error.

(3) Publish a notice of final rulemaking at least thirty days before the effective date of the rule, which includes a statement of the basis and purpose of the rule and which responds to all substantive comments received. The APA makes an exception from the requirement for publication of the final rule thirty days before its effective date if the rule makes an exemption or relieves a restriction, or if the agency makes and publishes a finding that an earlier effective date is required "for good cause." Rulemaking proceedings are usually started by an agency at its own initiative. However, the APA provides that each agency of the U.S. Government shall afford interested persons the right to petition for the issuance, amendment, or repeal of a rule. According to law, agencies must respond to the request. If the request has merit, work will commence on developing a proposed rule. In some cases, Congress (by statute) directs an agency to begin a rulemaking proceeding. The APA also contains provisions for advance notice of proposed rulemaking. This allows agencies to seek general comments on issues prior to developing the specific regulatory proposal.

OTHER U.S. STATUTORY AND LEGAL OBLIGATIONS IN THE CERTIFICATION AREA

In addition to its openness and transparency obligations under the APA Act, the U.S. Government has other domestic and international obligations which affect the conformity assessment area. The U.S. Government is a signatory to a number of international trade agreements which affect conformity assessment, including certification. For example, the U.S. Government was a signatory to the Agreement on Technical Barriers to Trade (also known as the "Standards Code") under the General Agreement on Tariffs and Trade (GATT), one of the first international agreements related to trade that recognized the importance of standards and certification systems for "improving efficiency of production and facilitating the conduct of international trade." The U.S. Trade Agreements Act of 1979 implemented the Standards Code in the United States. Title IV of the Act specifies obligations for the federal government, including responsibilities bearing on certification. Each federal agency must ensure that foreign products are treated in the same manner as domestic goods. Moreover, the federal government is to take reasonable measures to promote similar practices by state governments and the private sector. December 15, 1993 saw a successful conclusion of the Uruguay Round of trade negotiations. In April 1994, the United States signed the Uruguay Round Agreements. These Agreements included a revision of the Agreement on Technical Barriers to Trade (the TBT Agreement). The Uruguay Round also created a new institution as a successor to the General Agreement on Tariffs and Trade (GATT), the World Trade Organization (WTO). The new TBT Agreement sought to ensure that technical regulations and standards, as well as testing and certification procedures, do not create unnecessary obstacles to trade. However, it recognized that countries have the right to establish protection at levels they consider appropriate (for example for human, animal or plant life or health or the environment), and should not be prevented from taking measures necessary to ensure that those levels of protection are met. The new agreement encourages countries to use international standards whenever appropriate, but does not require them to change their prescribed levels of protection as a result of standardization. The revised agreement also covers processing and production methods related to the characteristics of the product itself. The coverage of conformity assessment procedures was enlarged and the disciplines made more precise. Provisions applying to sub-national government and non-government bodies were elaborated in more detail than in the prior TBT agreement. In addition to its obligations under the new TBT Agreement, the U.S. Government has related conformity assessment obligations under the North American Free Trade Agreement (NAFTA). The U.S. Government actively participates in a number of regional efforts, designed to harmonize conformity assessment procedures and requirements and to promote the mutual recognition and acceptance of conformity assessment results. The U.S. Government also has domestic requirements placed on it with respect to the conduct of conformity assessment activities. Recently, Section 12, "Standards Conformity," of the National Technology Transfer and Advancement

Act of 1995 was passed with "the goal of eliminating unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures." NIST was given responsibility for coordinating "Federal, State, and local technical standards activities and conformity assessment activities, with private sector technical standards activities and conformity assessment activities." The objective of Section 12 is to encourage federal agencies to make greater use of and place increased reliance on private sector standards and conformity assessment activities and programs.

CONCLUSION

The United States has an extensive and sometimes complex system for ensuring the conformity of products sold in the U.S. marketplace to both mandatory and voluntary standards and requirements. Like the U.S. standards system, the U.S. certification system has evolved in a decentralized manner. It is based largely on declarations of conformity by manufacturers and suppliers of products sold in the U.S. marketplace, as well as on industry self-regulation. Many U.S. private sector organizations, as well as federal, state and local government agencies are involved in certification for a variety of reasons. The assurance of product conformity can involve one or more levels of government and increasingly involves reliance on private sector programs and activities. As both federal and state budgets shrink, greater emphasis is likely to be placed by government agencies at all levels on the use of and cooperation with certification programs available within the private sector. Despite its complexity, however, the U.S. certification system remains one of the most effective, open, and transparent systems in the world

(1) ISO is the acronym for the International Organization for Standardization, while IEC stands for the International Electrotechnical Commission. The International Organization for Standardization (ISO) is a worldwide federation of over 90 national standards bodies. ISO covers standardization in all fields, except the electrical and electronics fields which are covered by the International Electrotechnical Commission (IEC). IEC has members from over 40 countries which represent some 80% of the world's population. Together ISO and IEC form the world's largest nongovernmental system for voluntary industrial and technical collaboration in the field of standardization

(2) Some organizations use other terms to refer to the process, such as product listing, product evaluation, product regulation, product approval, or the publication of research reports, but in this discussion, we will use the term "certification." The reader should be aware of the existence and use of other terms, however, to describe this activity.

(3) In Europe, quality and environmental system registration is often referred to as certification.

(4) These laws are enforced by the U.S. Federal Trade Commission (FTC) at the national level and by most states through the Offices of the State's Attorney General.

(5) OSHA is responsible for the regulation of all electrical products used in the work place. For a list of the products under OSHA's jurisdiction which require certification by a Nationally Recognized Testing Laboratory (NRTL)

END of the US Government Prospective Report

PRINCIPLES FOR FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION

CAC/GL 20-1995

SECTION I - INTRODUCTION

1. Official and officially recognized inspection and certification systems are fundamentally important and very widely used means of food control; the following principles apply to such systems. The confidence of consumers in the quality (including safety) of their food supply depends in part on their perception as to the effectiveness of food control measures. A substantial part of the worldwide trade in food, for example in meat and meat products, depends upon the use of inspection and certification systems. However, inspection and certification requirements may significantly impede international trade in foodstuffs. Consequently it is desirable that the design and application of these systems should reflect appropriate principles.

2. Inspection of food may occur at any stage in the production and distribution process. For some foods, inspection oversight of harvesting, processing, storage, transport, and other handling of product may be the most appropriate means of ensuring food safety. According to the methods of preservation used, it may be necessary to maintain inspection oversight on a continuous basis up to the time of retail sale. Inspection systems may be focused on the foodstuffs themselves, on the procedures and facilities employed in the production and distribution chain, on the substance and materials which can be incorporated into or contaminate foodstuffs.

3. Inspection should be carried out at the most appropriate stages (e.g. control of refrigeration at every stage of the cold chain). For some requirements, e.g. those pertaining to product description, it may be possible to limit inspection to the distribution process and prior to final sale.

4. In both design and use, food inspection and certification systems should be governed by a number of principles which will ensure an optimal outcome consistent with consumer protection and facilitation of trade.

SECTION 2 - DEFINITIONS

5. **Audit** is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.

Certification is the procedure by which official certification bodies or officially recognized certification bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.

Inspection is the examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform to requirements.

Official inspection systems and official certification systems are systems administered by a government agency having jurisdiction empowered to perform a regulatory or enforcement function or both.

Officially recognized inspection systems and officially recognized certification systems are systems which have been formally approved or recognized by a government agency having jurisdiction.

Requirements are the criteria set down by the competent authorities relating to trade in foodstuffs covering the protection of public health, the protection of consumers and conditions of fair trading.

Risk assessment is the evaluation of the likelihood and severity of adverse effects on public health arising, for example, from the presence in foodstuffs of additives, contaminants, residues, toxins or disease-causing organisms.

SECTION 3 - PRINCIPLES

6. Food inspection and certification systems should be used wherever appropriate to ensure that foods, and their production systems, meet requirements in order to protect consumers against food-borne hazards and deceptive marketing practices and to facilitate trade on the basis of accurate product description.

FITNESS FOR PURPOSE

7. Inspection and certification systems should be fully effective in achieving their designated objectives having regard to the determination of the acceptable level of protection which is required.

RISK ASSESSMENT

8. Inspection systems to ensure food safety should be designed and operated on the basis of objective risk assessment appropriate to the circumstances. Preferably the risk assessment methodology employed should be consistent with internationally accepted approaches. Risk assessment should be based on current available scientific evidence.

9. Inspection systems should be applied to particular commodities and processing methods in proportion to the assessed risks. In undertaking a risk assessment or in applying the principles of equivalence, importing countries should give due consideration to statements by exporting countries on a national or area basis of freedom from food-related disease.

NON-DISCRIMINATION

10. Countries should ensure that they avoid arbitrary or unjustifiable distinctions in the level of risk deemed to be appropriate in different circumstances so as to avoid discrimination or a disguised restriction on trade.

EFFICIENCY

11. Inspection and certification systems should have adequate means to perform their task. In the choice of inspection and certification systems, there should be regard to costs to consumers and to the costs in money and time to the affected food industry and government

consulting with interested bodies as appropriate. Such systems should be no more restrictive of trade than is necessary in order to achieve the required level of protection.

HARMONIZATION

12. Member countries should use Codex standards, recommendations and guidelines (or those of other international organizations whose membership is open to all countries) whenever appropriate as elements of their inspection and certification systems. Countries should participate actively in the work of the Codex Alimentarius Commission and other relevant international bodies to promote and facilitate the development, adoption and review of Codex norms.

EQUIVALENCE

13. Countries should recognize that different inspection/certification systems may be capable of meeting the same objective, and are therefore equivalent. The obligation to demonstrate equivalence rests with the exporting country.

TRANSPARENCY

14. While respecting legitimate concerns to preserve confidentiality, the principles and operations of food inspection and certification systems should be open to scrutiny by consumers and their representative organizations, and other interested parties.

15. Importing countries should provide information on existing requirements and proposed changes to requirements should be published and, except in the case of serious and immediate danger, an adequate time period permitted for comment. The views of exporting countries, and particularly those received from developing countries, should be taken into account in taking a final decision. A reasonable period should be allowed before a new requirement takes effect in order to permit exporting countries, and in particular developing countries, to make necessary changes to methods of production and control measures.

16. Importing countries should make available to the exporting countries, upon request, timely advice as to the basis of the decision they have taken regarding the compliance of foods with their relevant requirements.

17. Upon request by the competent authorities of the importing countries, the exporting countries should provide access to view and assess the actual working of their relevant inspection and certification systems.

SPECIAL AND DIFFERENTIAL TREATMENT

18. In the design and application of food inspection and certification systems, importing countries should take into account of the capabilities of developing countries to provide the necessary safeguards.

CONTROL AND INSPECTION PROCEDURES

19. Importing countries should complete without undue delay any procedures necessary to assess compliance with requirements. Information requirements and any fees imposed by importing countries should be limited to what is reasonable and necessary.

CERTIFICATION VALIDITY

20. Countries that certify exports of food and those importing countries which rely on export certificates should take measures to assure the validity of certification. Validation measures by exporting countries may include achieving confidence that official or officially recognized inspections systems have verified that the product or process referred to in the certificate conforms with requirements. Measures by importing countries may include point of entry inspection systems, audit of exporting inspection systems, and ensuring that certificates themselves are authentic and accurate.