ACP-EU TBT Programme

The Main Sanitary and Phytosanitary (SPS) and related Technical Barriers to Trade (TBT) and conformity assessment issues that should be addressed as part of the Economic Partnership Agreement

Johannesburg, South Africa
23 and 24 January 2017

Overview of the WTO agreement on Sanitary and Phytosanitary Measures and core principles and objectives of the WTO SPS and TBT Agreements

The WTO Agreement on Application SPS Measures

- The SPS Agreement is a legal trade instrument that is based on balancing the economic benefits of trade against a scientifically based motion of public welfare.
- It outlines WTO rules, and sets constraints, on Member States' policies related to animal and plant health issues as well as food safety issues **(**microbial contaminants, additives, pesticide and veterinary drug residues, inspections and labelling).
- The reason for a separate SPS Agreement was the desire for deeper integration of agriculture with general international trade and a decision to closely regulate the use of quantifiable non-trade constraints.
- The main concerns of trading countries relate to the potential for trade in certain products to result in the unintentional import animal and plant pests and diseases as well as the spread of human food – borne diseases
- The protection of fish and wild fauna, forests and wild flora are included, but protection of the environment and animal welfare is not yet an issue. These are treated under the Bio-security approach of the Food and Agriculture Organization (FAO).

The Nature of the WTO SPS Agreement

SPS measures are defined as any measures applied:

- To protect human or animal life from risks arising from additives, contaminants, toxins or disease causing organisms in their food;
- To protect human life from plant or animal carried diseases;
- To protect animal or plant life from pests, diseases or disease causing organisms;
- To prevent or limit other damage to a country from entry, establishment or spread of pests and diseases.
- These include SPS measures taken to protect the health of fish and wild fauna, as well as of forests and wild flora

SPS measures are intended to **address market access failures.** Their net effect on welfare is positive when they are applied as intended.

Core principles of the SPS Agreement

The WTO SPS Agreement aims to facilitate trade. Member countries agree to develop and apply their SPS requirements for imports in such a way as to minimize negative impacts related to international trade.

The principles used to achieve this include:

- **Risk assessment** – *measures must be based on a scientific assessment of risk conducted in accordance with internationally accepted techniques*;
- **Equivalence** – *the importing country must accept different measures for a given product if they achieve the same level of protection as its own sanitary measures for the same product (Article 4);*
- **Adaptation** - *to regional conditions and changes in disease status (Article 6); and*
- **Transparency** – *mandatory notification to WTO of change(s) in sanitary requirements (Article 7).*

Objectives of the WTO TBT Agreement

- Ensure that national technical regulations, standards and conformity assessment procedures do not constitute unnecessary barriers to international trade.
- Achieve a balance between allowing WTO Members to take regulatory measures to protect legitimate interests and ensuring that national technical regulations, standards and CA procedures do not become unnecessary obstacles to international trade.
- Harmonization is central to the TBT Agreement and is articulated in particular in two requirements:
  - WTO members should use international standards, guides and recommendations, or relevant parts of them, as a basis for their national technical regulations and conformity assessment procedures.
  - WTO members should play a full part in the preparation of international standards, guides and recommendations by participating in international standardizing bodies.

SPS Management Capacity

It is now widely recognized that SPS management capacity, what is also commonly referred to as food safety and agricultural health capacity, is of vital importance to agricultural and food exports from developing countries.

Whereas much of the focus of SPS controls at the national level is on domestic security issues, including protection of consumers against food-borne hazards and the agricultural sector against animal and plant pests and diseases, such capacity is also necessary in order to comply with SPS requirements in export markets, particularly in industrialized countries.

Importing countries frequently require guarantees that exports are derived from areas that are free from certain pests or diseases, that minimum standards of hygiene have been applied in the manufacture of a food product, or that products are free of contaminants such as pesticides residues and dioxins.

The exporting country must have the capacity both in the public and private sectors to comply with these requirements and to undertake the necessary conformity checks in order to ensure that compliance has been achieved.

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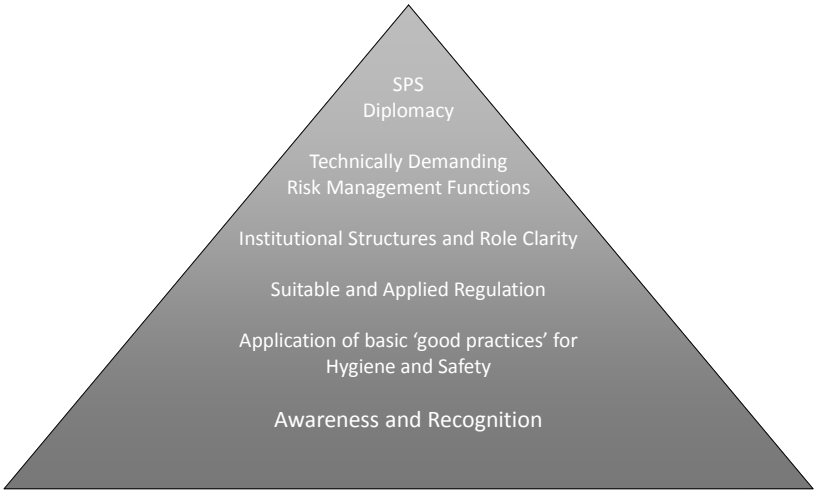
Hierarchy of trade-related SPS management functions



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SPS Management Functions

Basic national SPS management functions are:
- Apply GAP, GMP, HACCP, and QM at farm and enterprise levels
- Develop appropriate legislation and standards;
- Register/control agro-chemicals;
- Conduct basic research, diagnosis, and analysis;
- Accredit laboratories/other third party entities for official duties;
- Develop/apply quarantine procedures, including for emergency situations;
- Carry out epidemiological surveillance and information management
- Inspect/license food establishments
- Develop/maintain pest free areas
- Test products for residues, contaminants and microbiological content
- Verify/certify biological materials (seeds)
- Verify/certify imported/exported products related to established risks
- Establish/maintain identity of products (for example traceability)
- Report possible hazards to treaty/trading partners
- Notify WTO/trading partners on new SPS measures
- Participate in international standard-setting processes

(World Bank 2005)

SPS measures and trade

It is widely acknowledged that SPS standards can act to impede trade in agricultural and food products. The trade impacts of SPS measures can be conveniently grouped into three categories:
- Those which prohibit trade by imposing an import ban or by prohibitively increasing production and marketing costs.
- Those which divert trade from one trading partner to another by laying down regulations that discriminate across potential supplies.
- Those which are trade reducing measures that increase costs or raise barriers for all potential suppliers.

SPS measures and trade

In certain cases higher food safety standards are applied to imports than domestic supplies, for example where higher risks are associated with supplies from other countries.

However, even where food safety standards are neutral, they can impede trade in agricultural and food products. This potential to distort trade flows relates to two separate (although inter-related) elements of the standardisation process:

• ***Technical standards***, whereby qualitatively or quantitatively distinct technical standards are laid down for a particular product in different countries.

• ***Conformity assessment procedures***, whereby separate and/or distinct procedures are required to demonstrate compliance with product standards in different countries.

SPS measures and trade

In assessing the impact of technical standards and conformity assessment procedures on trade, the key issue is whether such measures are discriminatory.

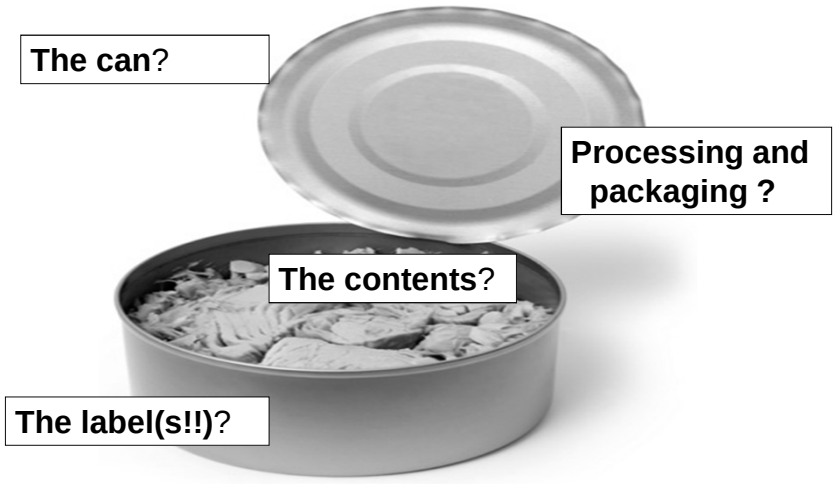
The scope for standards, which are applied in an equivalent manner on domestic suppliers and importers, to be discriminatory occurs when there are differences in technical standards and/or conformity assessment procedures between markets.

National technical requirements generally reflect the institutional structures within that country. Domestic suppliers will be more accustomed to operating within these structures, indeed they will have themselves developed in response to them. Overseas suppliers, however, may have to learn and become accustomed to very different procedures to those in their own country.

Costs of compliance with SPS standards in export markets will reflect the degree to which standards differ from those that prevail in the supplier's domestic market. Further, they will depend on the degree to which standards in different export markets differ (see study by Henson et. al.)

A practical example – A can of fish

A can of fish



A can of fish

The can
- Materials used
- Coating inside the can
- Size
- Shape

The label(s!!)
- Ingredients
- Marks
- Size/Weight
- Barcode

Other issues

Did the vessel and factory comply with relevant SPS health and safety standards ?

How did the factory make sure that it was not contaminated (HACCP)?

How was it packaged in the factory?

Did it have appropriate management system(s) in place?

Wider issues ?
- Quality
- Origin
- Traceability
- Legality of the catch ?

The contents
- What fish is it?
- What else? (Oil, salt, water?)
- Weight (Gross / net ?)

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Overview of the National Quality Infrastructure, Technical Regulations and Standards in support of the objectives of the SPS and TBT Agreements

National Quality Infrastructure

Although the National Quality Infrastructure can (and does) vary from one EU – SADC EPA member country to another, the following elements have been found to be the key components for it to be accepted internationally:

- **Capability** to develop, adapt or adopt appropriate legislation, regulations and standards;
- **Access** to physical, chemical and biological standards of **measurement;**
- Provision of a **legal metrology system**;
- **Availability** of appropriate **inspection, testing and calibration services** to support the needs of local commerce and industry;
- **Availability** of **third party conformity assessment services** (such as product certification) to meet the requirements of regulators and others (e.g. exporters and / or importers);
- A mechanism to ensure all conformity assessment **service providers are competent**.

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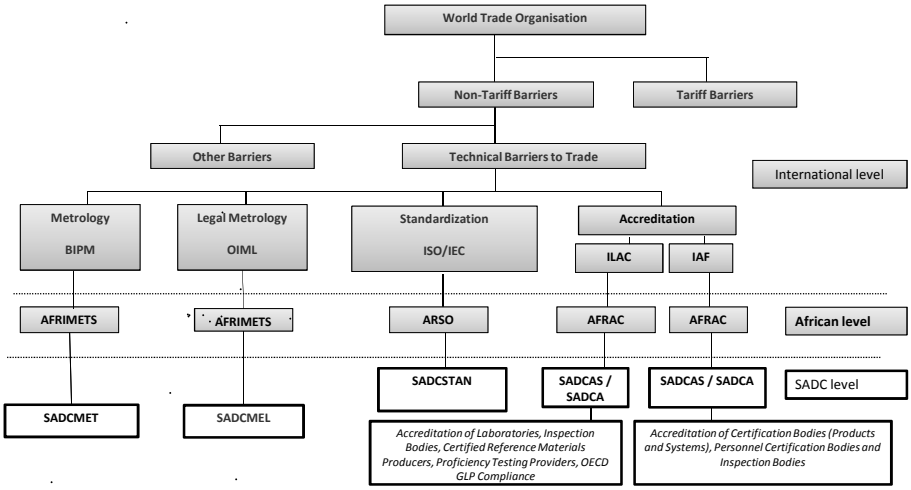
Technical infrastructure in trade policy



Technical Regulations

Almost every economy has technical regulations specific to the country (EU has a “common approach”). They often include compliance with an international or national standard but can also contain additional requirements.

A technical regulation may only require compliance to some parts of an international standard such as those related to **health** and **safety**.

It is critical for international trade that conformity assessment results are accepted by regulators from one country to another. This is made possible by conformity assessment bodies (CABs) operating under international standards.

Additional confidence can be achieved if the CABs are independently assessed for competence through being accredited.e national regulator.

Regulations and Standards

Regulations	Standards
Regulatory development process.	Standards development process.
Governments are responsible to lead in the development of regulations.	Standards development organizations (SDOs) facilitate development of standards in response to requests.
Governments consult interested parties, not necessarily seeking consensus. May reference standards or require use of accredited conformity assessment bodies .	SDOs seek consensus on content of standards.
Assurance of Compliance.	Assessment of Conformity.
Governments enforce regulations and remain accountable for enforcement when others do so on their behalf.	Certification and Inspection bodies and laboratories (conformity assessment bodies) assess conformity.

Administration of WTO SPS measures

WTO SPS measures are administered under three (3) main International Standard Setting bodies:

1. The World Organization for Animal Health (commonly used acronym OIE) is based in Paris, France, and mandated in terms of the Application of the WTO SPS Agreement to set trade standards in animals, They also collaborate with the Codex Alimentarius Commission on standards for fresh meat, particularly veterinary drug residues in meat and meat borne zoonosis;
2. The International Plant Protection Convention (IPPC), an organization hosted by the FAO at its Rome headquarters – Italy, and is responsible for international standards in trade that affects plant health;
3. The Codex Alimentarius Commission, hosted by FAO and jointly run by FAO and the World Health Organization (WHO), is mandated by the WTO to set standards for foods and food safety

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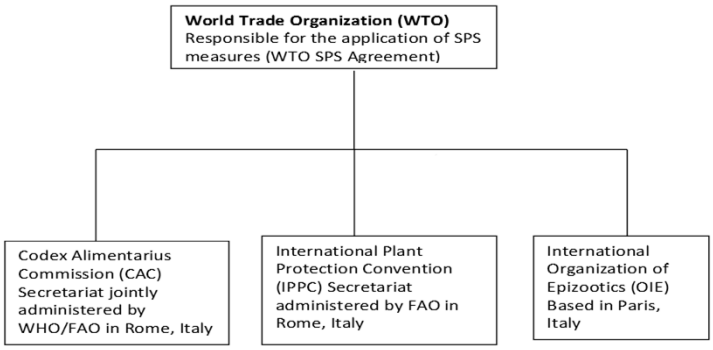
Administration of WTO SPS measures

The following figure shows the relationship between the WTO SPS Agreement and the sub-division of responsibilities between the WTO, WHO, IPPC and the OIE.



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Classification of SPS Standards

Import Bans		Technical Specifications			Information Requirements	
Total Ban	Partial Ban	Process Standards	Product Standards	Technical Standards	Labelling Requirements	Controls on Voluntary Claims

Source: Roberts (1997; 1998)

Associated with SPS standards, whatever their form, are conformity assessment procedures by which suppliers demonstrate that they are in compliance with regulatory requirements.

These might include product testing, certification, information disclosure etc.

In certain cases these procedures are themselves prescribed by governments.

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Role of Conformity Assessment in the implementation of the SPS and TBT Agreements

Role of conformity assessment

Major benefits of appropriate standardization are:

- Improved economic efficiency
- Provision of access to world markets
- Improved competitiveness

This cannot be achieved without the ability to make reliable measurements (metrology) and to demonstrate that items conform to requirements that are specified in technical regulations and standards

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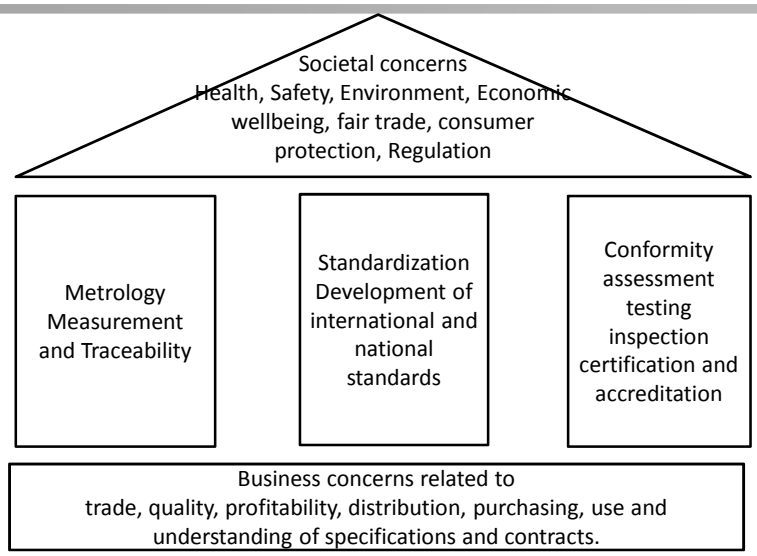
Conformity Assessment in the National Quality / technical Infrastructure



Conformity assessment demystified

Conformity assessment simply means to **check** if a product, service, material, process, system or personnel **demonstrably meets** the requirements contained in standards, regulations or other specifications.

European Union (EU) approach

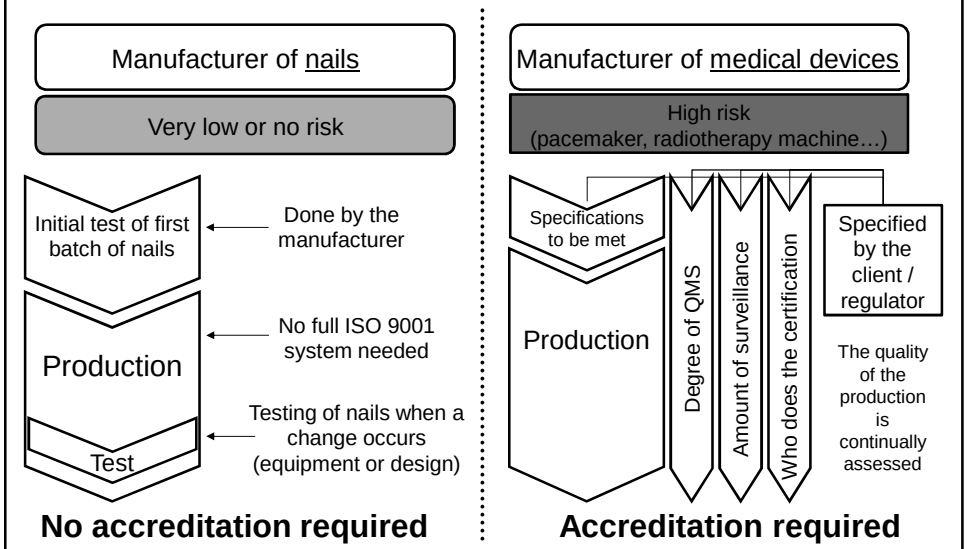
European legislation is designed to remove technical barriers to trade and to facilitate trade within and with Europe.

It specifies a series of conformity assessment modules to be used by legislators when drafting legislation to align the laws of the various member bodies relating to safety.

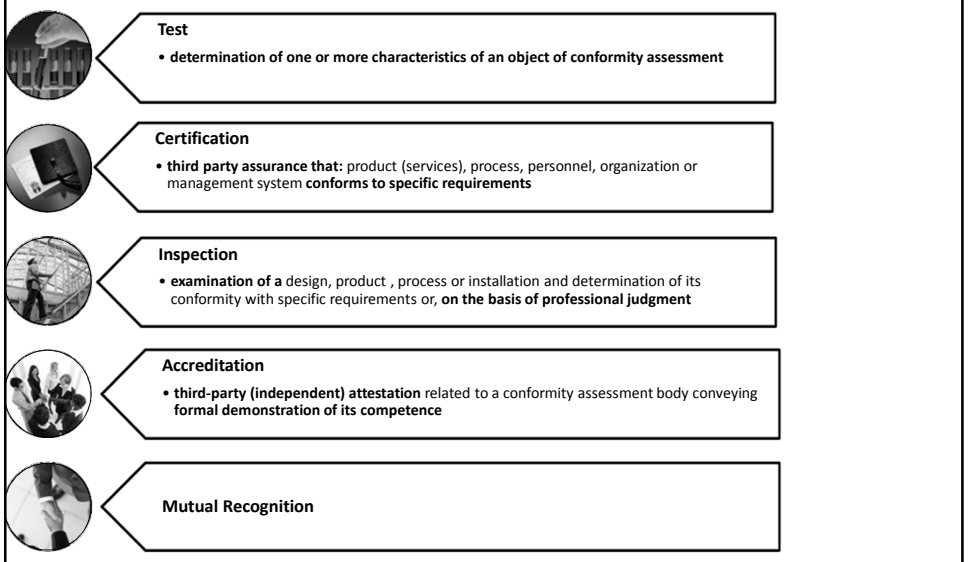
Legislation is in the form of an EU Directive and the appropriate CA modules are chosen according to the risk of non conforming product.

For higher risk products third party assessment is required.

Examples of risk-based conformity assessment



Conformity assessment activities and techniques



Conformity assessment techniques used

Assessment	Determining whether an organisation **fulfils requirements related to its technical competence**. An example is the assessment of conformity assessment bodies (e.g. laboratories, inspection bodies and certification bodies) to ensure that the results that they produce can be relied upon.
Auditing	A **systematic, independent and documented** process for **obtaining** audit **evidence and evaluating it objectively** to determine the extent to which the audit criteria are fulfilled
Evaluation	Evaluation is the process of **gathering evidence** about whether a product, process or service meets **specified requirements**. (selection and determination activities)
Inspection	can include: visual examination of physical items; measurement or testing of physical items; examination of specification documents such as design drawings; comparison of the findings with the requirements of specification documents or with generally accepted good practice in the field; and drawing up a report on the results of the inspection.

Who is responsible for conformity?

The **organization** that owns the product or service or supplies them to the marketplace:

- **The supplier** of a product has a **contractual** and **legal duty** to the user that the product will perform its declared function and will not endanger heath or safety.
- Even when the supplier obtains a certificate from an independent body, stating that the product conforms to the relevant requirements, if anything goes wrong **the supplier remains responsible**.
- The independent body may incur some liability (especially if it had been negligent) in performing the conformity assessment but this does not absolve the supplier of their prime responsibility.

Determination of CA - Testing

Testing, measurement and **calibration** have huge impact on trade and commerce and, in fact on every facet of our daily lives, from the water we consume, to the amount of petrol we buy.

Testing typically applies to materials, products or processes.
Examples are: chemical tests to determine composition of materials, hardness testing for building materials, water testing for composition, blood analysis, alcohol testing etc.

C**alibration** of equipment can also sometimes be considered as a conformity assessment activity.
Examples of calibration are a thermometer, a ruler or an instrument

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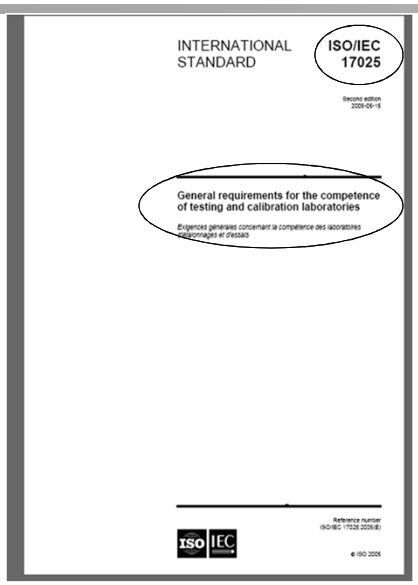
Testing and calibration (ISO/IEC 17025)



INTERNATIONAL STANDARD

ISO/IEC 17025

Second edition
2005-05-15

General requirements for the competence of testing and calibration laboratories

Exigences générales concernant la compétence des laboratoires d'étalonnages et d'essais

Reference number
ISO/IEC 17025:2005(E)

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Determination of CA - Inspection

Inspection bodies examine a huge range of products, materials, installations, plants, processes, work procedures and services, in the private as well as the public sector.

Inspection bodies can report on quality, fitness for use and continuing safety in operation. For example inspection of products at a port for quantity, quality and safety , compliance of plants and installations.

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Inspection bodies (ISO/IEC 17020)


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ISO/IEC 17020

Conformity assessment — Requirements for the operation of various types of bodies performing inspection

Definition: ***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 (e.g. inspection of fire extinguishers, lifts, restaurants, road vehicles).

Provides **objective evidence** that an inspected item meets the specified needs of the customer (purchaser, manufacturer regulator).

Substantial reliance on **professional judgment** of the inspector whose competence is crucial to the success of this activity.

Determination of CA - Inspection

The definition of inspection refers to ***"…on the basis of professional judgment…"***

- This implies that the **competence** of the **inspector** is **fundamental** to the integrity of the inspection process.
- Thus, the competence of an inspection body relies on the **knowledge, experience and skills of the inspectors.**
- Because of this, in some areas, the competence criteria that inspectors must meet are clearly defined and specified.
- **Reduce risk to the buyer, owner, user or consumer**.

Determination of CA - Certification

What is certification?

When a third party gives written assurance that:

- A product (including services),
- A process,
- Personnel,
- An organization or
- Management system

conforms to specified requirements.

Requirements for Certification bodies

3 main types of certification activity:

- **Product certification,** ISO/IEC 17065 (products, processes and services certified)
- **Management system certification,** ISO/IEC 17021 (e.g. **ISO 9001** certified company, **ISO 14001** environmental management and **ISO 22000** food safety management systems)
- **Bodies operating certification of persons,** ISO/IEC 17024 (Certificated Person)

Product, process and service certification

4 basic drivers for product, process and service certification

- To provide consumers (users) of products with sufficient information to allow them to **make informed decisions** on products and services;
- To assist the suppliers of certified products to **achieve market acceptance.** If the product has a recognizable mark on it consumers may be more willing to make the purchase;
- Product certification plays a role in **regulated products** (subject to technical regulations);
- **Assists manufacturers** in selecting the components for their own products;
- Retailers have **confidence** in the products they are selling.

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Accreditation

Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

- Management System Accreditation indicates to the client of the certification body that it is competence to carry out certification.
- Accreditation of testing laboratories, product certification and inspection bodies is an independent verification that they are competent to perform the specific activities for which they are accredited.
- Accreditation involves the use of assessors with expertise in the area being accredited. For example an assessment team accrediting a laboratory will have technical experts specific to the scope of accreditation of that laboratory.
- ISO/IEC 17011, *Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.*

Accreditation

Conformity assessment body (CAB)

- **Body that performs conformity assessment services** (laboratory, inspection body, certification body)
- NOTE: An accreditation body (AB) is not a conformity assessment body.

Accreditation body (AB)

- **Authoritative body** that **performs accreditation**
- NOTE: The authority of an AB is normally derived from a government.
- Requirements for an AB are contained in ISO/IEC 17011.

Reducing Risk- The Role of Accreditation

Accreditation = Transparent and impartial examination of the **competence** of a conformity assessment body against a **specific scope** by an **independent** body.

Without Accreditation?

- **Risk** based on **assumption**
- **How much** risk ?

Three Vital Questions for all customers of Conformity Assessment Bodies

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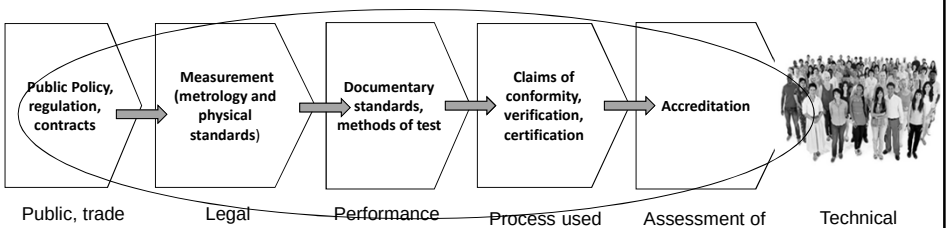
In Conclusion



Public, trade and corporate policy	Legal measurement (OIML)	Performance standards	Process used to claim conformity	Assessment of technical competence	Technical outcomes that society can trust, and use in decision making
Trade facilitation	Scientific and technical measurement	Prescriptive standards	Auditing, Calibration, Evaluation, Examination, Inspection, Testing	Mutual Recognition Arrangements (MRA)	
	Government or private laboratories and research interests	Test methods	1st, 2nd and 3rd party claims of conformity and marking		
		Many different standards developers			

SPS measures and the implementation of the SPS Annex to the SADC Protocol on Trade

Overview of SPS Annex to the SADC Protocol on Trade

The SADC SPS Annex to the Protocol on Trade is based on the WTO SPS Agreement and draws regulatory requirements from it. The main obligations of the SADC SPS Annex some of which are additional to the WTO SPS Agreement contained in Annexes A, B, C are:

- Members to base their standards on international SPS standards;
- Members base their standards on scientifically based Risk Assessment (Article 8);
- That SPS measures of SADC Member States make provision for adaptation to regional conditions including pest or disease free areas and areas of low pest or disease prevalence (Article 4) *;
- Members cooperate and work towards harmonization of SPS measures or standards in SADC, and to use international standards and guidelines as a basis for such harmonization (Article 6)*;
- Members enter into Equivalence agreements with each other*;
- Transparency - Members notify laws and regulations, procedures and requirements to the SADC Secretariat, and also publish them (Article 10, Appendix)*.

* Indicates these are in additional to WTO Annex requirements

Implementation of the SPS Annex to the SADC Protocol on Trade

It is often assumed that the management of food safety and agricultural health is predominantly the responsibility of the public sector. Indeed, there are many crucial regulatory, research and management functions that are normally carried out by governments, and a variety of circumstances where importing countries require that certain functions be performed by a designated public sector 'competent authority'.

However, the private sector also has a fundamentally important role to play.

Implementation of the SPS Annex to the SADC Protocol on Trade

I. The private sector should contribute to standard-setting at the national level given their insights regarding technical options and the associated costs and benefits for business.
II. Specific actions of individual producers and processors are required to ensure that compliance with food safety and agricultural health requirements is achieved. An example is the application of Hazard Analysis and Critical Control Point (HACCP) by food processors or fresh produce packers.
III. Capacity building in the private sector can complement (or even substitute for) public sector capacity, as with the investment in accredited laboratory testing facilities.
IV. The private sector normally plays an important role through the pressures it places on public agencies to effectively implement their SPS management responsibilities.

Implementation of the SPS Annex to the SADC Protocol on Trade

The key to successfully implementing the SADC SPS Annex in support of implementation of the EU SADC EPA is the formation a SADC SPS Coordinating Committee comprising of appropriate representatives from each of the National Committees on SPS Measures.

Article 14 (Administration) requires that each Member State establish a national SADC Sanitary and Phytosanitary Committee and also sets out the tasks for this committee.

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Project funded by the EU at the request of the ACP Group