

## KEY DEFINITIONS AND POTENTIAL ROLE OF WTO

## DEFINITIONS

- STANDARDS
- TECHNICAL REGULATIONS
- CONFORMITY ASSESSMENT
- HARMONIZATION
- EQUIVALENCE
- MUTUAL RECOGNITION

## DEFINITIONS

- Basis for Definitions
  - Should be a recognized international definition wherever possible
  - Examine definitions in the context of our subject
- Resources for Definitions
  - WTO TBT (1994, 2002, 2003)
  - ISO/ICE Guide 2 (1991 and 1996)
  - Codex Alimentarius (refers to WTO/TBT)
  - European Directive 98-34
  - USDA/US State Department

## STANDARD

- Existing Definitions
  - WTO-TBT
  - ISO/ICE Guide 2
  - EU Directive 98-34
  - US State Department
- Recommendation
  - ISO/ICE Guide 2, "plus"
  - "plus" = standards are voluntary
  - Rationale: ISO definitions are more elaborated
  - Note: ISO language applies very generally to processes as well as products, and therefore could also refer to norms for conformity assessment as well as for organic production and processing.

## STANDARD

- Recommended DEFINITION (ISO-plus)
  - Document established by consensus, and approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics of *activities or their results*, aimed at the achievement of the optimum degree of order in a given context.
  - *Standards are voluntary in nature.*

## STANDARD

- WTO Definition
  - Document approved by a recognised body, that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, *with which compliance is not mandatory*. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.



## STANDARD

- Recommended DEFINITION
  - Document *established by consensus*, and approved by a recognized body, that provides for common and repeated use, rules, guidelines or characteristics of activities or their results, aimed at the achievement of the optimum degree of order in a given context. *Standards are voluntary in nature.*
- WTO/TBT Definition
  - Document approved by a recognised body, that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.



## TECHNICAL REGULATIONS

### Recommended Definition (WTO/TBT)

Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, *with which compliance is mandatory*. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.



## CONFORMITY ASSESSMENT

- Recommended Definition (ISO)
  - Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.



## CONFORMITY ASSESSMENT

- ISSUE: **Terms for the requirements of conformity assessment**
  - **Guidelines** (ISO 65, 61) for bodies conducting certification, accreditation
  - **Procedures** (WTO): . . . “any procedure” used, directly or indirectly to determine that the relevant requirements in technical regulations or standards are fulfilled.
  - **Criteria** (IFOAM) : for the Accreditation of Bodies Certifying Organic Production and Processing
  - **Standard** (again ISO) because definition of standard includes processes, activities (even though ISO itself calls their conformity assessment rules, not standards, but guidelines).



## HARMONIZATION

- Term is not defined in WTO or ISO
- ISO defines:
  - “harmonized standards,”
  - “unified standards,”
  - “identical standards,”
  - “internationally harmonized standards,”
  - “regionally harmonized standards,”
  - “multilaterally harmonized standards”
  - “bilaterally harmonized standards,”
  - “unilaterally ALIGNED standards”



## HARMONIZATION

- ISO 6.1 Harmonized standards
  - A. Equivalent standards
  - B. Standards on the same subject approved by different standardizing bodies, that establish interchangeability of products, process and services, or mutual understanding of test results or information provided according to these standards.

## HARMONIZATION

- Recommended Definition (paper)
  - The process by which standards on the same subject approved by different standardizing bodies (including requirements for conformity assessment) establish interchangeability of products, processes and services, or mutual understanding of test results or information provided according to these standards.

## EQUIVALENCE

- WTO: (1994) A mechanism to recognize and accept another system by acknowledging that variations between the systems uphold the respective systems' objectives.
- ISO/IEC Guide 2: equivalent and harmonized standard are synonymous. (Def. 6.1)
  - Recognizes that harmonized standards can be different in substance and presentation, but provide for interchangeability of results.

## HARMONIZATION

### EQUIVALENCE

The process by which different standards/technical regulations on the same subject approved by different standardizing bodies are determined to meet common objectives and therefore establish interchangeability of products, processes and services, or mutual understanding of test results or information provided according to these standards.

The process by which standards on the same subject approved by different standardizing bodies establish interchangeability of products, processes and services, or mutual understanding of test results or information provided according to these standards. The process may include using identical standards, or determining equivalence.

## CONVERGENCE

### Background:

- Used in Courville/Cruefix, 2003: Existing and Potential Models and Mechanisms for Harmonization, Equivalency and Mutual Recognition
- Used internationally, only in the EU "New Approach," where harmonization is defined as "the drawing up of identical rules or use of common international standard and convergence as "any process of trade coordination in a generic way."

### Recommendation

- Use "convergence" in its general English meaning and not in a technical sense. Use the term "harmonization" to refer to any process of establishing more interchangeability and flow of trade within the context of the ITF.

## (MUTUAL) RECOGNITION

- WTO: not defined, but usage implies use of results of conformity assessment
- ISO/ECE Guide 2: defines "recognition arrangement (15.1)" as use of result of conformity assessment.
- US State Department: defines "mutual recognition agreements" following along the lines that conformity assessment results may be used.

## RECOGNITION

### Recommended definition:

- **Arrangement for the use of results of conformity assessments.**

- Note: whether the arrangements are mutual or not is best described by bi- or multi-lateral, but since the phrases "mutual recognition arrangement" is widely used, including in TBT text, it should be understood as encompassing bi- and multilateral arrangements.

- What framework for ITF work is established in the WTO/TBT?
- How have organic standards and harmonization efforts followed that framework?
- How to use that framework in the ITF work?

- **Harmonization in the TBT**
  - §2.6 **Technical Regulations**: Members shall play a full part in the preparation of international standards.
  - §5.5 **Conformity Assessment Procedures**: Members shall play a full part in the preparation of guides and recommendations for conformity assessment
  - Annex 3 **International Standards**: Standardizing bodies shall play a full part in the preparation of international standards. (private sector).

• **THE TBT GIVE A VERY HIGH STATUS TO INTERNATIONAL STANDARDS**

- §2.4 Where technical regulations are required and relevant international standards exist . . . *Members shall use them . . . as a basis for their technical regulation . . . (except for climatic, geographic, technological problems.)*
- §2.5 Whenever a technical regulation is prepared, and is in accordance with relevant international standards, it shall be presumed not to create an unnecessary obstacle to international trade.
- Annex 3 Where international standards exist, . . . *The standardizing body shall use them as a basis for the standards it develops (except for climatic, geographic, technological problems).*

• **Second triennial review (2000)**

FACILITATING RESULTS OF CONFORMITY ASSESSMENT -

- Mutual Recognition Agreements (highest priority)

- But also
- Co-operative arrangements between domestic and foreign conformity assessment bodies.
  - Use (recognition) of accreditation (schemes)
  - Government designation of specific conformity assessment bodies
  - Unilateral recognition
  - Manufacturers'/suppliers' declarations

**Third TBT Triennial Review (2003)**

- Recognizes difficulties for MRAs among nations, and proposes a "menu" of approaches
  - Use international standards and base conformity assessment on them. (reiteration)
  - Or, use relevant parts of international standards
  - Participate in elaboration of international standards (reiteration)
  - If no international standards, then use the steps for facilitating results of conformity assessment (previous slide) to determine if standards/technical requirements are met.
  - Use step-by-step approach to build trust and confidence.

**TOOLBOX OF INSTRUMENTS**  
- to obtain different degrees of regulatory co-operation

