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Canada

Conformity Assessment Obligations in the WTO-TBT Agreement

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World Trade Organization:

- Only global international organization dealing with the rules of trade between nations
- Goal: to help producers of goods and services, exporters, and importers conduct business
- Established in 1995, 151 current members
- Three broad WTO Agreements:
 - General Agreement on Tariffs and Trade (GATT)
 - General Agreement on Trade and Services (GATS)
 - Trade-related Aspects of Intellectual Property Rights (TRIPS)
- Sector-specific agreements under GATT: Agriculture, Sanitary and Phytosanitary Measures (SPS), Rules of origin, **Technical Barriers to Trade (TBT)**, Anti-dumping measures, Import licensing, Safeguards, others



Why there is a TBT Agreement:

High number of technical regulations and standards:

- Increasing standard of living means more regulations
- Need for safe, high quality, environmentally friendly products
- Impact on international trade:
 - cost of translation of foreign documents
 - adjustment of production facilities
 - Need to prove that exported product meets foreign regulations
 - Regulations and standards may be used to protect domestic industries



TBT- recognizes the right to ensure:



Protection of:

- human safety or health
- animal and plant life or health
- the environment
- legitimate, essential security interests



Prevention of:

deceptive practices

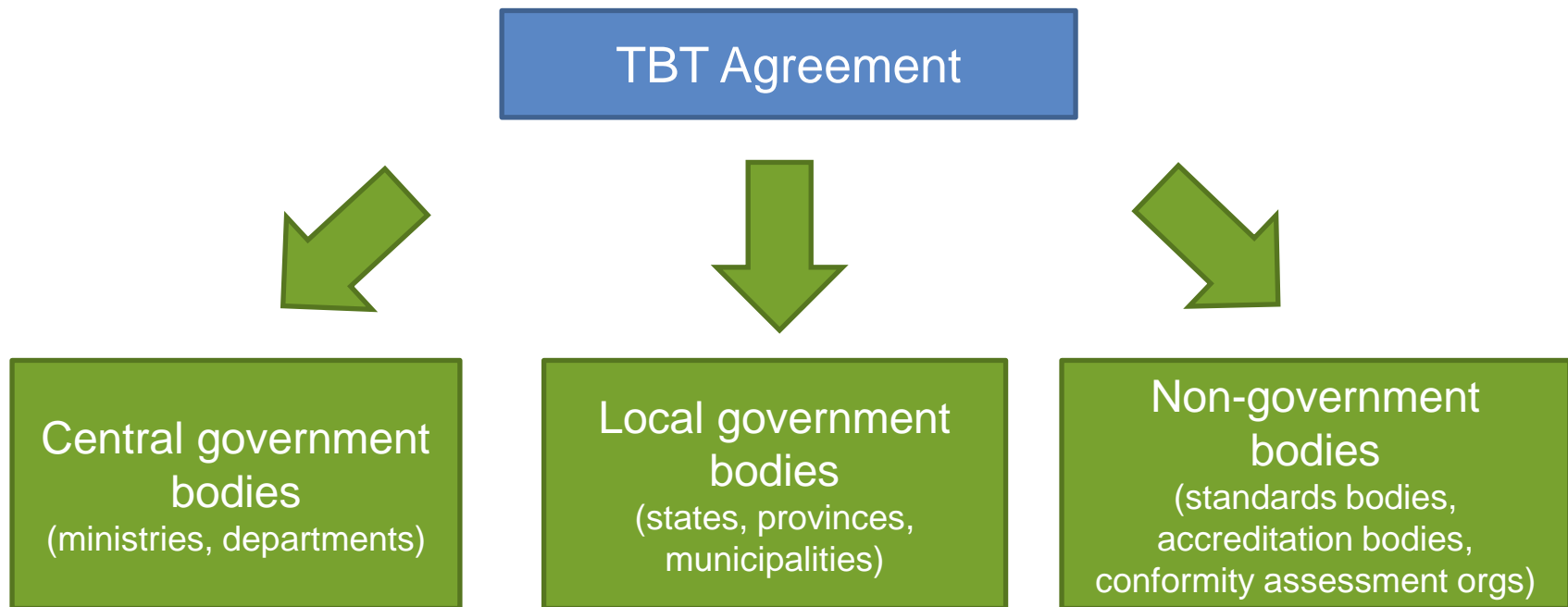


Quality of:

exports



Who is subject to the TBT Agreement:



Central government is responsible for compliance with the Agreement



Typical TBT measures deal with:

| Nutrition Facts | | Amount/erving | %DV* | Amount/erving | %DV* |
|--|----------------|---------------|------|---------------|-----------|
| Serv. Size 1 cup (249g) | Total Fat | 12g | 18% | Sodium | 940mg 39% |
| Servings About 2 | Sat. Fat | 6g | 30% | Total Carb. | 24g 8% |
| Calories 250 | Polyunsat. Fat | 1.5g | | Dietary Fiber | 1g 4% |
| Fat Cal. 110 | Monounsat. Fat | 2.5g | | Sugars | 1g |
| | Cholest. | 60mg | 20% | Protein | 10g 20% |
| *Percent Daily Values are based on a diet of 2,000 calorie diet. | Vitamin A | 0% | | Vitamin C | 0% |
| | Calcium | 6% | | Iron | 8% |

INGREDIENTS: WATER, CHICKEN STOCK, ENRICHED PASTA (SEMOLINA WHEAT FLOUR, EGGS, WHEAT GERM, SUGAR, YEAST, THIAMINE MONONITRATE (VITAMIN B1), NIACIN (VITAMIN B3) AND FOLIC ACID), CREAM (PREPARED FROM MILK), CHICKEN, CONTAINS LESS THAN 2% OF SPICES (GARLIC, FENUGREEK AND ROMAINE PASTE), PASTEURIZED SWISS MILK CULTURES, SALT, ENZYMES, WATER, SALT, LACTIC ACID, STYRENE ACID AND SODIUM HYDROGENSULFITE, BUTTER, PASTEURIZED WHIPPED CREAM (PREPARED FROM MILK) AND SALT), MODIFIED CORN STARCH, SALT, SPOULE EGG BLENDS, SUGAR, BAKING POWDER, SALES, SPICES, LANTHANUM, CHICKEN FLAVOR, PARTIALLY HYDROGENATED COCOA OIL, FLAVORINGS AND SMOCK FLAVORING), MUSTARD FLOUR, EMULSIFIER AND PROTEIN AND COCOA POWDERING.

Labeling of food, drink and drugs



Quality of fresh food



Packaging of fresh food



Packaging/labeling of dangerous chemicals & toxic substances



Regulations for electrical appliances



Labeling for textiles and accessories



Safety regulations for toys



Definition of conformity assessment:

A conformity assessment procedure is any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. Conformity assessment procedures include procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations ([Annex One, Paragraph 3](#)).

Key principles - Art. 5.1:

- Non discrimination/national treatment in terms of access to conformity assessment procedures for “like products”
- Conformity assessment procedures should not create unnecessary obstacles to trade



Article 5.4-5.6 – standards and guides:

- Use standards and guides issued by international standardizing bodies as the basis of conformity assessment
- To achieve harmonization, participate in development of guides and recommendations by international standardizing bodies (e.g. ISO/CASCO)
- Notify procedures that have a significant effect on trade and which are not in accordance with guides and recommendations



CASCO standards and guides:

- ISO Committee on conformity assessment (CASCO) provides a tool box covering all aspects of definition, implementation, evaluation, recognition and use of conformity assessment (calibration, testing, certification, inspection, accreditation)
- CASCO documents provide neutral platform for establishment of internationally recognized procedures for 1st, 2nd and 3rd party conformity assessment.



Article 6 - *Recognition of Conformity Assessment by Central Government Bodies:*

- Conformity assessment procedures of other Members **should be accepted**, even if procedures are different, provided they give an assurance of conformity similar to domestic procedures (6.1). Prior consultation may be necessary regarding:
 - establishing technical competence of CABs, for example, **through accreditation based on international standards and guides**
 - acceptance of CA results only from designated bodies
- Members encouraged to develop **mutual recognition agreements** on results of each others' conformity assessment procedures (6.3)
- Members encouraged to provide **national treatment** for conformity assessment bodies (6.4)



Approaches to facilitate acceptance of CA results (Annex 5), 2nd Triennial Review:

- Mutual recognition agreements (MRAs) for conformity assessment
- Voluntary co-operation arrangements between domestic and foreign conformity assessment bodies
- Use of accreditation to qualify conformity assessment bodies
- Government designation of specific bodies
- Unilateral recognition of results of foreign conformity assessment
- Declaration by manufacturer or supplier



Mutual Recognition Agreements (MRAs):

| Traditional MRA | MRA based on common rules or standards |
|---|--|
| Recognition of test results carried out in exporting party to importing parties' requirements | <ul style="list-style-type: none">• OECD Good Laboratory Practices• IMO conventions |



Traditional MRAs:

- Recognize the results of conformity assessment (testing, certification) carried out in the exporting party to the importing party's mandatory requirements
- Legally binding agreements negotiated between governments based on specific regulated products
- No harmonization of the regulations of each party is required
- Different from voluntary MLAs between accreditation bodies which are not legally binding
- Bilateral and regional agreements



Examples of MRAs:

- APEC Electrical & Electronic Equipment MRA
- APEC telecommunications MRA
- US-EU MRA (telecoms, EMC, electrical safety, recreational craft, pharmaceuticals, medical devices)
- Canada-Mexico MRA for telecommunications
- Australia-Singapore MRA for Electrical & Electronic Equipment and telecommunications



Impact of MRAs on trade:

- Mixed results in terms of reduction/elimination of duplicative testing and certification
- Traditional MRAs difficult to negotiate and implement
- MRAs based on international standards easier to negotiate
- Single sectors seem more promising (e.g. Telecoms)
- Accreditation-based MLAs becoming more important
- Bilateral regulatory cooperation agreements may be more effective in long term



Arrangements between CABs:

- Article 8 of TBT Agreement recognizes role of non-governmental bodies; CABs may enter into agreements with each other to help facilitate trade

IECEE CB Scheme:

- Participants in over 50 countries
- Covers more than 1000 IEC standards, 23 product categories
- Direct acceptance by regulators and buyers
- Accelerates products to markets

Subcontracting arrangements between CABS:

- CSA/UL MOU enables joint recognition of test/certification reports
- Manufacturer can obtain two marks at same time



Use of accreditation to qualify CABs:

- Third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (ISO/IEC 17000, 5.6)
- formal recognition of competence
- applied to conformity assessment organizations – testing, inspection, and certification
- performed by independent, impartial body that applies internationally recognized standards and guides
- often recognized by governments



Trade benefits of accreditation:

- Prerequisite for international trade (as part of a larger national standardization infrastructure)
- Beneficial to government and regulators and promotes good regulatory practice (GRP)
- Offers potential to benefit from wide range of conformity assessment activities
- Provides opportunity for developing countries to participate in multilateral arrangements



Multilateral Accreditation Arrangements (MLAs):

- Article 9 of TBT Agreement encourages members to participate in and adopt international and regional systems for conformity assessment
- Voluntary multilateral recognition arrangements (MLAs) are agreements between accreditation bodies to recognize each other's accreditation
- MLAs contribute to global acceptance of conformity assessment results:
 - reduce need for multiple assessments
 - traceability of measurements to SI units
 - recognized by industry and regulators
 - help underpin government-to-government mutual recognition agreements (MRAs)



Examples of MLAs:

International Level



Regional Level



Country Level

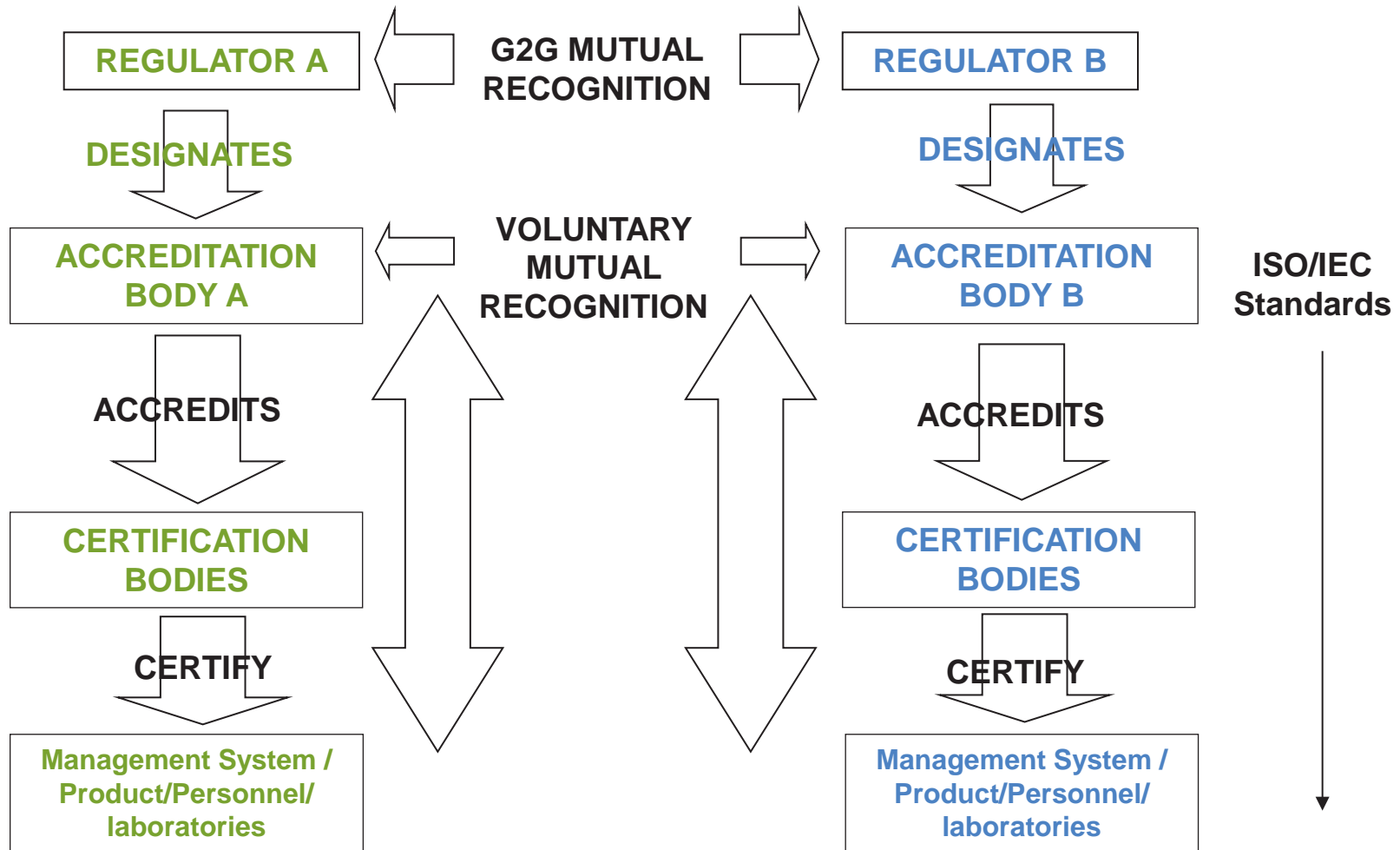


Accredited Certification Bodies/Laboratories





MLAs underpin MRAs:





MLAs as a regulatory tool:



| |
|---|
| <ul style="list-style-type: none">■ Health & safety imperatives■ Market access requirements■ Legal frameworks |
| <ul style="list-style-type: none">■ Guidance documents supported by peer assessments |
| <ul style="list-style-type: none">■ Verifies CAB competence■ Based on Int'l documents■ Independent process |
| <ul style="list-style-type: none">■ Verifies 'product' conformity■ Based on Int'l documents■ Often a regulatory requirement |
| <ul style="list-style-type: none">■ Consensus-based documents■ WTO/TBT Compliant |



Government designation of CABs:

- Article 6.1.2 of TBT Agreement permits governments to limit acceptance of conformity assessment results to designated bodies in exporting country
- Designation may take place:
 - in the context of an MRA through unilateral designation by authority in import market
 - designation/registration of CABS
 - designation of accreditation bodies
- Examples:
 - Japan – Registered Overseas Certification Bodies
 - (ROCBs) – forest products, organics
 - EU Notified Bodies



Unilateral recognition of foreign CA results:

- TBT Agreement requires members to consider accepting as equivalent other countries' technical regulations and CA procedures even if different, as long as they adequately fulfill the objectives of their own requirements
- Not used very often in practice – requires high degree of confidence between countries & there has been little attempt to examine concept more closely and identify principles, criteria or good practice for assessing equivalency
- Some TBT members have adopted this requirement in regulatory policy (e.g. Canada's *Cabinet Directive on Regulatory Management*)



Supplier's Declaration of Conformity (SDoC):

- Manufacturer/supplier, not regulatory authority, assumes responsibility for compliance & provides written assurance that product complies with specific requirements
- Most trade friendly approach to conformity assessment, but only works well under certain conditions:
 - effective product liability laws
 - market surveillance system with resources and enforcement powers
 - penalties for false/misleading declarations
 - appropriate incentives to encourage compliance
 - customer redress system



Next Steps:

- At its 6th Triennial Review in 2012, TBT committee identified three broad areas where more work is needed to develop practical guidance on facilitating acceptance of CA results:
 - 1) criteria and methods of analysis used to inform evaluation of range of choices in CA procedures
 - 2) how to use relevant existing international standards, guides or recommendations, or the relevant parts of them, as a basis for CA procedures
 - 3) how international and regional systems for CA (e.g. regional and intergovernmental initiatives, MLAs, arrangements between CABs) can contribute to building globally robust and trade facilitative schemes



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Questions/ Comments?
Thank you!