Conformity Assessment & Quality Infrastructure

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Scope of TBT Agreement

technical regulations

conformity assessment procedures (CAP)

standards

"Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Explanatory note

Conformity assessment procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations."

Conformity assessment is one part of the **Quality Infrastructure**.

Quality Infrastructure: a definition

The system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes.

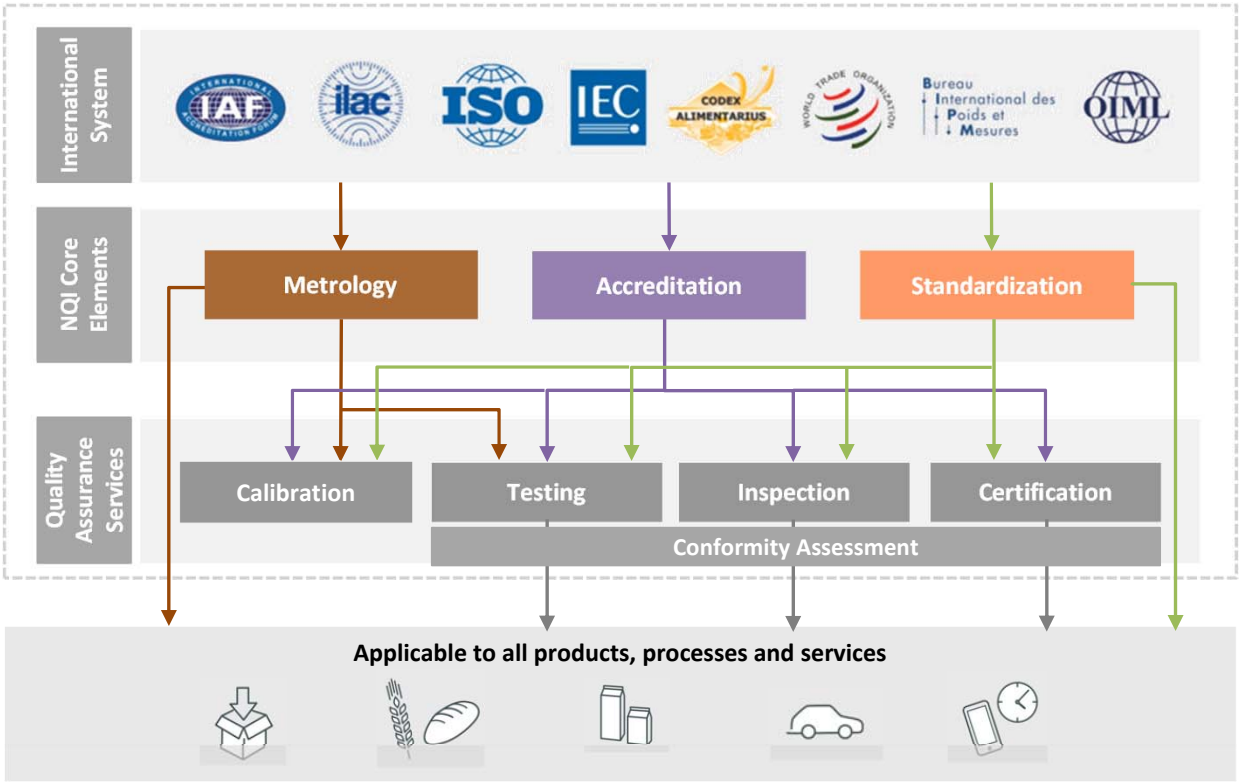
The quality infrastructure is required for the effective operation of domestic markets, and its international recognition is important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing.

It relies on:

- metrology,
- standardisation,
- accreditation,
- conformity assessment, and
- market surveillance.

Source: DCMAS (2017). DCMAS network members are : IEC, ISO, ITU, UNECE, BIPM, OIML, UNIDO, ILAC, IAF, ITC

Quality Infrastructure: an illustration of the "ecosystem"



Source: World Bank Group, 2017

International recognition of national **Quality Infrastructure** is vital for trade.

Standardization?

Metrology?

How does QI relate to the TBT agreement?

Accreditation?

Conformity assessment?

Conformity assessment procedures are a significant source of **trade costs.**

What kinds of trade costs arise from CAPs?

WHAT?

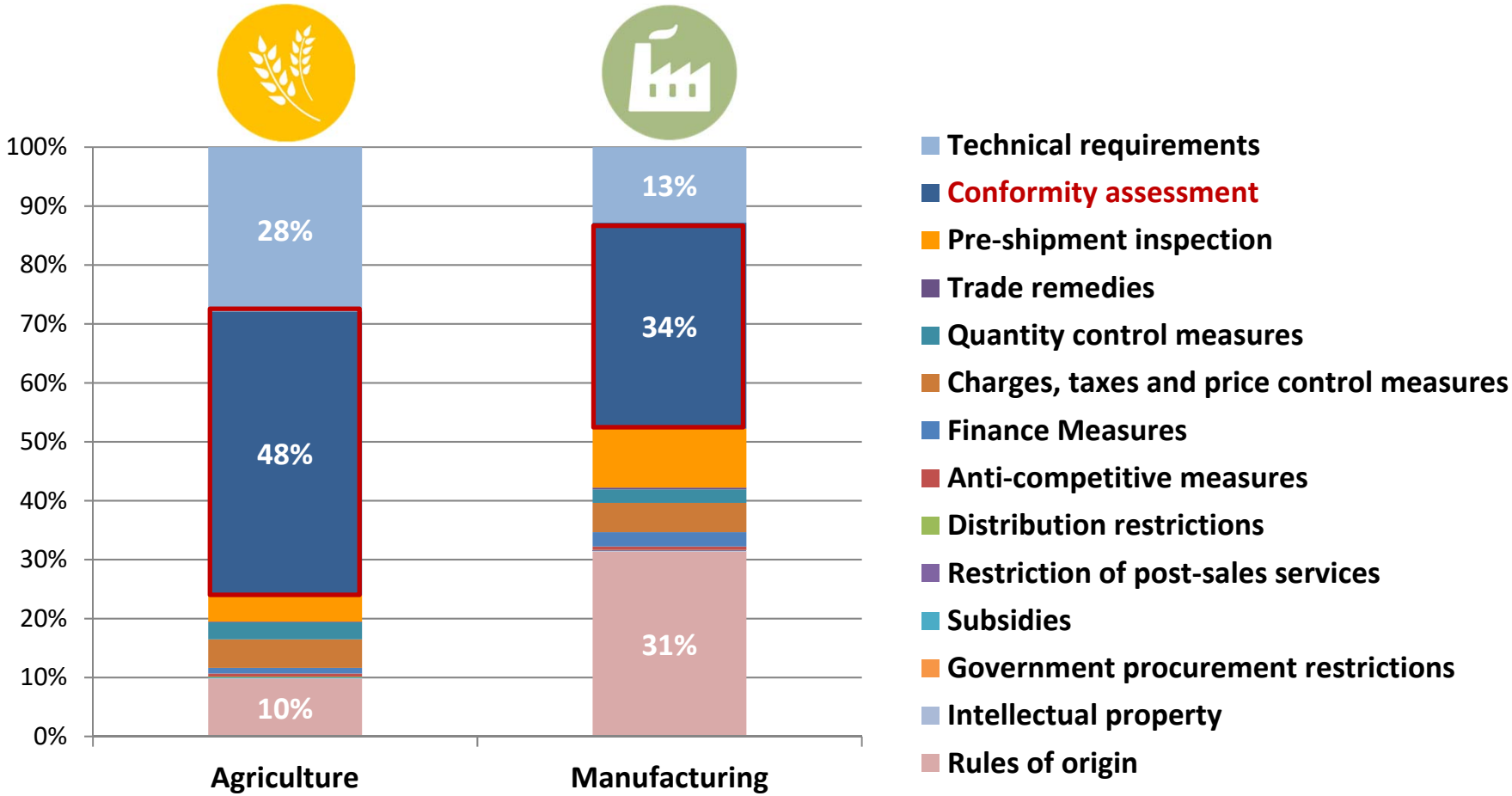
Differences in <u>what</u> is assessed in a CAP (testing, sampling and inspection) from economy to economy increases costs

WHO?

Limitations on the bodies <u>who</u> can perform CAPs (e.g. only CABs with a business presence in a economy can be accredited by that economy's regulator) adds costs

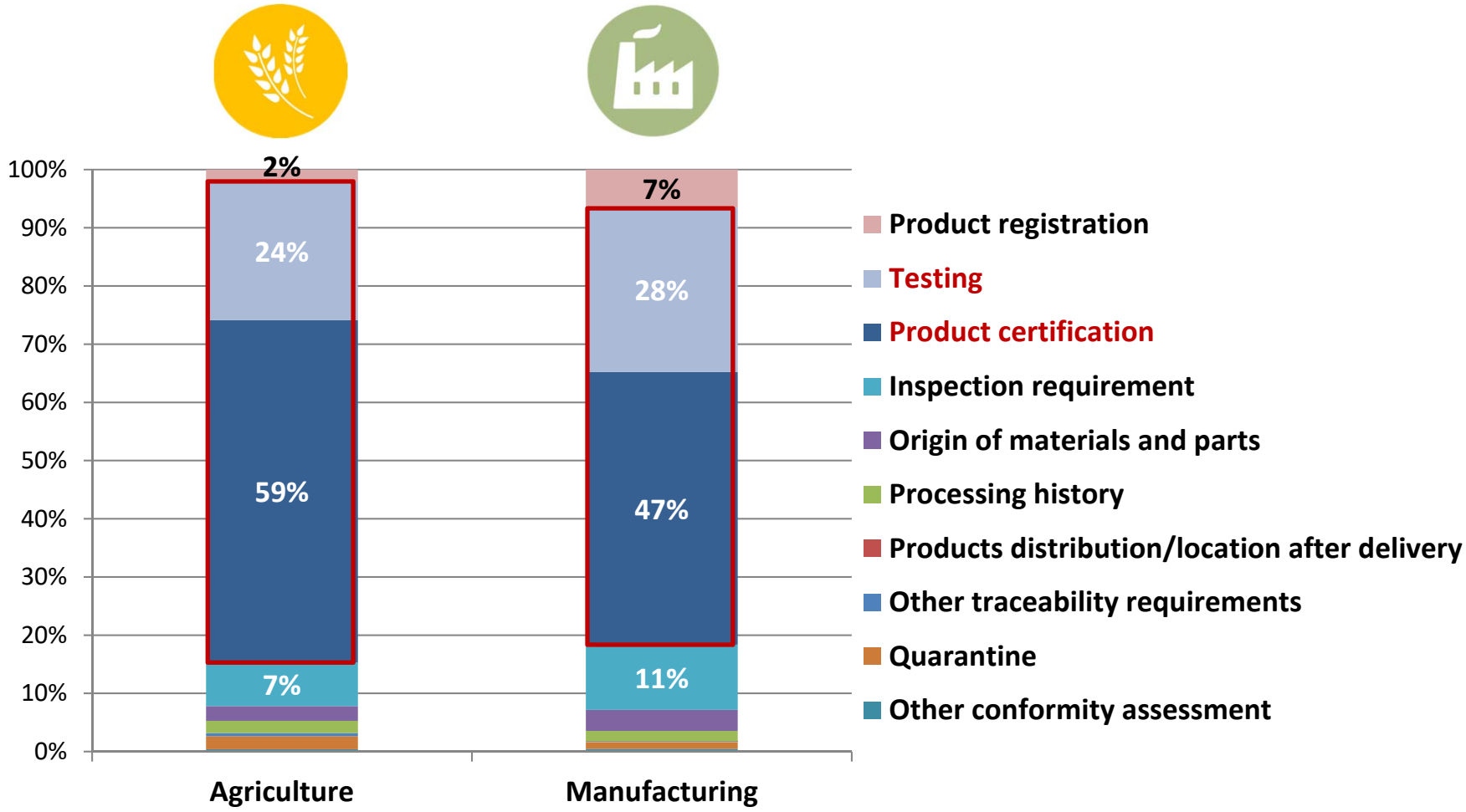
Reference: OCED, 2016
International Regulatory Cooperation and Trade: Understanding the Trade Costs of Regulatory Divergence and the Remedies

CAP is the first burdensome NTMs faced by both agri-food and manufacturing exporters



Source: ITC Businesses Survey on NTMs in 37 countries, www.ntmsurvey.org,
Presentation "What companies teach us about conformity assessment procedures (CAP), Insights from ITC Business Survey on Non-Tariff Measures" by Mathieu Loridan, TBT Committee, Thematic session on CAP, 28 March 2017

Product certification and testing represent 80% of CAP obstacles



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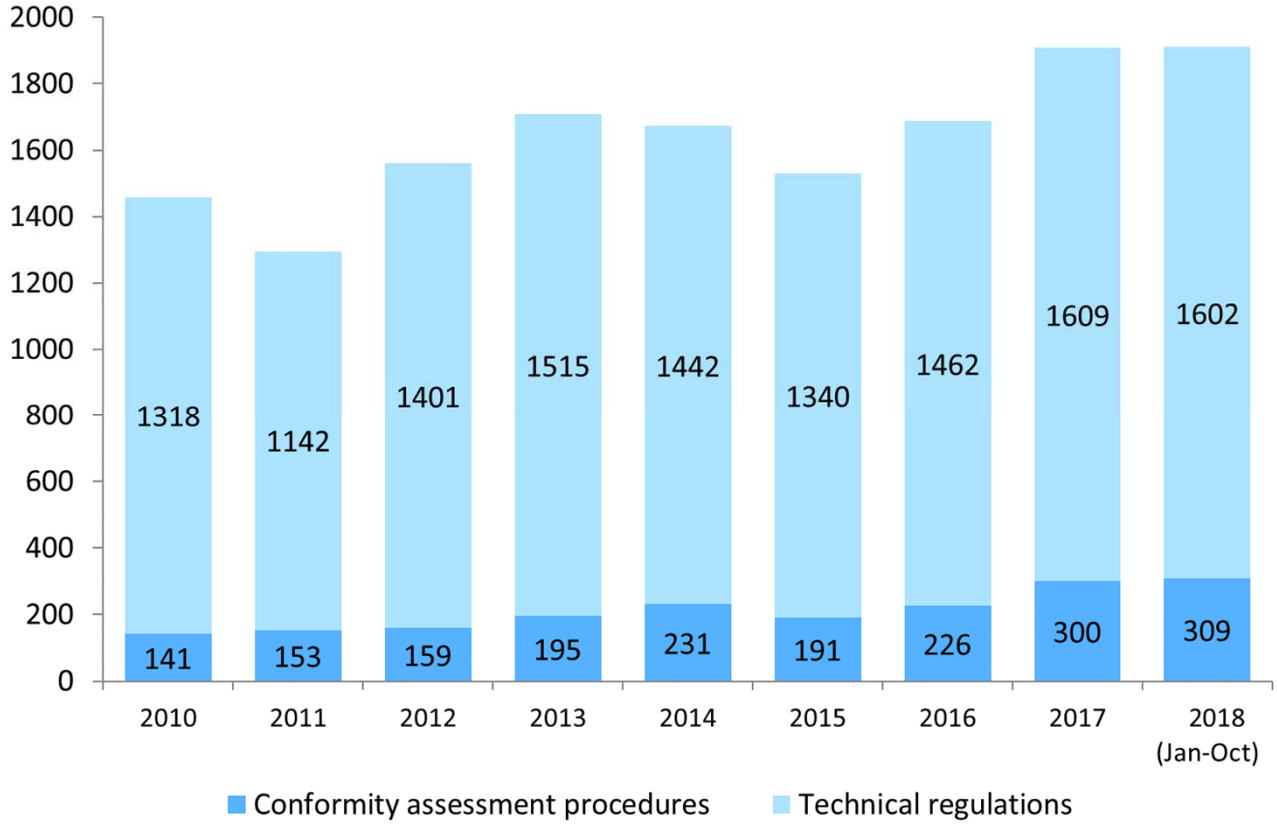
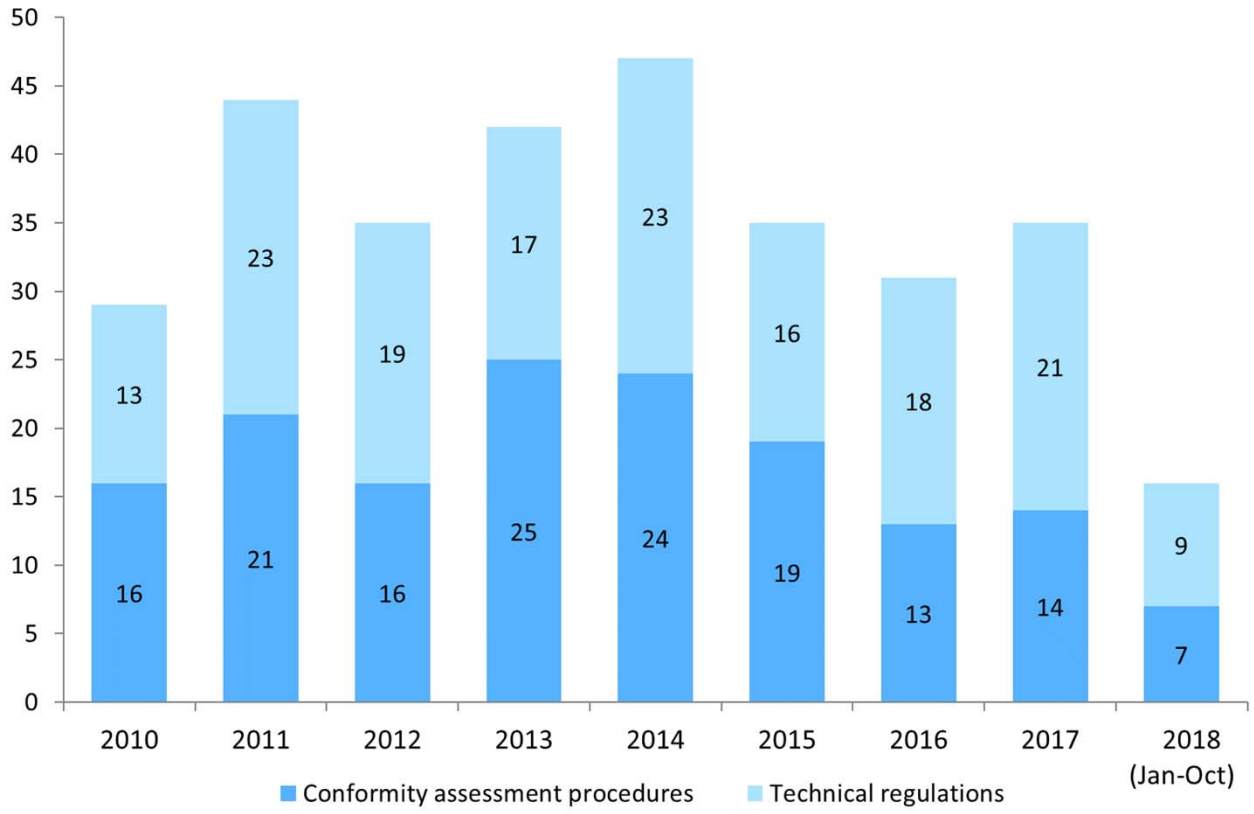
New notifications of CAPs and technical regulations (2010-2018)



New STCs related to CAPs and technical regulations (2010–2018)



Balancing costs and benefits

- Choice and design of CAPs involves trade off between:
  - Costs to suppliers (administrative, compliance, information)
  - Benefits of preventing non-compliant products form reaching the market (risk)
- **Guiding principle**: analysis of choice and design of CAPs should be aligned with the risk posed by the product/sector:
  - High risk product = stricter CAP
  - Low risk product = less strict CAP

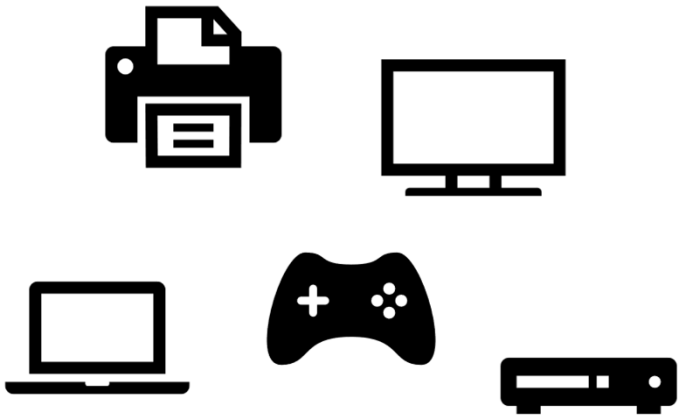
How does the TBT Agreement help?

TBT Agreement principles for CAP

(positive assurance of conformity required by central government bodies, Article 5.1 and 5.4)

- **Non-discrimination**
  - *Access for (foreign) suppliers under conditions no less favourable than accorded to suppliers of like products in a comparable situation*
- **Avoid unnecessary barriers to trade**
  - *CAP shall not be more strict than necessary to give importing Member adequate confidence of conformity*
- **Use of international guides and recommendations** (harmonization)

two examples



"Mandatory third party testing by a government laboratory approved by the appeared excessively burdensome, and more strict than necessary, given the low risk nature of the products concerned." (STC 367)

Necessity?

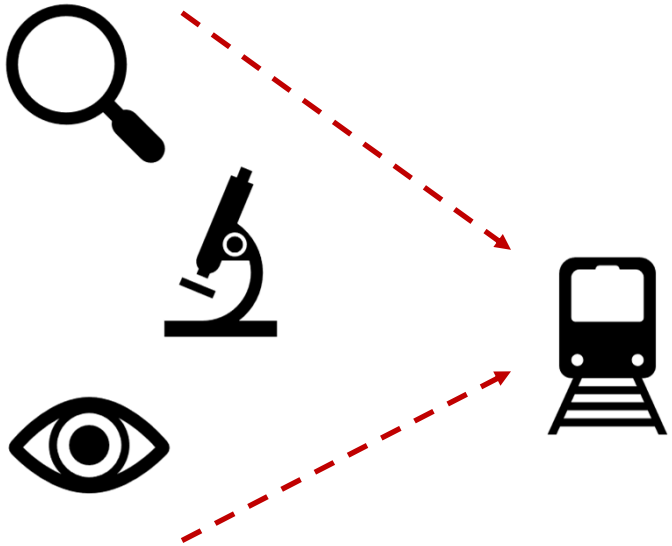
"the draft regulation provided exemptions for domestic manufacturers from the requirement of conducting batch tests and quality management by lot number… understanding that only domestic manufacturers would benefit from these derogation" (STC 292)

Discrimination?

Specific provisions for non-discrimination and avoiding unnecessary barriers to trade (Art. 5.2)

- Undertaken as **expeditiously** as possible
- **Processing period** of CAP is published, informs applicant in a precise and complete manner of all deficiencies, information provided on stage of application
- **Information requirements** limited to what is necessary
- **Confidentiality** of information and commercial interests protected
- **Fees equitable**
- **Siting of facilities** does not cause unnecessary inconvenience
- CAP to changed product requirements limited to what is necessary to provide **adequate confidence of conformity**
- Procedure exists to review **complaints** and take corrective action

An example: Russia – Railway Equipment (Ukraine) (DS 499)



"inspection control"

"conditions for the conduct of inspection control were lacking"

WT/DS499/R, para. 7.583

Article 5.2.2, third obligation

*…the competent body transmits … the results of the assessment in a **precise and complete manner** to the applicant*

in respect of 13 instructions suspending certificates: "Russia has acted inconsistently with the third obligation in Article 5.2.2."

WT/DS499/R, para. 7.591

Current status

Panel report under appeal on **27 August 2018**

Arrangements to facilitate CAP

(encouraged in TBT Agreement)

- International or regional systems for conformity assessment (article 9)
  - "Members shall, wherever practicable, formulate and adopt international systems for conformity assessment"
- Recognition of foreign conformity assessment results (article 6)
  - "verified compliance, for instance through **accreditation**, with relevant guides or recommendations issued by international standardizing bodies shall be taken into account as an indication of adequate technical competence"
  - Encouragement to negotiate **MRAs**

Conformity Assessment and Quality Infrastructure

CONFORMITY WITH TECHNICAL REGULATIONS AND STANDARDS

TBT agreement, article 5.4

In cases where a positive assurance is required that products conform with technical regulations or standards, and relevant guides or recommendations issued by international standardizing bodies exist or their completion is imminent, Members shall ensure that central government bodies use them, or the relevant parts of them, as a basis for their conformity assessment procedures, except where, as duly explained upon request, such guides or recommendations or relevant parts are inappropriate for the Members concerned, for, *inter alia*, such reasons as: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment; fundamental climatic or other geographical factors; fundamental technological or infrastructural problems.

TBT agreement, article 9.1

Where a positive assurance of conformity with a technical regulation or standard is required, Members shall, wherever practicable, formulate and adopt international systems for conformity assessment and become members thereof or participate therein.

Enforcement of Technical Regulations ("positive assurance is required")

- Interpretation of the law
  - Understanding the direct and indirect requirements in the law

- Execution of Authority through:
  - Control of the fulfilment of formalistic administrative provisions
  - Risk assessment
  - Document control
  - Physical control
    - Inspection
  - Analytical control
    - Testing and inspection
  - Trust building
    - Certification
  - Corrective actions
    - Correcting non compliances
    - Transparency approaches
    - Sanctions/Fines
    - Courts
    - Etc.

Conformity Assessment (Private/public)

Competent Authority Decision

Legal Framework,

Bases for the Regulatory and Quality Infrastructure Development

- **Three main types of laws:**

- Sectorial laws where the minimum requirements for safety of product on the market are established, including administrative provisions (legitimate objectives, accountability, enforcement mechanisms, roles and responsibility of involved parties, corrective actions, sanctions etc.)

Note: Quality not an issue for the legislator

- Generic laws where the roles and responsibility of support institutions are defined such as Standardisation, Accreditation and Metrology. Product safety and product liability legislation etc.

Note: Requirements on testing, certification and inspection are usually included in the sectorial laws as a part of the administrative provisions, however in some cases generic laws covering testing, inspection and certification might be needed (kind of policy making, regarding their status and roles and responsibilities)

- Consumer protection laws

Definition (ISO 17 000)

Accreditation

Third-party **attestation (5.2) related to a conformity assessment body (2.5) conveying formal demonstration** of its competence to carry out specific conformity assessment tasks

Attestation

Issue of a statement, based on a decision following **review (5.1), that fulfillment of specified requirements** (3.1) has been demonstrated

NOTE 1

The resulting statement, referred to in this International Standard as a “statement of conformity”, conveys the assurance that the specified requirements have been fulfilled. Such an assurance does not, of itself, afford contractual or other legal guarantees.

NOTE 2 First-party and third-party attestation activities

are distinguished by the terms 5.4 to 5.6. For second-party attestation, no special term is available.

Use of Accreditation

- International Aspects

  International trade

  Tool for establishement of Mutual Recognition of Tests Inspection and Certification

- National Aspects

  Regulatory purposes

  Assessment and establlishment of competence of bodies performing technical coontrol activities

Definition (ISO 17 000)

Inspection

Examination of a product design, product (3.3), process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements

NOTE:

Inspection of a process may include inspection of persons, facilities, technology and methodology.

Definition (ISO 17 000)

Testing

Determination of one or more characteristics of an object of conformity assessment, according to a **procedure (3.2)**

NOTE

"Testing" typically applies to materials, products or processes.

Definition (ISO 17 000)

Certification

Third-party attestation (5.2) related to products, processes, systems or persons

NOTE 1 Certification of a management system is sometimes also called registration.

NOTE 2 Certification is applicable to all objects of conformity assessment except for conformity assessment bodies (2.5) themselves, to which accreditation (5.6) is applicable.

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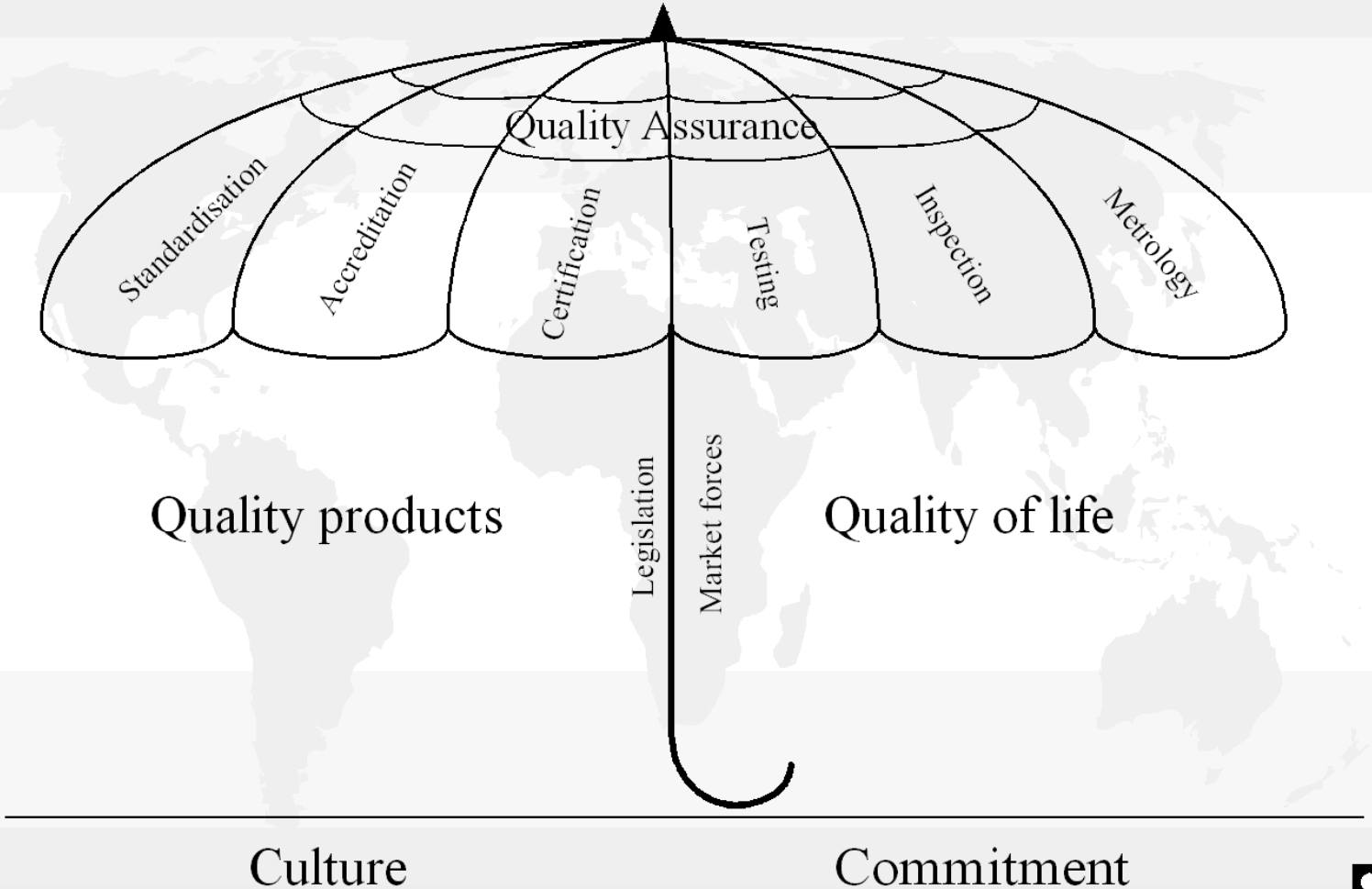
Quality Infrastructure



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TBT Agreement and Accreditation

- Trade facilitating benefits of accreditation are recognized in the TBT Agreement
  - Tool to facilitate acceptance of CA results across borders
  - Use of accreditation to establish technical competence of bodies, and provide confidence in reliability of results

How to promote trade facilitating benefits of NQI?

QI and TBT

How to enhance regulator's reliance on NQI (and understanding of its benefits)?

QI and TBT

How to enhance regulator's reliance on NQI (and understanding of its benefits)?

Examples of challenges

Regulators not aware of how to use or trust voluntary (private) international or regional arrangements (e.g. for accreditation, conformity assessment)

Regulators unsure of the type/approach of conformity assessment (1st party? 3rd party?) required relative to risk of the product

Lack of capacity for post market controls (market surveillance)

Legislative framework (incl. establishing QI) does not give regulators needed support or assurance

Lack of domestic coordination between regulators and QI bodies

What’s next in the WTO on conformity assessment and QI?

8th Triennial Review outcomes

- Start negotiation of new guidelines on conformity assessment procedures for regulators

b. with respect to "Approaches to conformity assessment" to *initiate work* on developing non-prescriptive practical guidelines[162] to support regulators in the choice and design of appropriate and proportionate conformity assessment procedures, including, but not limited to, the following areas:

i. criteria related to risk assessment and other relevant factors, including for identification of lower and higher risk products;

ii. the range of approaches to conformity assessment available to regulators within different regulatory frameworks;

iii. elements of conformity assessment that regulators can use in designing appropriate procedures;

iv. legal and administrative frameworks that enable regulators to confidently rely on a particular conformity assessment regime (for example, SDoC may need to be supported by appropriate product recall, product liability laws and consumer protection legislation);

G/TBT/41, para. 4.17

8th Triennial Review outcomes

- Deepen discussion in thematic sessions on CAP:

c. In parallel to the above work, to *hold* thematic sessions on:

i. risk assessment, including: categorization of risks, and methods of risk assessment;

ii. post market controls (e.g. market surveillance) and other pre-market controls;

iii. "Certificates of Free Sale", without prejudice to their use by Members, including on: the range of appropriate and less trade restrictive available alternatives; related challenges faced by regulators and exporters, including with respect to producing certificates when they are not in use in the exporting market; and how these apply to re-exports;

iv. the development of National Quality Infrastructure (NQI), including metrology, standardization, conformity assessment, and accreditation, and its use by regulators;

v. the use of international and/or regional systems for conformity assessment by regulators in both national and regional regulatory regimes; and,

vi. case studies of practical examples of how Members arrive at the acceptance of conformity assessment results (including by using the approaches mentioned in the Committee's "Indicative List"[163]).

G/TBT/41, para. 4.17

Thank you, any questions?

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