

NON-TARIFF MEASURES WEEK

NTMs: The Good, the Bad, and the Ugly

14 - 15 October 2019

Using International Standards to support regulatory cooperation

By

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The views expressed are those of the author and do not necessarily reflect the views of UNCTAD

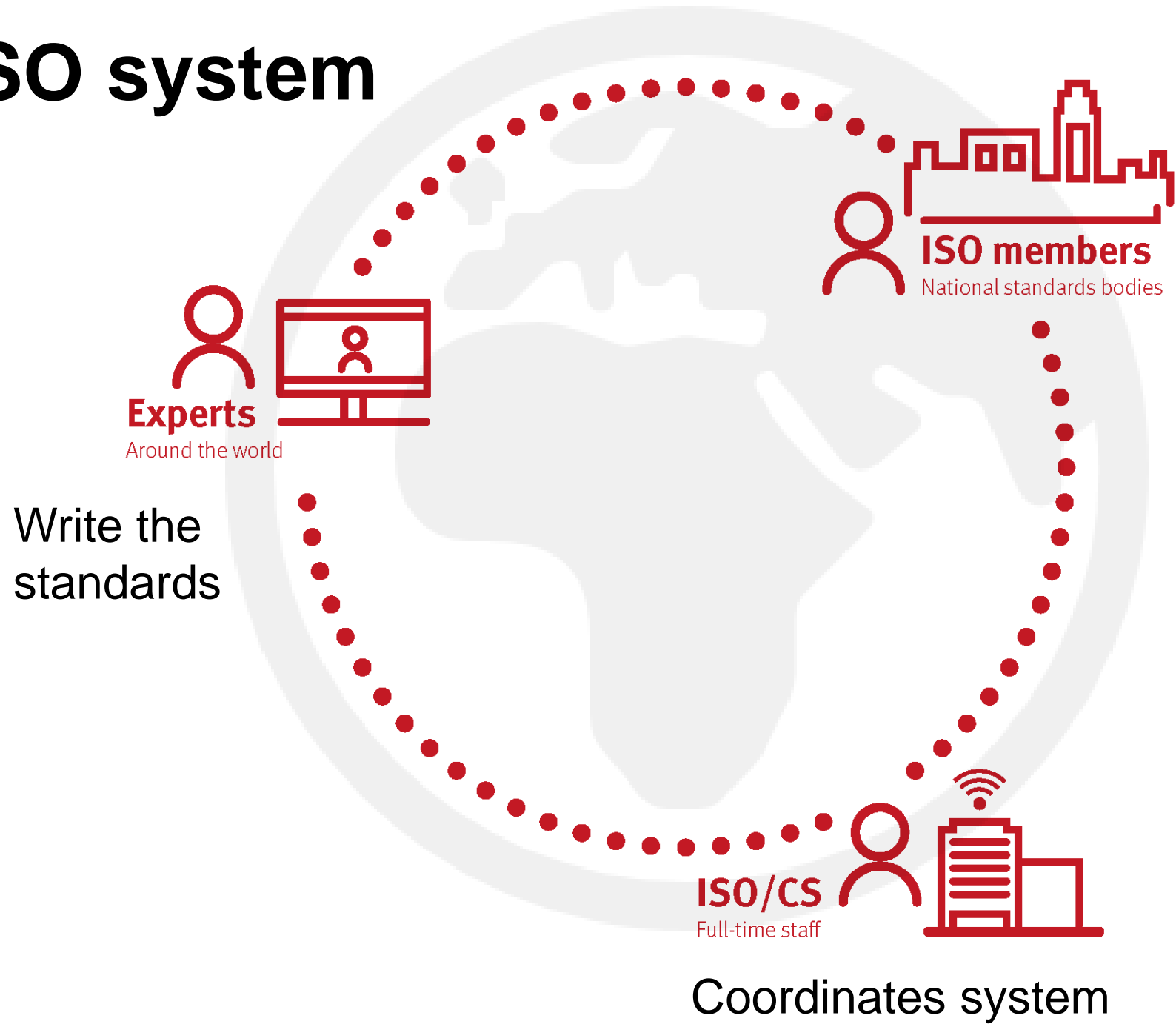
Using International Standards to support regulatory cooperation

Sergio Mujica, ISO Secretary-General

14 October 2019, UNCTAD NTM week



The ISO system



- Represent ISO in their country
- Initiate/approve new standards

What are **International** Standards?

- Represent **global consensus** on a solution to a particular issue
- Embody universally agreed procedure or practice
- Provide requirements, specifications, guidelines or characteristics to consistently ensure that materials, products, processes and services are fit for their purpose

ISO standards do NOT:

- Seek to establish, drive or motivate public policy or regulations, social or political agendas
- Set performance thresholds (these are set by policy makers/regulators according to their requirements)

The Six Principles

WTO TBT Committee Decision on Principles for the Development of International Standards, Guides and Recommendations (November 2000, G/TBT/9)

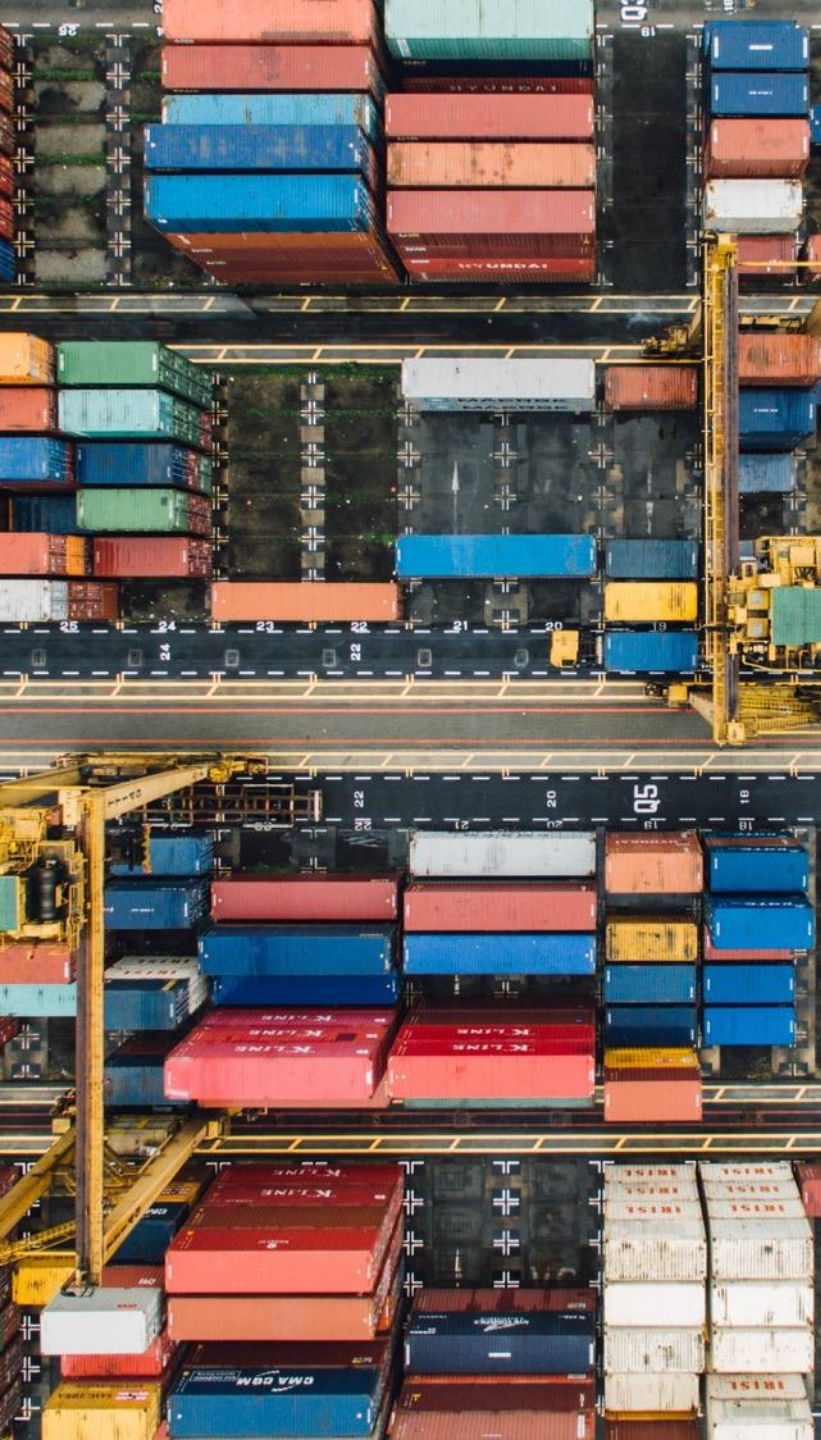
- Transparency
- Openness
- Impartiality and consensus
- Effectiveness and relevance
- Coherence
- Development dimension



Standards and TBT

Referencing ISO standards in regulation is consistent with obligations of the WTO TBT Agreement:

2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.



Trade facilitation

Regulatory differences between countries is amongst the key factors in explaining trade costs related to regulations

Referencing int. standards in regulation

- Drives **regulatory harmonization**
- Boosts export performance
- Facilitates integration into GVCs
- Reduces testing and certification costs



Example: ISO 13485

In Spring 2018, the US FDA announced it will adopt ISO 13485:2015 for medical devices, quality management systems

This will modernizes regulations and **harmonize US domestic and international requirements**, reducing compliance and record-keeping burdens on manufacturers

Cooperation between regulators and standardizers

The core objective:

Policy makers and regulators are enabled to select the most **appropriate**, **effective** and **flexible** instruments to address public policy issues



Best practice

Regulators and NSBs:

- Use tools such as **MoUs**
- Develop a **long-term** relationship and strategy
- Aim for **mutual representation** at each others meetings
- Ensure focused and targeted **liaison** in specific projects
- Consider aligning **technical structures**
- Avoid **duplication** of work

Challenges for ISO

To promote the use of International Standards by regulators, ISO needs to:

- Improve speed to market of standards
- Make standards more easily accessible
- Raise the awareness of regulators (and their trust in standards)
- Communicate better and more often to understand each other's needs and context

Questions?

www.iso.org/policy