Using International Standards to support regulatory cooperation

By

Mr. Sergio Mujica, ISO

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

ISO members
National standards bodies

Experts
Around the world

Write the standards

ISO/CS
Full-time staff

Coordinates system

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

The ISO system
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