

Good Regulatory Practices (GRP) and Technical Barriers to Trade (TBT)

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S T A N D A R D S A L L I A N C E - P H A S E 2



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The term Good Regulatory Practices (also referred to as GRPs) speaks to the quality and consistency of the domestic rulemaking process.

It refers to the internal coordination and review process under which the whole of government works to ensure that rules and regulations are crafted in an open, transparent and participatory manner, and that outcomes are risk-based and grounded in the best available data.



Good Regulatory Practices

3 Things to Remember:

- GRPs aren't about more regulation or less regulation. They're about facilitating better regulatory outcomes.
- Political processes make directional decisions, but GRPs create a professional process to rule-making that follows the political course set. They achieve this by adhering to a transparent and participatory rule-making process, and to evidence-based decision making.
- GRPs are an important precursor to regulatory cooperation. Only quality regulatory outcomes avail themselves of regulatory cooperation opportunities.



Regulatory Cooperation and Regulatory Convergence

- **Cooperation:** it refers to any interaction between regulators from different countries that results in some form of cooperation, with a view to increasing efficiency, while achieving the desired regulatory results.
- **Convergence:** is a form of cooperation – when different countries decide, individually, to modify their existing or proposed regulatory frameworks to bring them to a closer alignment. This can take place throughout the time, but the moment of drawing up regulations in the respective countries is often independent of each other and difficult to synchronize

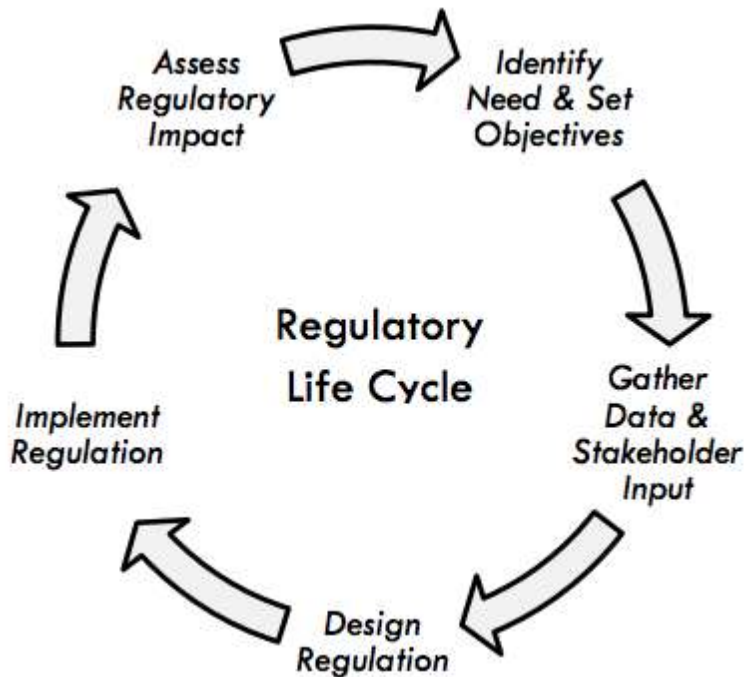


Good Regulatory Practices

1. Issue a Regulatory Forecast
2. Have a National Regulatory Register
3. Provide Opportunity for Public Comment
4. Publish Evidence and Conduct Regulatory Analysis
5. Respond to Stakeholder Input
6. Use Quality Data and Sound Science
7. Employ Risk-Based Approaches
8. Conduct Regulatory Impact Assessments (RIAs)
9. Conduct Pro-Competitive Analysis
10. Assess the International Impact of a Regulation
11. Use International Standards as a basis for National Regulations
12. Conduct Ex-Post Assessments of Regulatory Impacts
13. Establish a Central Regulatory Coordination Body



Regulatory Life Cycle



Important! The implementation of good regulatory practices is a significant step towards cooperation, and that the regulations being designed produce results that generate less cross-border rights.



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USAID Internal Launch Meeting

Good Regulatory Practices

- Good Regulatory Practices encompassing the use of regulatory impact assessments, stakeholder engagement and ***ex post* evaluation** are a **critical tool** in the hands of governments to ensure that regulation achieves its objectives.
- Over the past several years, attention has grown for the **trade costs of regulatory divergence**. Diverging regulation may increase the costs to trade goods and services across borders.



OECD Guidelines for GRP

- The 2012 OECD Recommendation highlights a number of principles and tools that can help policy makers develop, implement and update regulations that promote their policy goals in the public interest
- The recommendation recognizes the importance of international regulatory cooperation for regulatory quality and the relevance of the tools of regulatory policy – **encompassing *ex ante* Regulatory Impact Assessment (RIA), stakeholder engagement and *ex post* evaluation** – to base regulatory policy making on evidence, including the evaluation of the likely benefits, costs and effects of regulation and the consideration of the voice of the regulated.



Example: USMCA GRP Chapter

- **Central Regulatory Coordination Body**
- Internal Consultation, Coordination, and Review
- Information quality
- Early Planning
- Dedicated Website
- Use of Plain Language
- Transparent Development of Regulations
- Expert Advisory Groups
- Regulatory Impact Assessment
- Final Publication
- Retrospective Review
- Suggestions for Improvement
- Information About Regulatory Processes
- Annual report
- Encouragement of Regulatory Compatibility and **Cooperation**
- Committee on Good Regulatory Practices
- Contact Points
- Dispute Settlement



Q & A



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The WTO Technical Barriers to Trade Agreement (TBT) as GRP

STANDARDS ALLIANCE - PHASE 2



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Outline

- WTO General Rules
- Non-Tariff Trade Barriers
- Coverage of the TBT Agreement
- Main Principles of the Agreement
- Relevant Provisions
- ePing System



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WTO General Rules

- The only international body dealing with rules of trade between nations (164 Members).
- WTO agreements provide the legal ground-rules for international commerce.
- They bind governments to keep their trade policies within agreed limits.
- Help trade flow as freely as possible (e.g. by removing obstacles, providing confidence, transparency and predictability).



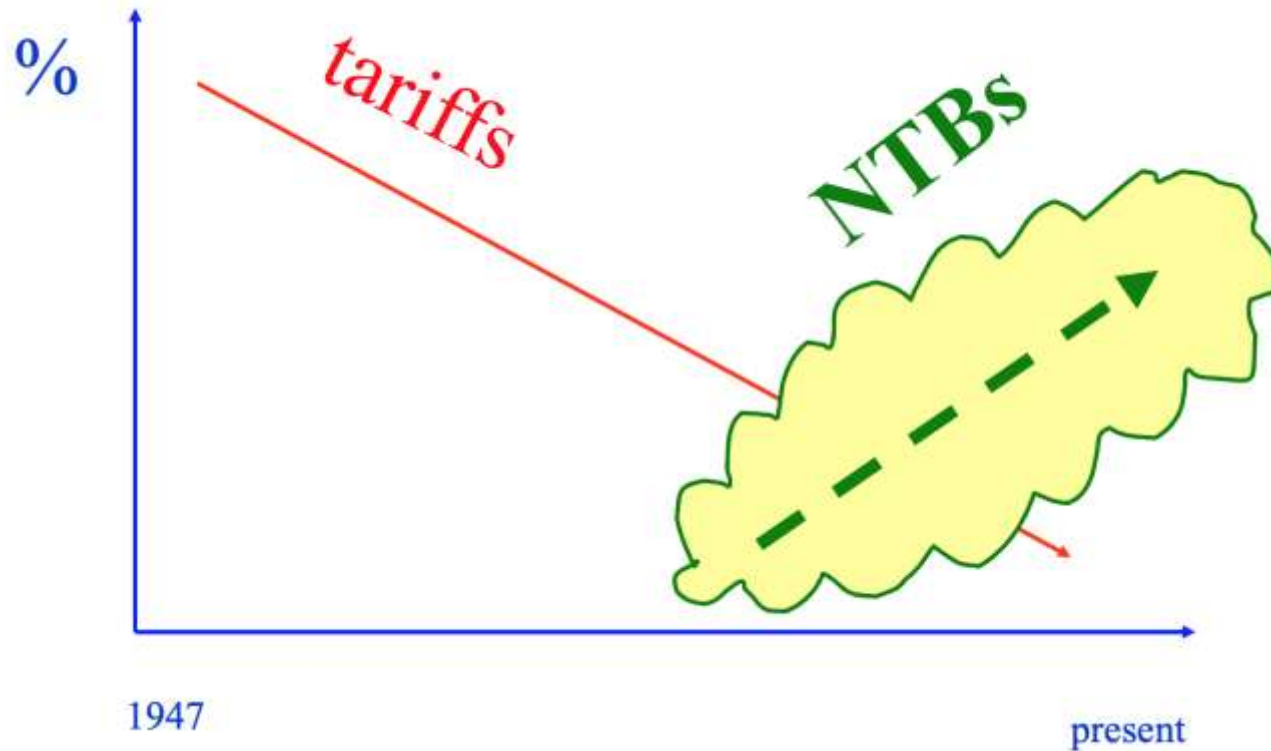
Non-Tariff Barriers to Trade

- Technical measures (e.g. in standards)
- Internal taxes or charges
- Customs rules and procedures
- Quantitative import restrictions
- Public procurement practices
- Subsidies and related government supports
- Investment restrictions or requirements
- Transport regulations or costs ...



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Non-Tariff Barriers to Trade



Coverage of the TBT Agreement

- Technical measures (e.g. in standards)
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The TBT Agreement

- It acts as an instrument to:
 - Encourage Members to use less-trade restrictive approaches to meet regulatory objectives
 - Harmonize through the use of relevant international standards
 - Provide transparency
 - Avoid and resolve trade disputes related to standards matters



- **The Agreement safeguards against:**

- The use of technical requirements as disguised restrictions on trade
- The development of inefficient technical requirements and procedures

The TBT Agreement



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The relevance of the WTO for GRP

- Unnecessary regulatory differences can impose costs that prevent businesses from engaging in trade.
- The WTO plays an important role in supporting efforts to facilitate trade through regulatory cooperation among its 164 members, offering a **multilateral platform for dialogue among governments on trade rules, and throughout the full rule-making cycle.**
- The disciplines of the TBT Agreement can help contribute with effectiveness and efficiency of regulations through GRP. It lays down specific legal disciplines, which directly address the preparation, adoption and application of domestic regulations on goods.
- The TBT Agreement provides a unique multilateral transparency framework for regulations affecting the trade in goods.



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TBT Agreement: main principles

- Non-discrimination
- Avoidance of unnecessary barriers to trade
- Harmonization through the use of international standards, guides and recommendations
- Transparency (notifications and enquiry points)
- Concepts of equivalence of technical regulations and mutual recognition of results of conformity assessment procedures



TBT Agreement

- Article 2.2: Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of **creating unnecessary obstacles to international trade.**
- Article 2.3: Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a **less trade-restrictive manner.**
- Article 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.



Principles to Develop International Standards

- The WTO Committee on Technical Barriers to Trade adopted a set of principles to which an organization engaged in the development of international standards must comply.
- These principles have been captured in document “G/TBT/ 1/REV. 8. Section IX,” titled ***Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement.***



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TBT Agreement - Definitions

Annex 1 of the TBT Agreement

Technical Regulation:

A document that lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory.

Standard:

A document approved by a recognized 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

Conformity Assessment: Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled. Includes, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval.



Major Medical Technology Regulatory / Trade Challenges

1. TBT agreement not implemented with most medical device regulators

- Most medical device regulators (staff drafting regulations) either not aware of the TBT agreement or not required to implement it by trade ministries
- Most medical device regulators are not aware of the IMDRF guidance documents and the hundreds of relevant medical device standards upon which they should be basing their regulations (ISO, IEC, et al.)
- Most medical device regulators still opting to dedicate their limited public health resources towards developing their own country/agency-unique requirements
- If there is awareness of the TBT agreement, implementation is ex post and not ex ante

2. Medical devices improperly regulated as drugs



ePing system - WTO



ePing is an SPS & TBT notification alert system is a publicly available and self-subscribing service, whereby subscribers are able to receive email alerts regarding SPS and TBT notifications covering particular products and/or markets of interest to them.



In addition, users can search notifications, share notifications, upload additional information and participate in discussions.



ePing also offers an Enquiry Point Management Tool to facilitate domestic as well as international information sharing and discussion.



ePing system - WTO

 **track product requirements in export markets**



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ePing enables timely access to evolving product requirements and facilitates dialogue amongst the public and private sector in addressing potential trade problems at an early stage.

Search

Search notifications on product requirements, filtering by specific products or export markets

Receive alerts

Register for free to receive email alerts on new SPS & TBT notifications

Collaborate

Once registered, benefit from additional features such as the national forum

64108

notifications included

[#epingalert](#),
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Step-by-step video on how to set up an email alert on COVID-19 related notifications



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Country/territory	City	Address	Contact	Email	Phone	Website
Search by country/territory =						
Afghanistan		Jalalabad Highway Industrial Parks, Kabul P.O Box No: 5172 Central Post Office, Kabul	WTO/TBT Enquiry Point	noorhabib31@gmail.com	(+93) 75 20 86 743; (+93) 77 1 76 79 95	
Afghanistan		Kabul - Jalalabad Highway Industrial Parks Kabul P.O Box No: 5172 Central Post Office, Kabul	Afghan National Standards Authority (ANSA)	tbt@ansa.gov.af	(+ 93)75 20 86 74 3; (+93)77 17 67 99 5	http://ansa.gov.af
Albania		Rr: "Mine Peza", Nr.143/3	General Directorate of Standardization Tirana - Albania Contact person: Mr. Riza Hasanaaj, General Director of General Directorate of Standardization Head of Sector of WTO/TBT	info@dps.gov.al; hasanaaj.r@dps.gov.al; dea.nimi@dps.gov.al	+(355 42) 22 62 55; +(355 42) 22 71 76	http://www.dps.gov.al/



Q & A



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Thank You!



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