# WORLD TRADE

# **ORGANIZATION**

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**Committee on Technical Barriers to Trade** 

### COMPILATION OF SOURCES ON GOOD REGULATORY PRACTICE

Background Note by the Secretariat<sup>1</sup>

At the Fifth Triennial Review of the WTO Agreement on Technical Barriers to Trade (hereafter "the TBT Agreement"), in November 2009, delegations agreed inter alia to compile a list of guidelines for Good Regulatory Practice taking into account Members' experiences and existing relevant work of other organizations.<sup>2</sup> The present note is intended to compile a first, non-exhaustive list of sources on Good Regulatory Practice, including - where they exist - guidelines. It also contains summarized information drawn from Members' submissions and discussions to date in the TBT Committee on the subject of Good Regulatory Practice.

Members are invited to provide further inputs to this note, including by identifying other relevant references (Section 2) and/or by updating the summarized information in Section 3.<sup>3</sup>

### I. **INTRODUCTION**

There has been considerable information exchange on Good Regulatory Practice in the WTO TBT Committee. The subject has been addressed in all five triennial reviews of the TBT Agreement and discussed at a Workshop on Good Regulatory Practice held on 18-19 March 2008.<sup>4</sup> In addition, background information has been provided in three notes by the Secretariat, including a recent one on regulatory cooperation between Members.<sup>5</sup>

- In the context of TBT Committee discussions, Good Regulatory Practice is used to describe the practical implementation of the TBT Agreement. The emphasis is on how best to implement the provisions of the Agreement to achieve a particular policy objective. Effective implementation through best practices is seen as an important means to avoid unnecessary obstacles to trade.
- Multilateral efforts to address governments' regulatory policies are not limited in relevance to the TBT Agreement, or even to international trade. Indeed, "regulatory reform" - which applies in

<sup>&</sup>lt;sup>1</sup> This document has been prepared under the Secretariat's own responsibility and is without prejudice to the positions of Members and to their rights and obligations under the WTO.

<sup>&</sup>lt;sup>2</sup> G/TBT/26, para 11(a).

<sup>&</sup>lt;sup>3</sup> Such information may be communicated to the WTO Secretariat by e-mail to Ms Una Flanagan (una.flanagan@wto.org).

<sup>&</sup>lt;sup>4</sup> A Summary Report of the WTO TBT Workshop on Good Regulatory Practice is contained in document G/TBT/W/287.

<sup>&</sup>lt;sup>5</sup> Background note for the preparation of the Fourth Triennial Review (JOB(05)/107, 14 June 2005), Good Regulatory Practice (JOB(08)/7, 22 February 2008), and Regulatory Cooperation Between Members (JOB/TBT/10, 18 May 2011), respectively.

<sup>&</sup>lt;sup>6</sup> The OECD defines this concept as "Changes that improve regulatory quality, that is, enhance the performance, cost-effectiveness, or legal quality of regulations and related government formalities. This term can mean: revision of a single regulation, the scrapping and rebuilding of an entire regulatory regime and its

connection with the Committee's discussions of Good Regulatory Practice - is a wide-ranging concept that relates to many areas where governments regulate, including, for instance, efforts to combat corruption. So as not to *a priori* exclude information that may be of use to delegations in the specific WTO TBT Committee context, the sources listed below may also cover areas that are relevant - in this broad sense - to regulatory reform.

### II. ORGANIZATIONS

### **APEC**

APEC has played a strong role in promoting the use of good regulatory practices since 1989. Two committees within APEC have been important in this respect. The Economic Committee of APEC works on identifying the principles and procedures constituting GRP. In addition, the Committee on Trade and Investment Subcommittee on Standards and Conformance analyses the role of GRP in strengthening the implementation of WTO rules and in the reduction of unnecessary barriers to trade. The following illustrate some other significant milestones in APEC's work on GRP:

1999: APEC Leaders' endorsement of the APEC Principles to Enhance Competition and Regulatory Reform highlighted the importance of concepts such as non-discrimination, transparency, and accountability in developing and implementing regulations.

2000: APEC members endorsed the APEC-OECD Cooperative Initiative on Regulatory Reform. It was recognized in this context that regulatory reform is a central element in the promotion of open and competitive markets, and a key driver of economic efficiency and consumer welfare.

2001: The SCSC was directed by the Osaka Action Agenda to implement initiatives aimed at improving regulatory programs and standards development processes, as well as at promoting more transparent and better aligned voluntary and mandatory standards.

2004: The Leaders' Statement to Implement APEC Transparency Standards laid down guidelines aimed at enhancing openness, accessibility, and participation with respect to laws, regulations, and rulings.

2005: APEC's endorsement of the APEC-OECD Integrated Checklist on Regulatory Reform – a policy tool for self-assessment, integrating questions about regulatory quality, competition policy, and market openness. The APEC Competition Policy and Deregulation Group and the OECD Horizontal Programme on Regulatory Reform cooperated closely in the preparation of this checklist.

2011: SCSC's 6<sup>th</sup> Conference on Good Regulatory Practice was held in Washington DC. The conference reviewed the experiences of different countries with the implementation of GRP, to allow an exchange of ideas, and encourage fresh perspectives aimed at pushing forward the GRP mandate. SCSC members also agreed that the information from the Conference would be used to respond to the SCSC's mandate, as indicated in the 2009 revision to the SCSC Terms of Reference to update and revise the SCSC's "Information Notes on Good Practice for Technical Regulation (2000)," "Guidelines for the Preparation, Adoption and Review of Technical Regulation (1996)," and "Principles and Features of Good Practice for Technical Regulation (2000). "http://www.apec.org/Home/Groups/Committee-on-Trade-and-Investment/Sub-Committee-on-Standards-and-Conformance"

	2011	6 <sup>th</sup> Conference on Good Regulatory Practice http://aimp.apec.org/MDDB/Pages/search.aspx?setting=ListMeeting&Date Range=2011/03/01%2C2011/03/end&Name=6th%20Conference%20on%2 0Good%20Regulatory%20Practice%202011
	2005	APEC-OECD Integrated Checklist on Regulatory Reform http://www.oecd.org/dataoecd/41/9/34989455.pdf
	2000	Information Notes on Good Practice for Technical Regulation http://www.jisc.go.jp/eng/apec-asem/pdf/grp_info.pdf

ASEAN	The promotion of Good Regulatory Practice is an integral part of the work programme of ASEAN Consultative Committee on Standards & Quality (ACCSQ). The Committee seeks to improve the consistency and transparency of technical regulations, thereby reducing unnecessary obstacles to trade.  Information about the work of ASEAN on Good Regulatory Practice can be found at: <a href="http://www.aseansec.org/4951.htm">http://www.aseansec.org/4951.htm</a>	
	2009	ASEAN Good Regulatory Practice (GRP) Guide http://www.aseansec.org/22487.pdf
	2005	ASEAN Policy Guideline on Standards and Conformance http://www.aseansec.org/20531.pdf

OECD	The OECD Programme for Regulatory Reform aims at helping governments improve regulatory quality. The Programme targets the reform of regulations that raise unnecessary obstacles to competition, innovation and growth, while ensuring that regulations efficiently serve important social objectives. The objective of this programme is promoted in four ways: policy recommendations, country reviews <sup>7</sup> , thematic discussions, and cooperation with non-member countries.  For more information on OECD's work with respect to regulatory reform see: <a href="http://www.oecd.org/topic/0,3373,en_2649_37421_1_1_1_37421,00.html">http://www.oecd.org/topic/0,3373,en_2649_37421_1_1_1_37421,00.html</a>		
	2009	Indicators of Regulatory Management Systems, 2009 Report, Regulatory Policy Committee <a href="http://www.oecd.org/dataoecd/44/37/44294427.pdf">http://www.oecd.org/dataoecd/44/37/44294427.pdf</a>	
	2009	Regulatory Impact Analysis: A Tool for Policy Coherence, OECD Publishing, Paris. <a href="http://www.keepeek.com/Digital-Asset-">http://www.keepeek.com/Digital-Asset-</a> <a href="Management/oecd/governance/regulatory-impact-">Management/oecd/governance/regulatory-impact-</a> <a href="mailysis-9789264067110-en">analysis-9789264067110-en</a>	
	2005	Guiding Principles for Regulatory Quality and Performance <a href="http://www.oecd.org/dataoecd/19/51/37318586.pdf">http://www.oecd.org/dataoecd/19/51/37318586.pdf</a>	
	1997	Recommendation of the Council of the OECD on Improving the Quality of Government Regulation, including the OECD Reference Checklist for Regulatory Decision-Making and Background Note <a href="http://www.oecd.org/dataoecd/17/25/2391768.pdf">http://www.oecd.org/dataoecd/17/25/2391768.pdf</a>	

 $<sup>^{7}</sup>$  To date, 23 reviews of OECD members have been completed as well as 3 reviews of non-members: Russia (2005), Brazil (2008), China (2009).

1995	Recommendations for Improving the Quality of Government Regulation
	"http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=OCDE/
	GD(95)95&doclanguage=en%20"

### **UNECE**

The UNECE Working Party on Regulatory Cooperation and Standardization Policies (Working Party 6) is an intergovernmental group of experts that elaborates recommendations and good practices on a variety of policy matters relating to technical regulations; standardization; conformity assessment (testing, certification, inspection, etc.); accreditation; market surveillance; quality/environmental management systems and metrology. The Working Party is open to all UN member States as well as intergovernmental organizations and non-governmental organization recognized by the United Nations Economic and Social Council (ECOSOC). Private sector representatives may also participate if nominated by a member State Head of Delegation or at the invitation of the secretariat.

More information about UNECE's work on Good Regulatory Practice can be found at: <a href="http://www.unece.org/">http://www.unece.org/</a>.

2009	What UNECE does for you UNECE works for better and convergent		
	regulations -		
	http://www.unece.org/trade/wp6/AreasOfWork/RegulatoryCooperation/Reg		
	ulatoryCooperation-Brochure.pdf		
2009	A Common Regulatory Language for Trade and Development		
	http://www.unece.org/publications/oes/TRADE.CommonRegulatoryTradeDev.E.pdf		

### World Bank

The Better Regulation for Growth Program is an initiative of the Investment Climate Advisory Services of the World Bank (in partnership with UK Department for International Development and the Dutch Ministry of Foreign Affairs). It develops guidance and tools to assist developing countries in undertaking regulatory reform In particular, the program is aimed at improving regulatory and investment environments in developing countries, towards the achievement of economic growth, private investment and poverty reduction. A core element of the program is the compilation of experiences and lessons from regulatory governance initiatives in developing countries, so as to better inform future reform efforts. The program also seeks to adapt and implement existing best practices for regulatory reform, such as the OCED regulatory reform agenda, to developing country contexts. For example, one study sought to adapt OECD best practice on Regulatory Impact Assessment (RIA) to meet the needs and constraints of developing countries, creating the so-called 'RIA Light' approach. A number of policy papers and guidelines (on regulatory quality indicators, RIA and other regulatory review mechanisms), as well as regulatory reform case studies have been prepared under this program.

More information on this work, and other relevant materials, can be found at: "https://www.wbginvestmentclimate.org/advisory-services/regulatory-simplification/business-regulation/better-regulation-for-growth/brg.cfm"

2010	Regulatory Quality Indicators "https://www.wbginvestmentclimate.org/uploads/OverviewRegulatoryQualityIndicators.pdf"
2010	Making it Work: 'RIA Light' for Developing Countries <a href="http://www.wbginvestmentclimate.org/uploads/RIALightNov2009.pdf">http://www.wbginvestmentclimate.org/uploads/RIALightNov2009.pdf</a>
2010	Tools and Approaches to Review Existing Regulations https://www.wbginvestmentclimate.org/uploads/BRGTools.pdf
2010	Regulatory Governance in Developing Countries  "https://www.wbginvestmentclimate.org/uploads/RegulatoryGovinDevCountries.pdf"
2009	Lessons for Reformers: How to Launch, Implement and Sustain Regulatory Reform  "http://www.ifc.org/ifcext/fias.nsf/AttachmentsByTitle/FIAS CaseStudies Lessonsforreformers/\$FILE/Lessonsforreformers.pdf"
2008	Project-Level Indicators <a href="https://www.wbginvestmentclimate.org/uploads/ProjectLevelIndicators.pdf">https://www.wbginvestmentclimate.org/uploads/ProjectLevelIndicators.pdf</a>

### III. MEMBERS

- 4. The following tables set out selected information submitted by Members on Good Regulatory Practice in the TBT Committee. Key elements are summarized in bullet form in the tables below. Information is listed alphabetically and in reverse chronological order (most recent first).
- 5. In summary, Members have stressed:
  - (a) the fundamental importance of transparency and accountability in the development of regulations, and the need for inclusiveness in consultation processes;
  - (b) the importance of internal/domestic cooperation, using a "whole-of-government" approach;
  - (c) the importance of analysis and review and the consideration of alternative measures, including the option not to regulate;
  - (d) the merits of the use of RIAs to facilitate regulatory decision-making;
  - (e) the benefits of a responsive regulatory system, including the capacity to detect emerging issues;
  - (f) the advantages of performance-based regulation;
  - (g) the importance of simplicity in regulation;
  - (h) that GRP is an important component of capacity-building initiatives;
  - (i) that the preparation of a "guide" on GRP could be particularly helpful for developing countries; and
  - (j) that regulatory cooperation between Members is an important component of GRP.

Brazil	• Effectiveness: Regulations need to be legally, politically, economically, and socially robust, to be effective. They must be in line with the law, and must account for the socio-economic and environmental aspects of their impact on society. The effectiveness of the regulation is also impacted by its rationality, in that it must be based on scientific grounds, and must stay within the bounds of meeting needs of society. It should also be implemented at a level as close as possible to the citizens.
	<ul> <li>Impartiality: Technical regulations must be impartial, clear, and expressed in a language accessible to all. The application of regulations must also be impartial, and similar situations must be treated similarly.</li> </ul>
	<ul> <li>Morality: Regulations must be based on and guided by public moral principles, and should respect the commitment of the government, as well as bilateral and multilateral international agreements. They should respect principles of competition, fair trade and investment facilitation.</li> </ul>
	• <i>Transparency:</i> Regulations must be transparent, and participation of all stakeholders must be ensured.
2008	The Brazilian Guide on Good Regulatory Practices http://www.inmetro.gov.br/qualidade/pdf/guia_ingles.pdf
2008	Boas Práticas Regulatórias: Guia para o Programa de Melhoria do Processo de Regulamentação da Anvisa <a href="http://www.anvisa.gov.br/institucional/anvisa/pmr/GuiaBPReg.pdf">http://www.anvisa.gov.br/institucional/anvisa/pmr/GuiaBPReg.pdf</a>

Canada	<ul> <li>Performance-based regulation: Performance-based regulation sets the objective to be met (by the measure) rather than prescribing the means to achieve it. There should be a focus on achieving a desired outcome, rather than assuming that a particular instrument, for example a law or regulation, is the most appropriate means to achieve it.</li> </ul>
	• Evidence-based regulation: Cost-benefit, risk analysis and performance measurement and evaluation result in better regulations. Added rigor and discipline to the analysis will promote more effective and efficient regulations.
	<ul> <li>Regulatory Impact Assessments (RIAs): An RIA is a practical tool to facilitate regulatory decision making, emphasizing desired objectives.</li> <li>Regulatory Cooperation: Regulatory cooperation has improved the identification of alternative approaches to addressing common problems and objectives.</li> </ul>
	• Capacity building: Good Regulatory Practice may be an important component of capacity building initiatives, particularly with respect to systems for regulatory review.

November 2007	Canada – Costa Rica Competitiveness Development Fund Projects National Quality System of Costa Rica G/TBT/W/283 (joint submission with Costa Rica)
March 2006	Advancing the Discussion of Instrument Choice under Good Regulatory Practice G/TBT/W/264
June 1998	National Experiences with Technical Regulations G/TBT/W/71
On-going Work	Extensive regulatory guidance and support documents including but not limited to the <u>Cabinet Directive on Streamlining Regulations (CDSR)</u> , <u>Triage Statements</u> , <u>Regulatory Impact Analysis Statement (RIAS)</u> and the <u>Canadian Cost-Benefit Analysis Guide</u> <u>www.regulation.gc.ca</u>

Colombia	• Regulatory Impact Assessment (RIAs): Regulation should be adopted, when necessary, solely on the basis of the risk associated with the products, and should be in conformity with international standards. Assessment of the impact of regulation is one of the key elements of achieving efficient and effective regulation.
	• Equivalence: Mutual adjustment may be facilitated by a procedure that facilitates equivalence of regulations between WTO Member, or, if that is not possible, a procedure that can shed light on the differences in regulatory processes.
	• Regional cooperation: Cooperation in the area of standardisation at the regional level (in Colombia's case the Andean Community) may enable achievement of equivalence of certain voluntary standards, which can be used as a starting point for developing technical regulations.
October 2006	Fourth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade G/TBT/W/269
June 2004	Colombia's Experience with Good Regulatory practice G/TBT/W/239

# Examining the costs of alternative measures: Evaluating countries' regulations means examining possible alternatives. A complete evaluation involves the examination of potential costs and consequences of each alternative, for both the country issuing the regulation as well as the countries which would have to comply with it. When assessing the costs and consequences of a regulation two main types of costs should be considered: the cost of complying with the regulation, and the cost of demonstrating compliance with the regulation. Often the latter exceeds the former. Capacity building: Good Regulatory Practice may be an important component of capacity building initiatives, particularly with respect

	to systems for regulatory review.
November 2007	Canada – Costa Rica Competitiveness Development Fund Projects National Quality System of Costa Rica G/TBT/W/283 (joint submission with Canada)
June 2006	Fourth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade G/TBT/W/266

European Union	Performance-based regulation: Performance based regulation is more easily adaptable and encourages innovation.
	<ul> <li>Proportionality, effectiveness, necessity: The process of formulation of regulations should ensure that while regulations might serve legitimate ends, regulation should not be more trade-restrictive than necessary to achieve set objectives. The principle of proportionality should ensure that the necessity and effectiveness of the measures is weighed against the objective pursued.</li> </ul>
	Better Regulation / simplification: Better regulation includes simplifying existing regulations, enhancing the preparatory process for new regulations, and efforts at reducing regulatory burden.
	<ul> <li>Regulatory Cooperation: Regulatory cooperation between countries can be viewed as an element of Good Regulatory Practice. It can help avoid unnecessary obstacles to trade and ensure that measures are not more trade restrictive than necessary.</li> </ul>
	<ul> <li>Regulatory Impact Assessment (RIAs): An RIA is an important tool to evaluate the potential economic, social and environmental implications of regulation, as well as to screen regulations for potential competitiveness and competition impacts. RIAs should also seek to simplify regulation, wherever possible, and include an analysis of the option of not regulating.</li> </ul>
(Regularly updated)	Better Regulation in the European Union <a href="http://ec.europa.eu/governance/better_regulation/index_en.htm">http://ec.europa.eu/governance/better_regulation/index_en.htm</a> (Thematic website providing comprehensive information and links to all regulatory and policy documents as well as any studies produced by or on behalf of the European Commission in the Better Regulation field)
2010	European Commission Communication "Smart Regulation in the European Union" (COM(2010)543 final)  "http://eur- lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:0543:FIN:EN:PDF"
2009	Third Strategic Review of Better Regulation in the European Union (COM(2009) 15 final)  "http://eur- lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0015:FIN:EN:PDF"
	European Commission Guidelines for carrying out impact assessments  "http://ec.europa.eu/governance/impact/commission_guidelines/commission_guidelines_en.htm"
2005	Good Regulatory Practice

	G/TBT/W/254
2003	Recent European Commission Developments in the Field of Better Regulation G/TBT/W/219
2002	A Policy Framework for the Facilitation of Trade in the Fields of Standardization and Conformity Assessment: A toolbox of Instruments G/TBT/W/173/Add.1

Hong Kong, China	• Equivalency: Hong Kong, China used examples of standards in the area of toys and children's products to illustrate how an effective implementation of the equivalency principle may facilitate trade.
November 2000	Equivalency Experience Paper – Toys and Children's Products Safety Ordinance G/TBT/W/148

# Mexico Preparation of a Guide: Some market access challenges result from incorrect implementation of the substantive obligations laid down within the TBT Agreement. One solution to this issue could be the preparation of a Guide to Good Regulatory Practice, which would allow Members to assess, in advance, the extent to which their regulations would meet obligations under the TBT Agreement. This could be particularly helpful for developing countries. Representativeness and consensus: Sectors that are considered to be affected by the application of technical standards and regulations, both within and outside the country, should participate in their drafting and eventual amendment. Transparency: In the interest of transparency and ease of access to regulations, it should be ensured that any interested party is able to access the content of the draft as well as final versions of the documents in question. All subjects covered by technical regulations should be published in one place and this publication should be notified to the TBT Committee. Analysis and review: Efforts should be made to ensure that regulations are not more trade restrictive than necessary to ensure the fulfilment of the desired legitimate objective. This requires analysis of economic and social impacts of the regulations, as well as periodic review. Rationale: In order to ensure that technical regulations are no more trade restrictive than necessary, it is important to prepare regulatory impact assessments (RIAs) with a view to carrying out a legal, economic and social study of the regulation that is to be published. Harmonization: Technical regulations and standards are expected to be consistent with international standards, or the relevant parts of

international standards, except where they do not constitute an efficient or suitable means to achieve the legitimate objective sought.

June 2009	Fifth Triennial Review of the Agreement on Technical Barriers to Trade G/TBT/W/313
November 2004	Good Regulatory Practice G/TBT/W/248
May 2003	Third Triennial Review of the Agreement on Technical Barriers to Trade G/TBT/W/209

New Zealand	• Responsiveness: A cost effective and responsive regulatory system anticipates future problems and opportunities and adapts quickly and effectively. This requires a system that has the capacity to detect and analyse emerging issues.
	<ul> <li>Internal coordination: Internal coordination is critical as Members seek to effectively implement GRP principles and to meet their international obligations. Furthermore, it is an essential basis for successful international regulatory cooperation. New Zealand's "Regulatory Forum" is a model for regulatory coordination among domestic administrative entities. It promotes better alignment between regulators, infrastructure bodies, and policy makers, allowing for a "whole-of-government" approach to Good Regulatory Practice.</li> </ul>
	• <i>Problem identification</i> : The first step in the development process for technical regulations should be to clearly identify the problem that needs to be addressed. Accurate problem definition reduces the risk of choosing inappropriate options for government action or ignoring more effective solutions, and reduces the likelihood of overregulating.
	• Consideration of alternatives: In order to ensure that government intervention meets the TBT objective of good regulation design, it is important that all feasible options are identified and assessed.
	• <i>Transparency:</i> The process of developing technical regulations should be as transparent as possible.
2011	Good Regulatory Practice Submitted by New Zealand at the 6th APEC Conference on Good Regulatory Practice <a href="http://aimp.apec.org/Documents/2011/SCSC/CON1/11">http://aimp.apec.org/Documents/2011/SCSC/CON1/11</a> scsc_con1_003.pdf
2009	Fifth Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade  Comments on the Proposals Discussed at the 25-26 June 2009 Committee Meeting  JOB(09)/74
2008	The Regulators' Forum: A New Zealand Example of Domestic Regulatory Coordination G/TBT/W/294
1997	Requirements of the Agreement on Technical Barriers to Trade Concerning the Preparation, Adoption, and Review of Technical Regulations  Communication from New Zealand - G/TBT/W/44

## **Uganda**

- Guide to Good Regulation: Good regulation is about providing proper protection without imposing harmful unintended side effects. It is also about motivating innovation, growth, formalization and improvement in business performance, by reducing the cost of doing business and creating an environment attractive to private investment.
- Key Questions to ask when considering to regulate:
  - o What is the problem or the risk that you are trying to address?
  - o Whom does the problem or issue affect?
  - O Do you have a good reliable data to show how serious and widespread the problem is/how serious the risk is that is being dealt with?
  - o Can the government realistically solve the problem?
  - o What would happen if no action were taken? What would be the risk?
  - O What outcome do you want are you sure you will achieve this by regulating?
  - What actions other than regulation might be effective?
  - o How will firms especially small firms, government departments, poorer people and the environment be affected by the proposed regulation?
  - O How would the regulation be managed and enforced in this case? If enforcement looks overly difficult or costly, are other options preferable?
  - o How would other potential options be managed and resourced?
  - Is the kind of regulation envisaged consistent with international commitments?
- Understanding the issue and defining the problem: Problem definition must contain an explanation supported by evidence of how serious and widespread the problem is, why the problem has arisen and how the proposed regulation will solve it.
- Risk Assessment: Identify how serious is the danger you are dealing with. Risk assessment helps to understand what the various risks associated with a particular situation are, what controls may be necessary and what form they should take.
- Consideration of Alternatives: For any problem, there will be a range of possible solutions. Making a new law may be one of the solutions, but may not necessary be the best. Alternatives to regulating may include, inter alia: retaining the status quo; reviewing existing regulations; improving information and education; introduction of voluntary schemes, guidelines or codes of practice; self-regulation; using economic incentives or disincentives; and using risk-based insurance or risk pricing.

- Core Themes for Designing Effective Regulations: Simplicity and transparency; avoidance of placing unnecessary burdens on businesses; use of goal-based regulations wherever possible; public accountability; and balancing risk, cost and practical benefit.
- Regulatory Impact Assessment: An analysis of the likely benefits and costs associated with the introduction of a new policy or regulatory proposal helps to understand the full consequences of the regulations on society. By identifying who wins and by how much, and who loses and by how much, it is possible to predict the sorts of decisions that people will likely make when faced with the new law, and the roll-on effects of those decisions. It will also be possible know whether particular groups are likely to be disproportionately or unfairly affected.

### **United States**

- Transparency and Accountability. Openness, transparency and accountability in the design and application of regulations are fundamental to ensuring public confidence in the approach taken to address a particular problem identified.
- Coordination: The development and application of technical regulations and associated conformity assessment requirements often falls within the purview of a broad range of regulatory agencies. Regulatory coordination and cooperation in ensuring Good Regulatory Practice and adherence to TBT obligations is important. Mechanisms for intra-governmental coordination and interface with relevant non-governmental parties are essential.
- "Internalizing" TBT obligations: To ensure domestic compliance
  with the Agreement's obligations, a Member would likely need a law,
  policy, or another administrative mechanism to provide practical
  guidance to ensure all agencies "internalize" TBT obligations when
  designing, revising, or applying technical regulations and associated
  conformance requirements.
- Establishing the need to regulate: Open and transparent processes for examining the need for regulation leads to better decisions. Well-done analyses are valuable tools in the decision-making process. Such processes, if used correctly, will enhance participation by the public and other governments, and regulations will be less likely to create unnecessary trade barriers.

### 2011

Regulatory Strategy: Executive Order 13563, of the US President "http://www.whitehouse.gov/the-press-office/2011/01/18/improving-regulation-and-regulatory-review-executive-order"

Remarks by Mr Cass R. Sunstein, Administrator, U.S. Office of the Information and Regulatory Affairs (OIRA), Office of Management and Budget (OMB), on the subject of "Regulation".

2009

Good Regulatory Practice: The Role of Strong Central Government Coordination in TBT Agreement Implementation US recommendations for the Fifth Triennial Review G/TBT/W/315

2008	Determining the Need to Regulate  Communication from the United States on key features of their regulatory process G/TBT/W/285
2005	Good Regulatory Practice G/TBT/W/258
2003	Third Triennial Review of the TBT Agreement Submission in context of Third Triennial Review G/TBT/W/220
2001	Labelling Good regulatory practice as applied to labelling G/TBT/W/165

Other papers of specific relevance to GRP		
Brazil	Good Regulatory Practice – National Experiences G/TBT/W/267, June 2006	
Chile	Competition Policy and Deregulation Meetings – APEC 2004 JOB(04)/163, November 2004	
Japan	The Introduction of Discussions on Good Regulatory Practice in APEC G/TBT/W/223, July 2003	

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