

Seminar on Good Regulatory Practices

The Brazilian Guide on Good Regulatory Practices

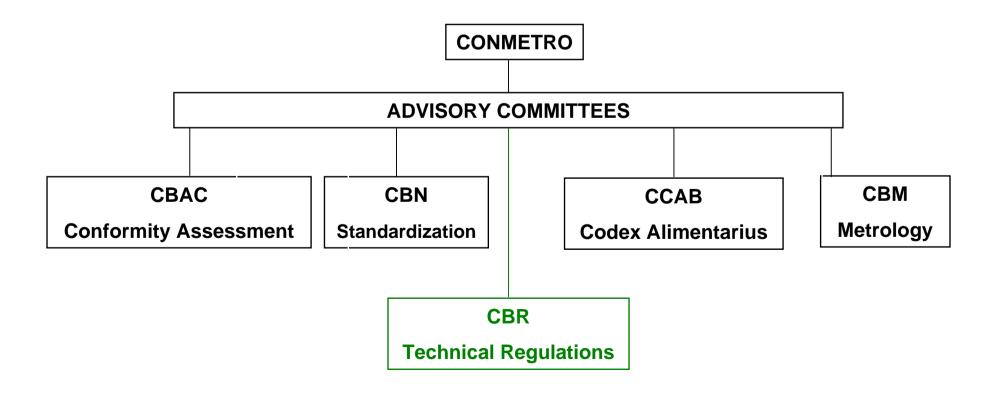
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Director of Quality, Inmetro, BRAZIL Geneva, 18th, March, 2008

- Approach -

- Organization and management
- Objectives
- References used
- Relevant topics
- Dissemination and implementation Plan

- SINMETRO Framework -





- Objectives -

- To facilitate the implementation of international, multilateral, regional and bilateral agreements, considering the Brazilian signatory position, aligning with the international regulatory practices;
- To contribute on the promotion of a major integration among Brazilian regulatory authorities;
- -To contribute to harmonization, consistency and coherence in regulatory practices adopted by Brazilian authorities;
- To contribute to improvement and incentive of technical standards adoption in the elaboration process of technical regulations;
- To contribute to the international recognition of conformity assessment practices adopted in Brazil; and
- To act as an effective instrument for Brazilian industrial and foreign trade polices, promoting the innovation, the social, economical and technological development of Brazil, therefore, facilitating the its international insertion.



- Elaboration Process -

Participation:

- -The effective participation on the elaboration of the national guide on GRP:
 - -14 central government agencies, among 27 existing agencies.

> Main actions:

- Consultancy for the text elaboration (a well-known professional in this area)
- Workshop (counting on the central government regulatory authorities participation)
- Four meetings to reach the consensus
- Final workshop (to analyze and discuss the comments received from the stakeholders)
- Conmetro approval

> Process Period:

- July /2006- December/2007

- References used -

- ✓ ISO/IEC Using and referencing ISO/ IEC standards for technical regulations, 2007;
- ✓ WTO Agreements (TBT, SPS, TRIPS, GATS);
- ✓ OECD Guiding Principles for Regulatory Quality and Performance and the OECD Reference Checklist for Regulatory Decision-Making, 1995;
- ✓ EU Mandelkern Group on Better Regulation: Final Report., 2001 and other EU publications;
- ✓ APEC Information Notes on Good Practice for Technical Regulation, 2000.



- Relevant Topics -

SUMARY

- 1. Introduction
- 2. Scope
- 3. Terms, definition and acronyms
- 4. References
- **5. General Principles on Good Regulatory Practices**
- **6 Technical Regulation: Structure and Content**
- **6.2 Application**
- **6.5 Conformity Assessment Procedures**
- **6.6 General & Transitory Provisions**
- 7 Technical Regulation: Elaboration
- 7.2 Risk Impact Assessment on the Regulation
- 7.3 Evaluation of the Relationship with the Legislation and Agreements
- 7.5 Notification, Consultation and Public Sessions



- Relevant Topics -

- **8 Technical Regulation Adoption**
- 8.1 Approval & Publication
- **8.2 Proceedings in Urgent Situations**
- **9 Technical Regulation Implementation**
- **9.1 Preliminary Cares**
- 9.2 Implementation Period
- 9.3 Assisted Implementation
- 9.4 Common Technological Base (the required infrastructure)
- 9.5 Inspection
- 9.6 Market Surveillance Practices
- 10. Final Considerations
- 10.1 Stakeholders Participation
- 10.3 Critical Analyses
- Annex A Legislation X Regulation X Standardization
- **Annex B The Conformity Assessment Procedure Choice**
- **Annex C Impact Assessment, Considerations and Examples**
- **Annex D Risk Analyses, Method Example**
- **Annex E Inspection and other Market Surveillance Practices**

- Dissemination and Implementation Plan -

- High level Meetings: The CBR Chairman relationship with Regulatory Agencies authorities;
- Guide publication, in Portuguese, Spanish and English;
- Folder publication;
- Material for dissemination actions: folder, presentation (slides set) and the Brazilian Guide;
- Research form;
- Workshop for the regulatory agencies staff;
- Capacity building activities;



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