Japan's Experience and Perspectives on Good Regulatory Practice

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I. What is GRP?

As described in the Fourth Triennial Review (G/TBT/19): ("Future Work")

(a) Factors used by regulators to determine whether there is a need to regulate in a given situation or whether other instruments are better suited to fulfil the legitimate objective sought

(b) The use of tools, such as **regulatory impact assessment**, to assist regulatory decision-making (including with respect to (a) above)

(c) The use of **performance-based regulations** by Members;

(d) How good regulatory practices have been integrated into Members' regulatory structures, including the use of **mechanisms to ensure openness, transparency and accountability of the regulatory processes**

(e) The establishment of domestic administrative mechanisms to facilitate **cooperation and coordination between competent authorities and coordination with other stakeholders**

(f) How **regulatory cooperation between Members** has contributed to the avoidance of unnecessary regulatory differences

(g) Steps taken and criteria used to arrive at an equivalency decision between Members (Article 2.7), or harmonization on the basis of international standards (Article 2.6)

I. What is GRP? (contd.)

Key elements from APEC's "Information Notes on Good Practice for Technical Regulation" (September 2000)

http://www.jisc.go.jp/eng/apec-asem/pdf/grp_info.pdf

Forms of Regulatory Responses

- Consider various forms of regulatory responses (not just technical regulations).
- **Apply tools for regulatory analysis** (e.g., cost-benefit analysis), and continually monitor the effectiveness of regulatory responses.

Technical Regulation

- **Performance-based regulations** are more flexible than prescriptive regulations.
- Make reference to **voluntary standards**; align with **international standards**.
- Achieve equivalency through recognition of standards from other economies.

Conformity Assessment

- **Ensure the greatest degree of compliance at the lowest level of government intervention** (in order of increasing intervention: supplier declarations, listing/registration, certification, approvals, batch testing, licensing, individual inspection).

Limiting the Need for Pre-Market Intervention

- **Regulatory safety nets** (e.g., consumer protection laws, product liability laws) and effective **post-market surveillance** limit the need for pre-market regulatory interventions.

I. What is GRP? (contd.)

Key elements from the "ASEM Guidelines for Best Regulatory Practice" (February 2000)

http://www.asemsca.org/ * ASEM (SCA): Asia Europe Meeting (Standards and Conformity Assessment)

(a) Identify clearly the object of regulation and the need to take account of the most efficient and least trade restrictive means of arriving at its goal.

(b) When establishing a regulation, ensure that:
- it is developed in a transparent manner;
- it does not create unnecessary obstacles to trade;
- it does not discriminate;
- it is limited to **product-related requirements specified in terms of performance characteristics** where appropriate;
- it is subject to review to maintain flexibility and adaptability to modern needs;
- it is streamlined and consistent.

(c) Ensure that regulations are specified in terms of product characteristics, and that **regulations are met or presumed to be met by compliance to standards or guidelines** (preferably aligned with international standards).

(d) Consider decentralization of conformity assessment procedures; **ensure technical competence of CABs by accreditation or peer evaluation**.

(e) Consider **negotiating MRAs** where it is feasible and appropriate.

(f) Seek to move to **supplier's declaration**, backed up by appropriate measures.

II. Japan's Experiences

Elements of Good Regulatory Practice efforts in Japan to be covered in this presentation:

1. Regulatory impact analysis
   - Introduction of RIAs (Oct. 2007)

2. Performance-based regulations

3. Coordination with stakeholders
   - "Market-Access Action Program for Technical Regulations, Standards and Conformity Assessment"
   - One-stop access for public comments on planned government measures

4. Conformity assessment
   - Finding the "best mix" of conformity assessment regimes
   - Conformity assessment by foreign CABs

1. Regulatory impact analysis

Since October 1st, 2007, regulatory impact analysis (RIA) has been made mandatory for all* new regulations, changes to existing regulations, and abolishment of regulations.

* Excluding those specified by Ministerial Ordinance of the Ministry of Internal Affairs and Communication.

The Ministry of Internal Affairs and Communications (MIC) coordinates and oversees the implementation of RIAs by the relevant branches of the government.

The introduction of mandatory RIAs follows a series of studies held by the MIC, as well as a 3-years trial period held between October 2004 and September 2007.

1. Regulatory impact analysis (contd.)

Preliminary studies commissioned by the MIC

- "Study Report on Policy Analysis Methods for Regulations" (July 2004) http://www.soumu.go.jp/hyouka/kisei040722.html
- "Final report of the Study Group on Policy Analysis for Regulations" (September 2007) http://www.soumu.go.jp/s-news/2007/070926_1.html

* Weblinks in Japanese.

Establishing the statutory framework for RIAs by MIC

- Preparation of the statutory framework
- Issuing of the "Implementation Guidelines for ex-Ante Evaluation of Regulations (August 2007)

1. Regulatory impact analysis (contd.)

Topics covered in the Implementation Guidelines for ex-Ante Evaluation of Regulation* (August 2007)

* Provides standard guidance for what kind of analysis should be conducted, the necessary procedures, and other related matters.

- Definitions of purpose, contents, and necessity of regulations
- Identifying: 1) the period of analysis, 2) baseline for estimating costs and benefits, 3) each element of costs and benefits, and 4) secondary or indirect effects
- Classifying cost elements (compliance costs, costs to government and other social factors
- Analyzing cost-benefit relationships (cost-benefit analysis, cost-effective analysis, cost analysis)
- Comparing with the alternatives
- Collecting the views of experts
- Timing for release and conditions for review
- Other points to consider (dealing with uncertainties; coordination between evaluating, legal planning, and other functions)
- Evaluation Report (items to be included, deadline for publication)

1. Regulatory impact analysis (contd.)

Topics covered in the final report (September 2007)

- RIA regimes in the U.S., U.K., and the European Union.
- Specific methods needed for implementing RIAs
  1) Definition of "**regulatory need**"
  2) Establishing the "**baseline scenario**"
  3) Exploring "**alternative scenarios**"
  4) Determination of the "**time-span**" for analysis
  5) Selecting the "**discount rate**" for future events
  6) "**Conceptualizing and defining costs and benefits**"
  7) Calculation methods for "**quantifying costs and benefits**"
     (e.g., risk analysis, monetary conversion, estimating indirect effects)
  8) "**Expressing the results**"
     (e.g., effect charts, cost-benefit analysis, multi-criteria analysis)
  9) Statistical methods for dealing with "**uncertainties**"
     (e.g., sensitivity analysis, break-even analysis, Monte Carlo simulations)
  10) Analyzing the "**effects on competition**"
     (e.g., effects on market structure, effects on new entrants/technology)

1. Regulatory impact analysis (contd.)

Trial period of regulatory impact analysis (October 2004 – September 2007)

- Participation by 13 ministries, 247 cases of RIAs performed.

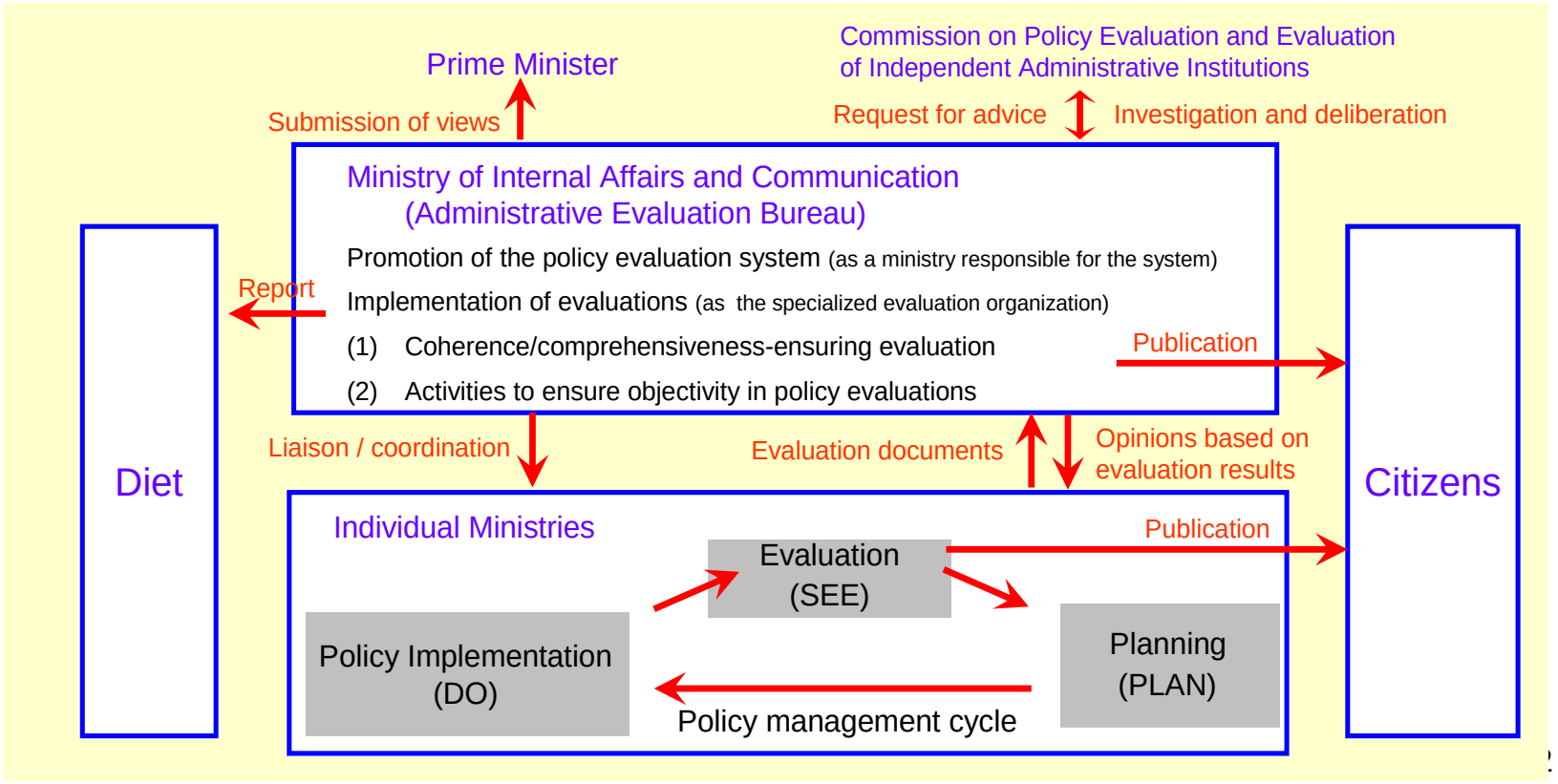
Government agency	Total	Level of regulation			
		Law	Cabinet ordinance	Ministerial ordinance	Other
Fair Trade Commission	3	3	-	-	-
National Public Safety Commission / National Police Agency	23	18	5	-	-
Financial Services Agency	3	-	3	-	-
Ministry of Internal Affairs and Communication	19	10	4	5	3
Ministry of Justice	8	-	-	5	3
Ministry of Foreign Affairs	1	1	-	-	-
Ministry of Finance	1	1	-	-	-
Ministry of Education, Culture, Sports, Science and Technology	12	2	6	10	-
Ministry of Health, Labor and Welfare	11	7	4	-	-
Ministry of Agriculture, Forestry and Fisheries	37	31	6	-	-
Ministry of Economy, Trade and Industry	50	2	9	37	11
Ministry of Land, Infrastructure, Transport and Tourism	27	25	2	-	-
Ministry of the Environment	52	38	14	-	-

1. Regulatory impact analysis (contd.)

Full-scale introduction of RIAs (October 1st, 2007)

- RIAs made mandatory in principle for all regulations by a revision to the “Cabinet Ordinance Implementing the Government Policy Evaluation Act” (Cabinet Ordinance No.157-2007).

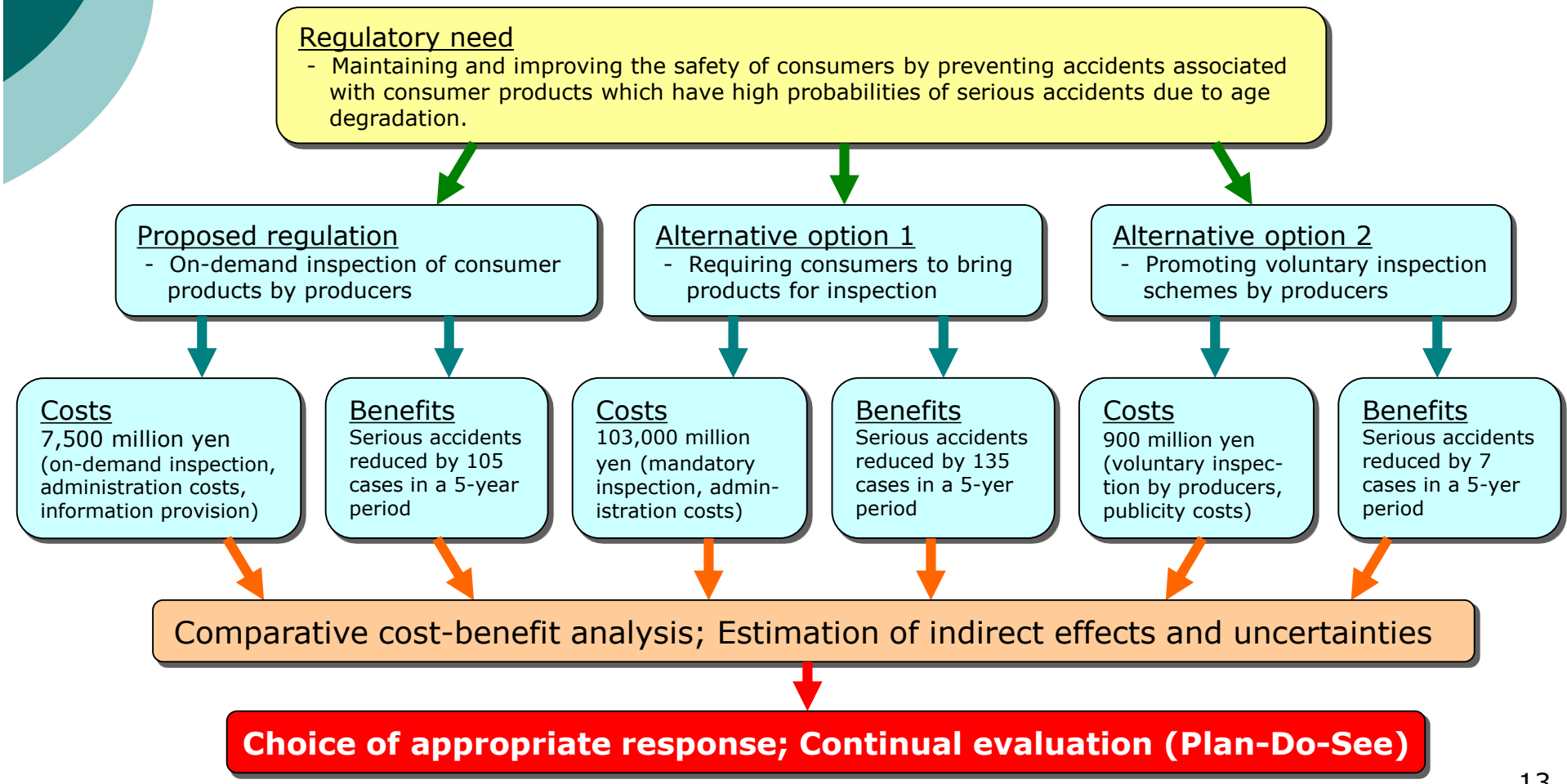
Policy evaluation mechanism in Japan (including RIAs)



1. Regulatory impact analysis (contd.)

Recent example of an RIA:

(Revision of the Consumer Product Safety Law, G/TBT/N/JPN/186, Ministry of Economy, Trade and Industry, RIA completed in June 2007)



2. Performance-based regulations

Excerpt from the "Three-Year Regulatory Reform Plan" (Cabinet Decision, March 19th, 2004)

- "Government agencies shall seek, in principle, to introduce performance-based regulations for all technical regulations which are currently based on product specifications."

Easier said than done….some examples of successful transition to performance-based requirements:

- Electricity Business Act
  (e.g., use of electrical cables that minimize risk of electric shocks)

- High-Pressure Gas Safety Act
  (e.g., use of gas containers appropriate to the given gas type, pressure, temperature and other environmental conditions)

- Construction Standards Act
  (e.g., requirement that certain outer walls must resist at least 30 minutes under fire before deforming, melting or collapsing)

3. Coordination with stakeholders

"Market-Access Action Program for Technical Regulations, Standards and Conformity Assessment"

- Introduced in July 1985, a decade before the creation of the WTO.

- Objective:
  1) to **limit the trade-disruptive effects** of technical regulations and standards
  2) to **provide access to non-Japanese firms and individuals** for keeping track of and expressing views on proposed technical regulations and standards

- Government agencies must:
  1) **demonstrate to the Cabinet Secretariat** that the proposed technical regulation or standard is not trade-distorting
  2) hold at least one **open committee sessions** where non-Japanese firms and individuals can participate.

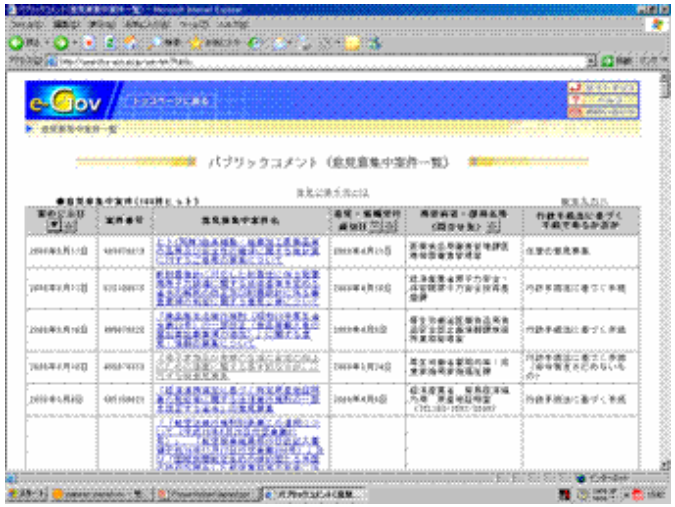
- Since the introduction of the TBT Agreement, the Program has served as a "**filtering mechanism**" before TBT notifications.

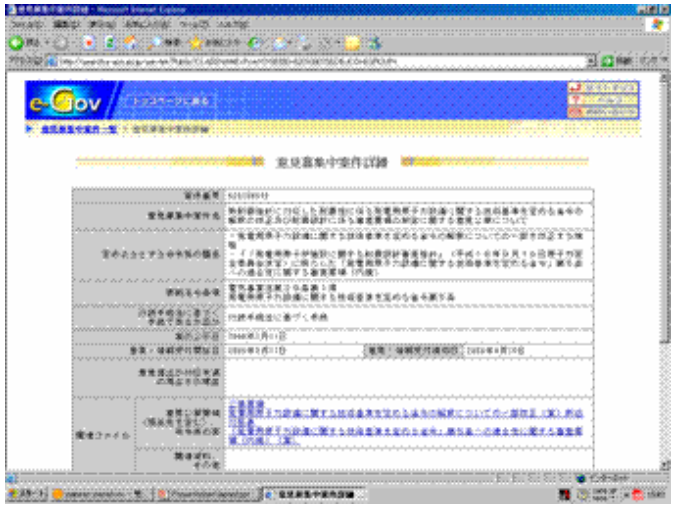
3. Coordination with stakeholders (contd.)

One-stop access for public comments on planned government measures

- "Administrative Procedures Act" (last revised in June 2006) provides opportunity for citizens to make public comments to any proposed "government orders" (i.e., regulations and similar measures. The public comment period is minimum 30 days, usually before or in parallel to the TBT notification.

- The Ministry of Internal Affairs and Communication provides **one-stop access** to all public comment opportunities (unfortunately, only in Japanese). http://search.e-gov.go.jp/servlet/Public





4. Conformity Assessment

Finding the "best mix" of conformity assessment regimes

- **Supplier's declaration is the least burdensome**, but must be considered in light of 1) effectiveness of post-market measures and 2) social/political sensitivity towards risks posed by the product.

- In the case of the Electrical Appliances Safety Act, regimes are determined by the **level of perceived risk**.

Total:
453 items

Specified Electrical Appliances and Materials

115items ⇒ Products considered to have particularly high risks of causing hazards or interference

→ Third-party conformity assessment

Other Electrical Appliances and Materials

338 items ⇒ Products of considered to have moderate risks

→ Supplier's declaration

- This method allows an **incremental shift towards supplier's declaration** as the regulatory environment evolves.

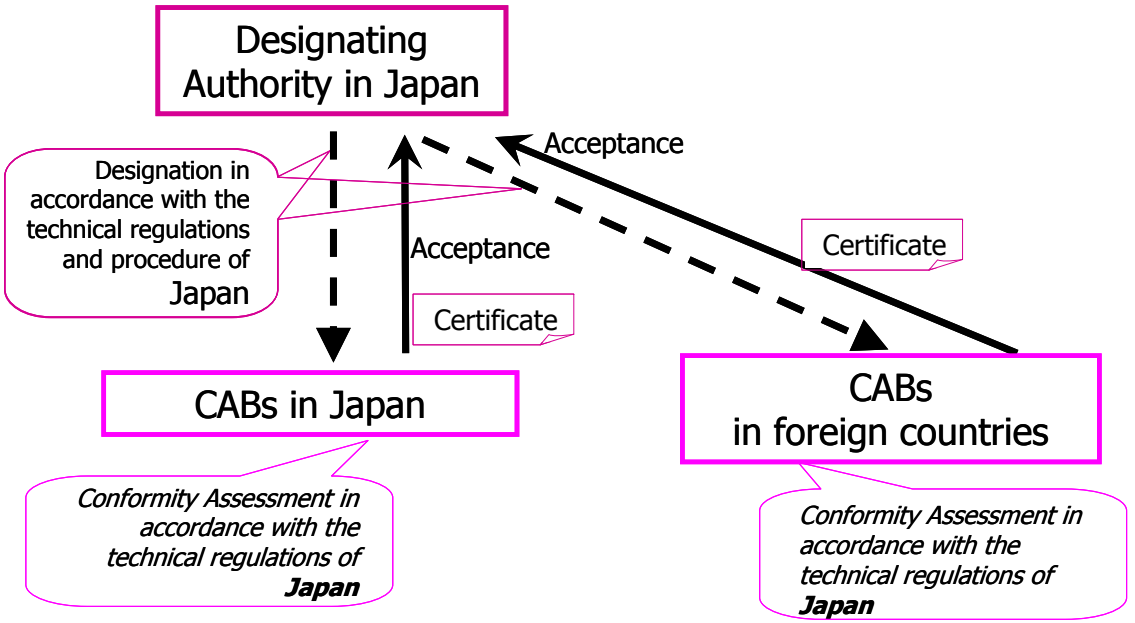
4. Conformity Assessment (contd.)

Conformity assessment by foreign CABs

- Unilaterally allowing foreign CABs to participate in the conformity assessment regime of a technical regulation is conducive to trade, and may be considered as a "good regulatory practice."

- If two countries bilaterally allow foreign CABs to be designated, this can be labeled as a "cross-border designation" MRA.

Designation of foreign CABs under the Electrical Appliances Safety Act



III. Lessons and perspectives

What constitutes a “good regulatory practice” may differ according to the regulatory environment.

If the regulatory environment (e.g., administrative capabilities, social/political factors) does not allow a direct leap to the “best” regime, then a step-by-step approach is key.

Ultimately, it is hoped that WTO members (including Japan) continue to adopt “good regulatory practices,” including, but not restricted to, the elements discussed in this presentation.