

ASEAN GOOD REGULATORY PRACTICE (GRP) GUIDE

BACKGROUND

Differences in the regulatory requirements of individual Member States are among those which have the greatest impact on trade. In certain situations, regulatory requirements may actually impede gains from trade liberalisation.

The impact of the work of the ACCSQ in alignment of standards and the development of mutual recognition arrangements (MRAs) on conformity assessment will be magnified, thereby generating gains in terms of trade facilitation, if GRP is adopted by Member States.

Recognition of the significance of GRP at the policy level is evident in the *ASEAN Policy Guideline on Standards and Conformance*, which had been endorsed by the ASEAN Economic Ministers in 2005. This document is to guide all ASEAN Bodies working in the areas of standards, technical regulations and conformity assessment procedures to facilitate the fast-track integration of priority sectors by 2010 and the realization of ASEAN Economic Community (AEC) by 2020, as described in the *Bali Concord II* and the *ASEAN Framework Agreement for the Integration of Priority Sectors*. The sections on technical regulations and conformity assessment of this Guideline incorporate several elements of GRP.

The promotion of GRP is an integral part of the work programme of ACCSQ, with the stated expectation of improving the consistency and transparency of technical regulations, thereby reducing unnecessary obstacles to trade. The ACCSQ Working Group 1 has incorporated GRP into its current work programme with the aim to promote GRP to ASEAN regulators.

OBJECTIVES

This GRP Guide is intended to provide similar approaches to regulatory management within ASEAN in the preparation, compliance to and review of technical regulations. It is intended to assist regulators in ASEAN Member States in the adoption of efficient regulatory arrangements which should improve the consistency and transparency of technical regulations, thereby leading to reduction in regulatory barriers to trade. Use of this GRP guide should be considered as one of the means for assisting Member States in meeting their international obligations under the WTO TBT Agreement and their commitment under the *Bali Concord II* and the *ASEAN Framework Agreement for the Integration of Priority Sectors*.

This GRP Guide should be used in conjunction with the *ASEAN Policy Guideline on Standards and Conformance*.

GOOD REGULATORY PRACTICE GUIDE

1. Introduction

1.1 GRP would be an essential tool in implementing several of the recommendations of the “High Level Task Force on ASEAN Economic Integration”. These include three elements:

- a) ensuring transparency on no-tariff measures and eliminate those that are trade barriers;
- b) accelerate completion and implementation of MRAs; and
- c) harmonisation of standards and technical regulations and where possible, developing ASEAN harmonised regulatory regimes – harmonisation of standards should be based on internationally accepted rules and regulations.

1.2 Technical regulations are neither efficient nor effective if they are not complied with or cannot be effectively enforced. Technical regulations that are outdated or poorly designed to achieve their intended policy objectives contribute to inefficient regulatory arrangements. When inappropriately applied, technical regulations can lead to unnecessary restrictions on industry and traders and unreasonable increase in costs. The challenge is to develop a regulatory system which can effectively deal with the increasing demands for regulation, and to ensure that regulatory interventions are optimised. This requires that the right incentives, principles, procedures, and institutions of government are in place and working effectively to ensure that regulation is necessary, cost effective, and in the best interest of society.

2. Principles for GRP

2.1 Taking into consideration current practices by national and regional bodies and obligations on GRP, there is a convergence of views on common principles for GRP, whereby good regulation should:

- a) serve clearly identified policy objectives, and be effective in achieving those objectives;
- b) have a sound legal and empirical basis;
- c) produce benefits that justify costs, considering the distribution of effects across society and taking economic, environmental and social effects into account;
- d) minimise costs and market distortions;
- e) be clear, simple, and practical for users;

- f) be consistent with other regulations and policies;
- g) be transparent to both regulators and those affected by regulation;
- h) be based on international or national standards that are harmonized to international standards, except where legitimate reasons for deviations exist;
- i) reference only those parts of a standard that represent minimum requirements to fulfil the desired objectives;
- j) be least trade restrictive to achieve the desired objectives;
- k) be performance based rather than prescriptive;
- l) accord equal treatment to products of national origin and like products imported from Member States; and
- m) be subject to review to maintain flexibility and adaptability to changes.

2.2 The greatest economic gains occur as regulators move towards open and transparent marketplaces where community interests are supported without excessive regulation being imposed on business. Therefore, before implementing the regulatory system, regulators should consider alternative approaches to fulfil legitimate objectives and the need to minimise the use of mandatory measures. In addition, regulatory processes and requirements should be as understandable and accessible as practicable and where possible, regulations should enable those affected to better understand the implications of regulatory measures.

3. Process for preparation, compliance to and review of technical regulations

When deciding to regulate, the regulator needs to consider how regulation is prepared, adopted and reviewed so that it will be effective over time. Generally, Member States should align their practices to the WTO TBT obligations when preparing, revising, or applying technical regulations and associated conformance requirements.

3.1 Preparation of technical regulations

3.1.1 In the preparation of technical regulations, the principles as listed in 2.1 should be considered.

3.1.2 It has been recognised by WTO members of the benefits of the use of specific tools for enabling GRP. This includes the use of the Regulatory Impact Assessment (RIA). The RIA requirements have been introduced as the means to ensure that the proposed regulation is assessed for its

need and net impact on society before it is put forward to regulators. RIA requires a series of steps to be followed:

- a) defining the problem;
- b) setting objectives;
- c) assessing all feasible options;
- d) analysing the impacts arising from these options; and
- e) consulting with stakeholders.

3.1.3 RIA imposes a common system of quality assurance on a wide range of regulatory proposals, with the aim of better achieving effective and efficient regulatory arrangements. RIA also promotes widespread consultation (see 3.4) with groups likely to be affected and leads to published documentation of why regulators have chosen particular regulatory options and how different groups will be affected.

3.1.4 The results of this analysis are detailed in the Regulatory Impact Statement (RIS). RIS is based on a set of steps that structure the preparation of regulatory proposals and has the following key elements, which set out:

- a) the problem which give rise to the need for action;

In defining the problem, some basic questions are required to be addressed, including whether:

- i. the unregulated market could be expected to reduce the problem within a reasonable timeframe;
- ii. why such regulatory action is necessary; and
- iii. how a regulatory scheme will improve the situation.

Accurate regulatory proposal definition reduces the risk of choosing inappropriate options for regulator action or ignoring more effective solutions, and reduces the likelihood of over regulation which will result in increased production costs, reduced competition, reduced innovation, or reduced customer choice.

- b) the desired objectives;

This element is a clear statement of the objectives that the regulator is pursuing with the proposed regulation.

- c) the options (regulatory and non-regulatory) that may constitute viable means for achieving the desired objectives;

This element sets out a range of viable options for addressing the proposed regulation. It is here that non-regulatory solutions (such as information and education campaigns, the use of codes of practice and voluntary standards) must be described, as well as possible regulatory options.

- d) an assessment of the impact (costs and benefits) on consumers, business, government and the community of each option, including the impact on small business paperwork and compliance costs;

This element is an assessment of the impact of a range of viable options (both regulatory and non-regulatory) on all groups affected. Each option should be considered carefully in terms of costs and benefits. The option preferred should be the option which either provides the maximum net benefit or the least net cost to society.

- e) a consultation statement (the process and results of consultation);

This element sets out what consultation (see 3.4) is undertaken and summarises the views of the main affected groups. This is an important aspect of the transparency of the regulation-making process and provides those most affected with adequate lead-in-time before the regulations take effect.

- f) a recommended option; and

This element is a statement of the recommended option.

- g) a strategy to implement (including consideration of appropriate enforcement mechanisms) and review the preferred option.

3.2 Compliance to technical regulations

3.2.1 Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the most appropriate level of regulator intervention and at the lowest possible cost to all parties and hence provide economic benefits and stability.

3.2.2 Conformity assessment is the comprehensive term used for measures taken or required by manufacturers, their customers, regulators and independent third parties to assess conformity to standards or technical regulations. Conformity assessment procedures include procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations.

- 3.2.3 In addition to the type of conformity assessment regimes chosen, Member States should consider the specifics of any conformity assessment regime such as the number of licenses, certifications, and approvals which should be kept to the minimum necessary to achieve regulatory objectives.
- 3.2.4 Costs to manufacturers can be reduced and/or eliminated if member countries unilaterally accept the results of conformity assessment activities undertaken by competent conformity assessment bodies in other Member States. Such a move would reduce the amount of re-testing, cost and the workload for the regulators.
- 3.2.5 When deciding on the conformity assessment, Member States should ensure that:
- a) conformity assessment procedures are not prepared, adopted or applied with the effect of creating unnecessary technical barriers to trade;
 - b) the same conformity assessment procedures are to be complied with by suppliers of products of national origin and those of like products imported from Member States;
 - c) in order to avoid delay of market entry, the implementation of registration, licensing or approval of regulated products prior to placing the goods onto market, where possible, should be limited to high risk products; and
 - d) results of conformity assessment produced by conformity assessment bodies designated by other Member States in accordance with the provisions of the ASEAN Framework Agreement on Mutual Recognition Arrangements and the provisions of the respective ASEAN Sectoral MRAs in all regulated areas should be accepted.
- 3.2.6 Member States should ensure that appropriate post market surveillance systems are in place to complement the implementation of ASEAN Sectoral MRAs and technical regulations to ensure that products comply, or continue to comply, with the relevant regulatory requirements. Member States that accept suppliers' declarations for certain products are encouraged to implement post market surveillance to validate the suppliers' declarations.

3.3 Review of technical regulations

- 3.3.1 To ensure that technical regulations continue to meet their intended objectives efficiently and effectively, it is important that provisions exist for the review of current regulation and the vetting of new regulatory

proposals. RIA is applicable not only to new regulatory proposals but also when reviewing the existing regulations. Monitoring is essential to assess whether the circumstances or objectives giving rise to their adoption have changed. It is also essential to assess whether the regulation is achieving the desired objectives in a proportionate way.

3.4 Consultation

3.4.1 The regulation making process should be transparent to both regulators and those affected by regulation. The process should ensure the issuance of notice of a proposed regulation with a sufficient consultation period to allow:

- a) all stakeholders, including consumers and business to have access to the draft proposals and to submit comments;
- b) adequate consideration and analysis of those comments; and
- c) responses to significant points and explanations of the rationale for revisions when adopting the final regulation.

Openness, transparency, proportionality and accountability in the preparation and application of regulations are fundamental to ensuring public confidence in the approach taken to address a particular problem that has been identified.

3.4.2 Member States may adopt a technical regulation as it finds necessary. However, before the technical regulation is amended or introduced, a Member States shall:

- a) notify other Member States of its intention to legislate through the Joint Sectoral Committee of the respective ASEAN Sectoral MRA, or if not applicable, the ASEAN Secretariat, giving sufficient information on the particular technical regulation proposed and the products covered, with a brief indication of the objectives and the rationale of the technical regulation, including the nature of the problems it is intended to address; and
- b) upon request, provide to other Member States the draft of the technical regulation and other information regarding the deviations from the relevant international standards and the applicable pre-market conformity assessment procedure.

3.4.3 Member States should allow at least a six-month period between the publication of technical regulations and their entry into force in order to provide sufficient time for producers in exporting Member States to adapt their products or methods of production to the requirements of importing Member States. In cases where urgent problems of health, safety, security or environment exist, Member States should notify other

members through the Joint Sectoral Committee of the respective ASEAN Sectoral MRA, or if not applicable, the ASEAN Secretariat as soon as practicable.

- 3.4.4 Consultation with all parties affected by the technical regulation is an essential element in the preparation and implementation of technical regulations. A well-designed and implemented consultation:
- a) increases the transparency of the process;
 - b) ensures that all perspectives on the issues have been considered;
 - c) highlights alternative approaches to achieve objectives;
 - d) can be a useful means of evaluating the accuracy of regulators' assessment of the costs and benefits; and
 - e) enhances awareness and therefore encourages compliance.
- 3.4.5 It is suggested that regulatory cooperation between regulators from different Member States could also be viewed as an element of GRP. This voluntary and "informal" activity, where regulators from different Member States exchanged information on regulations and conformity assessment procedures, could help to achieve a better understanding of different regulatory systems and avoid unnecessary regulatory differences (through means such as achieving harmonized, equivalent or compatible solutions).

BIBLIOGRAPHY

1. The World Trade Organisation (1994), "Agreement on Technical Barriers to Trade."
2. APEC (2000), Information Notes on Good Practice for Technical Regulations.
3. APEC (1997), Sub-Committee on Standards and Conformance, "APEC Guidelines for the Preparation, Adoption and Review of Technical Regulations."
4. OECD (1997), "Report on Regulatory Reform, Volume 2: Thematic Studies." OECD (1997), "Regulatory Reform: Summary."
5. OECD (2005), Guiding Principles for Regulatory Quality and Performance.
6. OECD (June 2005), Regulatory Impact Analysis in OECD Countries – Challenges for Developing Countries.
7. SEC (2005)791 – EC Impact Assessment Guidelines.
8. Regulation-making in Australia: Is it Broke? How do we fix it? – extracted from the Public Lecture Series, the Australian Centre of Regulatory Economics (ACORE) and the Faculty of Economics and Commerce, ANU, Canberra, 7 July 2005.
9. The WTO Committee on Technical Barriers to Trade (1997), "First Triennial Review of the Operation and Implementation of the Agreement on Technical Barriers to Trade."
10. Secretariat to the WTO Committee on Technical Barriers to Trade (1997), "Restrictive Trade Effects of Standards, Technical Regulations and Conformity Assessment Procedure."
11. 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. G/TBT/1/Rev.8.
12. G/TBT/W/258 submission on Good Regulatory practice in the USA .
13. G/TBT/W/254 submission on Good Regulatory practice by the EC.
14. G/TBT/W/248 submission on Good regulatory practice by Mexico.
15. G/TBT/W/223 submission by Japan on Good Regulatory Practice discussions in APEC.
16. Canadian Directive (November 2005) - Understanding the Government Directive on Regulating.

17. New Zealand Code of Good Regulatory Practice.