

ASEAN GUIDELINES ON GOOD REGULATORY PRACTICES



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ASEAN Guidelines on Good Regulatory Practices

The ASEAN Secretariat
Jakarta

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Foreword

The original *ASEAN Good Regulatory Practice (GRP) Guide* was developed by the ASEAN Consultative Committee for Standards and Quality (ACCSQ) and endorsed by the Senior Economic Officials Meeting (SEOM) at the SEOM 2/40 Meeting held from 2 to 4 February 2009 in Bangkok, Thailand. The Guide was designed to assist regulators in ASEAN Member States (AMS) in adopting efficient regulatory arrangements to improve the consistency and transparency of technical regulations, which will lead to reduction in regulatory barriers to trade.

In 2018, the ACCSQ completed the task to review the GRP Guide and further renamed the document to *ASEAN Guidelines on Good Regulatory Practices (ASEAN Guidelines on GRP)*. The ASEAN Guidelines on GRP was later endorsed at the SEOM 1/50 Meeting held from 16 to 18 January 2019 in Bangkok, Thailand.

Key updates to the ASEAN Guidelines on GRP include the relevant principles set out in the World Trade Organisation (WTO) Technical Barriers to Trade (TBT) Agreement, Regulatory Impact Assessment (RIA), and the ASEAN GRP Core Principles. These principles aim at assisting AMS in improving their regulatory practices, and to foster ASEAN-wide regulatory cooperation. The ASEAN GRP Core Principles were developed by the ASEAN High Level Task Force on Economic Integration (HLTF-EI), and adopted by the ASEAN Economic Ministers (AEM) at the 50th AEM Meeting in August 2018 in Singapore, which was endorsed at the 17th ASEAN Economic Community Council Meeting in November 2018 in Singapore.

The ASEAN Guidelines on GRP are intended to serve as a basis for AMS in designing and implementing adequate regulatory approaches towards the preparation and application of technical regulations.

This document was developed by Working Group 1 on Standards (WG 1) under ACCSQ with the support from Physikalisch-Technische Bundesanstalt (PTB), Germany.

Chair
ASEAN Consultative Committee for Standards and Quality
July 2019

1. Background

Good Regulatory Practices are internationally recognised processes, systems, tools and methods for improving the quality of regulations. GRP aims at making sure that regulations are fit for purpose and will deliver what they are set out to achieve in terms of policy objectives.

The context of regulatory reform in which GRP is implemented, has been recognised as a cross-cutting theme for ASEAN economic integration and regulatory coherence, as well as related measures at the level of individual ASEAN Member States.

ASEAN countries recognise that the economic agenda must be premised on productivity-driven and inclusive growth, aided by good regulatory practice. “*Effective, Efficient, Coherent and Responsive Regulations, and Good Regulatory Practice*” are regarded as playing a key role in achieving “*a Competitive, Innovative and Dynamic ASEAN*”.

The significance of GRP is also underlined in the ASEAN Policy Guideline on Standards and Conformance, which was endorsed by the AEM in 2005.

The ASEAN Guidelines on GRP shall take reference from the GRP Core Principles developed by the High Level Task Force on Economic Integration.

2. Scope

The focus of these Guidelines is on the application of GRP principles to the preparation and application of technical regulations. The WTO Agreement on Technical Barriers to Trade (TBT Agreement) defines a *technical regulation* as follows:

“A document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with

which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.”¹

3. Objectives

These GRP Guidelines intend to assist ASEAN Member States in designing and implementing adequate regulatory approaches towards the preparation and application of technical regulations. Such approaches, whilst benefiting all stakeholders through the adherence to identified good regulatory practices, are also expected to significantly contribute to the reduction of unnecessary technical barriers to trade within ASEAN.

These Guidelines are furthermore intended to assist Member States in meeting their international obligations under the WTO TBT Agreement and their commitment to the realisation of the ASEAN Economic Community (AEC) as indicated in the AEC Blueprint 2025.

The Guidelines should be used in conjunction with the *ASEAN Policy Guideline on Standards and Conformance*.

4. ASEAN GRP Core Principles

The recommendations and opinions expressed in these Guidelines are based upon a convergence of views amongst the ASEAN Member States on the core principles of GRP for ASEAN as follows:

1. clarity in policy rationale, objectives, and institutional frameworks;

¹ WTO TBT Agreement, Annex 1: Terms and their definitions for the purpose of the Agreement

2. produce benefits that justify costs and be least distortive to the markets;
3. be consistent, transparent, and practical;
4. support regional regulatory cooperation;
5. promote stakeholder engagement and participation;
6. be subject to regular review for continued relevance, efficiency, and effectiveness.

5. Good Regulatory Practices in the TBT Context

The specific application of GRP in the context of the avoidance of unnecessary barriers to trade should be guided by the principles set out in the WTO TBT Agreement. These include, but are not limited to: non-discrimination, transparency, and the use of relevant international standards wherever appropriate.

Through the use of recommended mechanisms and tools expressing these principles, GRP can be applied to the regulatory lifecycle of a TBT measure, i.e. a technical regulation, a standard, or a conformity assessment procedure², ranging from the definition of the issue the measure intends to address, to its effective application.

2 For a detailed list of mechanisms and their illustrations, following the steps from preparation to application of TBT measures, see "GRP: Voluntary mechanisms and related principles" (JOB/TBT/119/Rev.1) by the WTO TBT Committee

6. Elements of GRP and Mechanisms Recommended for Application

For the purpose of these Guidelines, GRP elements within their scope are categorised as follows:

1. establishing the potential need for government intervention (defining the problem);
2. assessing the options;
3. preparing and reviewing technical regulations;
4. notification and information;
5. consultation;
6. enforcing technical regulations.

These GRP elements and the corresponding mechanisms are discussed in the sub-sections below.

6.1. Establishing the Potential Need for Government Intervention (defining the problem)

Not all problems require government intervention. Therefore, any issue that is brought to the attention of government must be carefully examined in order to enable its clear definition and the precise statement of its nature and magnitude, including an explanation of why it has arisen. Only after this can the need for government action be established. Government intervention should be based on explicit evidence that government action is justified given the nature of the problem, the likely benefits and costs of action (based on a realistic assessment of government effectiveness), inadequacy of the existing technical regulations to address the problem and alternative mechanisms for addressing the problem.

The conventional reasons for government action are related to the wide area of social concerns and concerns about market failure. Specific trade related references for assessing the adequacy of technical regulations and their enforcement are provided by Art. 2.2 (legitimate objectives) and Art. 5.1.2 of the WTO TBT Agreement.

It is imperative that policy makers and regulators take into account that establishing the potential need for government intervention also includes considering the option of *not regulating* or *no intervention on the part of government*.

Definition of the problem and justification of government intervention as discussed above would be the first steps of Regulatory Impact Assessment or RIA. RIA is a tool to systematically identify and assess expected effects of regulatory proposals. The assessment is based on determining the underlying regulatory objectives and identifying different policy interventions that are capable of achieving the objectives. (See also Section 6.2 below)

6.2. Assessing the Options

After having established the need for government intervention, the policy objectives arising from the problem analysis have to be stated clearly. Next, the options (regulatory and non-regulatory) that offer realistic opportunities for achieving the desired objectives are identified.

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

Ideally, an assessment of the impact on consumers, business, government and the community of each option will follow, including the impact on small business paperwork and compliance costs. The required outcome of this assessment is a description of the impact of a range of viable options on all groups affected. Each option should be considered carefully in terms of costs and benefits. In simple terms, the option preferred should be the option which either provides the maximum net benefit or the least net cost to society.

RIA constitutes a tried and tested tool in this regard. RIA requires that all feasible alternatives are assessed, to inform decision-makers about the effectiveness and efficiency of different options.

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 Section 6.5) 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.

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:

1. the problem which gives rise to the need for action;
2. the desired objectives;
3. the options (regulatory and non-regulatory) that may constitute viable means for achieving the desired objectives;
4. an assessment of the impact on consumers, business, government and the community of each option, including the impact on small business paperwork and compliance costs;

5. a consultation statement (the process and results of consultation);
6. a recommended option;
7. a strategy to implement (including consideration of appropriate enforcement mechanisms) and review the preferred option.

The importance of RIA for better regulation is undisputed. However, the integration of RIA in the national policy making process is challenging. In order to be fully effective, RIA must be well-integrated with all decision-making processes and needs to commence at an early stage of policy development. The definition and consolidation of institutional responsibilities for RIA and the introduction of new requirements in the overall policy development process require high level commitment and the deployment of considerable human and financial resources. Moreover, full-fledged RIA can only be executed by interdisciplinary teams of well-trained specialists familiar with the different assessment methods (quantitative and qualitative).

ASEAN Member States are encouraged to explore possibilities to introduce RIA and gradually integrate the tool into the policy making process. Pilot exercises in priority policy areas of high visibility are deemed a good approach in preparation of a broader, very resource intensive application of the tool.

It should generally be kept in mind that according to recent Organisation for Economic Co-operation and Development (OECD) research, "*RIA's most important contribution to the quality of decisions is not the precision of the calculations used, but the action of analysing – questioning, understanding real-world impacts and exploring assumptions*".³

3 OECD Regulatory Policy Outlook (2015)

6.3. Preparing Technical Regulations

6.3.1. Generally, when preparing and reviewing technical regulations and/or conformity assessment procedures, Member States should observe the principles of good regulation (see Section 4) and meet the relevant WTO TBT obligations. In addition, the following specific requirements for technical regulations should be adhered to. Technical regulations should:

1. be based on international or national standards that are harmonised to international standards, except where legitimate reasons for deviations exist;
2. reference only those parts of a standard that represent minimum requirements to fulfil the desired objectives;
3. be least trade restrictive to achieve the desired objectives;
4. be performance based rather than prescriptive;
5. accord equal treatment to products of national origin and like products imported from Member States.

6.3.2. Where reference to standards is considered an appropriate option for achieving the regulatory objective, regulatory authorities should consider all possibilities for optimising interaction with the national standards body and participating in the development process of the relevant standards.

When referencing standards in technical regulations, regulatory authorities are encouraged, in addition to “exclusive reference”, which renders the standard or parts of the standard mandatory, to also apply the method of “indicative reference”. This method retains the voluntary application of the standard, thus allowing

for more flexibility with regard to the demonstration of compliance with the applicable legal requirements.

The regulatory authorities and the standards body shall identify and agree on ways to ensure that referenced standards are made available to all potentially interested domestic and foreign parties in the least restrictive manner possible.

6.4. Notification and Response to Comments and Requests for Information

The regulation making process should ensure the issuance of notice of a proposed regulation with a sufficient consultation period to allow:

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

Member States are further reminded of their parallel obligation to:

1. notify technical regulations before these regulations enter into force or are amended; and
2. provide information regarding draft technical regulations and, where applicable, any related measures, as per the relevant provisions of ASEAN Trade in Goods Agreement (ATIGA) and the WTO TBT agreement.

Member States should allow at least a six-month transition 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.

6.5. Regulatory Consultation

Effective regulatory consultation processes are a cornerstone of GRP and a major prerequisite for technical regulations that will meet with a high degree of acceptance and thus be enforceable. Regulators are advised to make systematic efforts to ensure that interested and affected parties have the opportunity to take part in meaningful consultations at all stages of the regulatory process, that is, development, implementation, evaluation, and review. Ideally, consultations should be integrated with all phases of policy development, including the selection of the instrument (i.e. legislation, regulations, voluntary mechanisms) that would best meet the public policy objective.

The OECD has identified five basic instruments for public consultation:⁴

1) *Informal consultation*

This can include all forms of contact between regulators and interest groups, ranging from phone calls, e-mails, and the use of online consultation platforms to informal meetings. It is a useful and flexible way of collecting information but its acceptability varies greatly.

4 OECD, Background Document on Public Consultation, 2006.

2) Circulation of regulatory proposals for public comment

This is a relatively low-cost method which offers advantages of flexibility in terms of timing, scope and form of responses. It is more systematic and structured than informal consultation and may have a basis in law, policy papers or instructions for regulators.

3) Public notice-and-comment

This is a very inclusive but more formal tool, that usually includes the publication of the draft regulatory proposal and assessment results that would typically be part of RIA.

4) Public hearings

These are meetings on particular regulatory proposals allowing interested parties and groups to comment in person, or submit written information and data at the meeting. A hearing is normally used in combination with other consultation procedures.

5) Use of advisory bodies

These bodies, such as Expert Advisory Bodies, Social and Economic Councils, Health and Safety Commissions, can be involved at all stages of the regulatory process. However, their most common role is to assist in defining positions and options at an early stage.

Consultation practices may vary from country to country, but there are common principles which observance is recommended. For discussions of these principles, which show a good deal of overlap with the general principles of good regulation, we refer to the specialised literature on regulatory consultation.⁵

⁵ Apart from national guides such as the "Guidelines for Effective Regulatory Consultation", published by the Treasury Board of Canada (2007), the "APEC Good Practice Guide on Regulatory Reform (2010)" also contains a detailed section on consultation.

6.6. Enforcing Technical Regulations

Conformity assessment regimes and systems for the purpose of enforcement of technical regulations should primarily be based on an assessment of the risks which could arise from nonconformity, looked at from the point of view of both the likelihood and the consequences of the product, service, etc. failing to conform to the specified requirements.

In applying a risk-based approach to conformity assessment Member States will also adhere to the general WTO principle that conformity assessment procedures should not be more trade-restrictive than necessary.

Costs to manufacturers can be reduced 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 retesting and the workload for the regulators.

The principle of non-discrimination must also be applied to conformity assessment. This means that Member States should ensure that the same conformity assessment procedures apply to products of national origin and products imported from Member States.

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.

For the enforcement of technical regulations, Member States should not rely only on pre-market checks and – where appropriate – suppliers' declarations of conformity, but also strive to maintain adequate post market surveillance systems. In implementing post market surveillance the

competent authorities should adhere to preventive, pro-active and risk-based approaches.

6.7. Reviewing Technical Regulations

Technical regulations should be reviewed at least every five years. These systematic reviews should be conducted against clearly defined policy goals, including consideration of costs and benefits, to ensure that regulations remain up to date, cost justified, cost effective and consistent, and deliver the intended policy objectives. In this sense, if and when Member States decide to introduce RIA, it should also apply to technical regulations that are already in place.

7. Regulatory Cooperation

In accordance with OECD⁶ descriptions, regulatory cooperation covers a significant number of mechanisms and options, ranging from integration and harmonisation through supranational or joint institutions and regulatory partnerships between countries, to “soft law”, such as codes of conduct and guidelines, and informal types of dialogue and exchange between regulators and stakeholders of different jurisdictions.

All options for regulatory cooperation are fully in line with the WTO TBT principle of identifying and applying least trade restrictive solutions in meeting common regulatory objectives. Soft law and informal exchanges of information are low-cost modes of regulatory cooperation that allow the sharing of practices and support a common understanding and language on regulatory issues. Informal exchanges foster regulatory transparency and may help reduce compliance and administrative cost. It is especially effective at bringing regulators together in new fields

⁶ Regulatory cooperation is among the topics that the Organisation for Economic Co-operation and Development (OECD) collects data upon as a basis for reviews and assessments whose results are published and can often be downloaded from the internet.

of regulation where common terminology and approaches need building from the onset.

The success of regulatory cooperation has been found to depend on a number of factors, including in particular:

1. the building of trust among regulators;
2. the progressive growth of a focused initiative;
3. strong industry buy-in and support.

8. Capacity Development

ACCSQ, the ASEAN Consultative Committee for Standards and Quality should continue to promote education and capacity development on GRP within the scope of the TBT Agreement for all major stakeholder groups. Special attention should be given to the task of enhancing regulators' understanding of the different options available for making use of standards in support of legislation.



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