

## ASEAN General Principles for Harmonisation of Regulatory Regimes

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## ASEAN General Principles for Harmonisation of Regulatory Regimes

### Introduction

The ASEAN Trade in Goods Agreement (ATIGA) defined a comprehensive framework for the market integration in ASEAN towards the realisation of the ASEAN Economic Community (AEC) when it entered-into-force on 17 May 2010. Article 47 of the Agreement (Principles on Trade Facilitation paragraph (f)) provided that *"While accepting the need of each Member State to regulate or set rules for legitimate objectives such as protection of health, safety or public morals and conservation of exhaustible natural resources, regulations, rules and procedures affecting the acceptance of goods between Member States to be harmonised as far as possible on the basis of international standards where appropriate."* In Article 73 in the Chapter 7 (Standards, Technical Regulations and Conformity Assessment Procedures, para 2 (c)) ASEAN Member States are directed to *"develop and implement ASEAN Sectoral Mutual Recognition Arrangements and develop ASEAN Harmonised Regulatory Regimes in regulated areas where applicable"*. In parallel, Article 84 of the Chapter on Sanitary and Phytosanitary Measures, Member States are directed to facilitate trade through the development of equivalence arrangements and mutual regional recognition of sanitary and phytosanitary measures.

Following from the direction provided in ATIGA, the ASEAN Consultative Committee on Standards and Quality (ACCSQ), with the support of its Product Working Groups (PWGs), has overseen development of a series of Mutual Recognition Arrangements and three Harmonised Regulatory Regimes that cover Electrical Electronic Equipment, Medical Devices and Cosmetics products. ACCSQ issued the *"Guidelines for the Development of Mutual Recognition Arrangements (MRA Guidelines)"* in 2014<sup>1</sup>. These Guidelines provide a uniform and definitive reference to the Product Working Groups and other stakeholders for the optimised development of high quality and effective Mutual Recognition Arrangements in a consistent manner based on the *"ASEAN Framework Agreement on Mutual Recognition Arrangements"* In parallel ACCSQ has developed the *"ASEAN Guidelines on Good Regulatory Practices (GRP)"* to support the implementation of appropriate and effective regulations.

The AEC Blueprint 2025 prescribes a comprehensive approach for developing an integrated and cohesive economy in ASEAN and that measures be taken to *"Minimise trade protection and compliance costs in dealing with Non-Tariff Measures (NTMs). Most NTMs address regulatory objectives such as environmental, health and safety, security or cultural considerations, but they can also significantly impede trade inadvertently or by design. Addressing NTMs involves the following: (i) accelerating work towards full elimination of nontariff barriers; (ii) standards and conformance measures, e.g. equivalence in technical regulations, standards harmonisation, alignment with international standards and mutual*

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<sup>1</sup> The Guidelines were revised in 2017

*recognition arrangements (MRAs); and (iii) streamlining procedures and reducing requirements for certificates, permits and licenses to import or export."*

*Mutual Recognition Arrangements* primarily deal with differences in conformity assessment procedures and may additionally prescribe the harmonisation of standards, whereas *Harmonisation of Regulatory Regimes* address trade barriers that arise from differences in standards and conformity assessment requirements and from differences in regulatory and administrative procedures. *Harmonised Regulatory Regimes* are thus appropriate instruments for a more comprehensive and deeper market integration.

The development of these principles is aimed at fulfilling recommendation in the ACCSQ 2016-2025 Strategic Plan that generic guidance for sector groups for establishing harmonised regulatory regimes, be developed to identify factors to be considered, elaborate on approaches and methods of harmonisation.

### **ASEAN's Experience in Harmonising Regulatory Regimes**

Three harmonised regulatory regimes that have been developed by ACCSQ's PWGs are:

1. Agreement on the ASEAN Harmonised Cosmetic Regulatory Scheme, Schedule B: ASEAN Cosmetic Directive (ACD) (2003)
2. Agreement on the ASEAN Harmonized Electrical and Electronic Equipment (EEE) Regulatory Regime (AHEEERR) (2005)
3. ASEAN Agreement on Medical Device Directive (AMDD) (2014)

It is noted that the ACD has been fully implemented, while the AHEEERR is in process of being implemented and the AMDD is at the initial stage of planning for implementation

The harmonised regulatory regimes in all the 3 sectors oblige Member States to harmonise their domestic regulatory requirements and processes. The ACD is differentiated from AHEEERR and AMDD in that the prescribed regulatory system relies on notification of products placed on the market, which is essentially a self-declaration of compliance by suppliers, whereas the AHEEERR and AMDD include the requirement for pre-market approval and conformity assessment.

Both the AHEEERR and the ACD are follow-up initiatives for market integration for the specific sectors. The AHEEERR is an extension and deepening of the ASEAN Sectoral MRA for Electrical and Electronics Equipment and the ASEAN Cosmetics Directive is preceded by Schedule A of the Cosmetics Agreement: ASEAN MRA for Product Registration Approvals for Cosmetics. The AMDD obliges Member States to ensure only medical devices that comply with the AMDD are placed on the markets. The AMDD requires that all ASEAN Member States harmonise regulations by adopting common templates for submission of technical documents for registration, for declaration of conformity and by harmonising post market surveillance systems, standards and risk classification of medical devices.

Currently, the Task Force on ASEAN Food Safety Regulatory Framework (TF AFSRF) is leading the development of the ASEAN Food Safety Regulatory Framework Agreement, which would effectively harmonise a comprehensive range of regulations and food safety measures dealing with food safety in the ASEAN region

## References

The following publications are referenced in this document and elaborate the underlying concepts that are incorporated in the ASEAN General Principles for Harmonisation of Regulatory Regimes.

- i. ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures.
- ii. ASEAN Standards and Conformance Strategic Plan 2016-2025
- iii. ASEAN Guidelines for the Development of Mutual Recognition Arrangements (MRA Guidelines)
- iv. ASEAN Guidelines for the Harmonisation of Standards
- v. ASEAN Guidelines for Accreditation and Conformity Assessment

## Scope

The principles contained in this document are applicable to harmonised regulatory regimes that are developed to support the implementation of the ASEAN Trade in Goods Agreement. The principles contained in this document supplement the guidance provided in the *"ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures"*.

## Objectives

The harmonisation of regulatory regimes across ASEAN's Member States is a complex process that impacts stakeholders in trade, investment and regulation at policy and operational levels. The elaboration of the principles for the Harmonisation of Regulatory Regimes provides direction and guidance to the development and maintenance of Harmonised Regimes that are developed and implemented by ACCSQ's Product Working Groups. The Principles should ensure that all pertinent factors are considered and that the harmonisation of regulatory regimes results in the most positive outcome for the whole of ASEAN from the trade, investment and social perspectives.

The application of the Principles will serve to ensure that the Harmonisation of Regulatory Regimes effectively removes unnecessary technical barriers to trade (TBT) and facilitates trade. The regulations implemented as a result of the harmonised regulatory regime should serve ASEAN Member States' needs in ensuring safety, protecting health, protecting the environment and in meeting other intended social objectives. The adoption of these

principles will avoid the pitfalls of inappropriate regulation that can lead to unnecessary restriction on trade, stifling of innovation and excessive costs for suppliers and regulators.

It is intended that parties engaged in Harmonisation of Regulatory Regimes examine the provisions of the harmonised regimes against the principles as elaborated in the following principles.

## **ASEAN General Principles for Harmonisation of Regulatory Regimes**

### **1. Defined Objectives for Harmonisation**

The objectives for the harmonised regulatory regime should be defined based on agreement of all Member States.

Harmonising regulatory regimes requires a substantial coordinated effort by regulatory authorities in Member States over an extended period of time. Such an undertaking is appropriate only if there are substantial measurable targets in line with the AEC target of creating an integrated and cohesive economy with a freer movement of goods. Such objectives should strengthen the implementation of the ASEAN Trade In Goods Agreement (ATIGA) and will include:

- Removal of unnecessary technical barriers to trade (TBTs)
- Addressing relevant non-tariff measures (NTMs) among ASEAN Member States
- Facilitation of trade.
- Upgrading of regulation to ensure safety, consumer health, environmental protection, consumer protection and meeting other social objectives.

Not all regulations need to be harmonised as some regulations serve a specific domestic needs in particular Member States. It should be established that the identified objectives are valid for the whole of ASEAN and not for a limited number of Member States.

### **2. Support Economic Integration in ASEAN.**

The Harmonised Regulatory Regime should lead to reduced TBTs and serve to enhance ASEAN Economic Integration.

Technical regulations lead to trade barriers for goods crossing borders. Harmonisation of Regulatory Regimes would oblige Member States to review existing regulations to ensure conformity with the harmonised regimes. It should be ensured that that harmonised regimes do not introduce new and more extensive barriers than those imposed by the existing arrangements in force in the ASEAN Member States. The harmonisation should lead to substantial reduction in barriers and support market integration.

### **3. Advancement of safety, health, environment and other defined public interests and social objectives.**

The harmonised regulatory regime should serve to address legitimate public interests and concerns.

Harmonisation of Regulatory Regimes should be justified such that the harmonised regime results in clearly defined public benefits. The manner of addressing these concerns should be assessed for consistency with the relevant provisions for technical regulations of the WTO/TBT agreement and the relevant provisions for sanitary and phytosanitary measures of the WTO/SPS Agreement.

#### **4. Competence of Conformity Assessment Bodies to Support Harmonised Regulatory Regimes.**

When requirements for conformity assessment are included in harmonised regulatory regimes, the competence of the conformity assessment bodies should be assured through accreditation based on the criteria contained in the *ASEAN Guidelines for Accreditations and Conformity Assessment* or through other equivalent means.

The reliance on third party conformity assessment bodies in the implementation of technical regulations may be permitted for selected sectors based on consultation between the relevant authorities of Member States. For products of relatively lower risk, Member States are encouraged to permit accredited third party conformity assessment bodies to undertake conformity assessment.

#### **5. Use of ASEAN Harmonised Standards.**

When conformance to standards is a requirement of harmonised regulatory regimes, the standards specified should, as the first preference, be standards that have been harmonised in accordance with the *ASEAN Guidelines for Harmonised Standards*. When appropriate ASEAN Harmonised Standards are not available, international standards may then be directly referenced in the harmonised regulatory regime and recommendations made for these international standards to be adopted as ASEAN harmonised standards. When appropriate international standards are not available, standards other than international standards may be referenced in line with the order of priority for identification of appropriate standards as stated in the *ASEAN Guidelines for Harmonised Standards*<sup>2</sup> and actions initiated for these standards to be adopted as ASEAN Harmonised Standards .

#### **6. Facilitating participation in global value chains**

The Harmonisation of Regulatory Regimes should leverage on international regulatory cooperation and international mutual recognition arrangements when these are available in order to ensure that the regimes developed facilitate the participation of ASEAN businesses in global value chains.

ASEAN derives several advantages from utilising the international initiatives that have led to harmonisation of requirements or regulations on a global basis. By adopting these international harmonised requirements, ASEAN does not need to independently develop its own requirements. Benefits derive from the expertise and knowledge embedded and regional industries will additionally comply with requirements of markets beyond ASEAN. ASEAN is

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<sup>2</sup> *Explanatory note:* ASEAN Harmonised Standards are standards that have been harmonised in ASEAN in accordance with the *ASEAN Guidelines for the Harmonisation of Standards*. The Guidelines prescribe that identification of standards that serve as a basis for harmonisation within ASEAN follows the following order of priority; (a) International Standard, (b) the Standard of an ASEAN Member State, (c) other non-ASEAN regional or national standards from non-ASEAN regions and (d) publicly available standards published by a standards body that has accepted the Code of Good Practice for the Preparation, Adoption and Application of Standards provided in Annex 3 of the WTO TBT agreement.



thus able to leverage on the global platforms without the additional costs and resource requirements of establishing parallel platforms for harmonising regulatory requirements. These regional and international arrangements additionally permit ASEAN Member States to participate in the development of international harmonised documents.

#### **7. Harmonisation of Regulatory Regimes not to place unreasonable demands on infrastructure and resources.**

The implementation of the provisions of the harmonised regulatory regime should not incur disproportionately high costs due to infrastructure and resource requirements.

The complexity and methods chosen in a technical regulation will determine the type of resources and infrastructure needed. Member States that do not have the required infrastructure or resources may find obstacles and incur delays in implementation. The availability of infrastructure and qualified personnel and operational costs should be factored in designing the harmonised regulatory regime.

#### **8. Special interests of the Micro, Small and Medium Enterprise (MSME) sector to be safeguarded**

The interests and well-being of the MSME sector should be safeguarded and not be adversely impacted by the harmonised regulatory regime.

The MSME sector in ASEAN is an important sector that provides a livelihood to a large portion of ASEAN's population and supports the economies of Member States. Technical regulations can lead to high entry barriers and be cumbersome and incur disproportionately high costs for MSME. The measures selected should take these factors into account and if indicated, special provisions should be included to safeguard the MSME to ensure their continued existence.

#### **9. Good Regulatory Practice (GRP) principles adopted in the harmonisation of regulatory regimes.**

The ASEAN GRP Core Principles and the ASEAN Guidelines on Good Regulatory Practices (GRP) should be referenced in the development of harmonised regulatory regimes.

In particular, the regulatory measures selected should be proportionate to risks encountered and not overburden industry and add undue costs, be fair to all parties ensuring a level field for trade, industry and consumers in ASEAN.

#### **10. Periodic Review of Harmonised Regulatory Regimes.**

Harmonised regulatory regimes should include a provision requiring parties responsible for the harmonised regulatory regime to periodically review the implementation.

The review should, as a minimum, include the impact and achievements of the harmonised regime as against the desired objectives and continuing suitability of the harmonised regulatory regime. It would additionally be useful for the review to include the impact on

trade and investment. The parties responsible for implementation should determine the future of the regime including its withdrawal, amendment or continuation.

#### **11. Implementation of the Principles for Harmonisation of Regulatory Regimes**

The scope and content of any regulatory regime is dependent on the sector, the regulatory objectives, the existing economic and social factors and the infrastructure and resources available. The Annex provides supplementary information on the application of the principles for the harmonisation of regulatory regimes. A series of generic logical process stages can be identified to aid the harmonisation of regulatory regimes for ASEAN. These recommended process stages are elaborated in the **Annex**.

## **Annex Recommended Process Stages for Harmonisation of Regulatory Regimes in ASEAN**

### **1. Establish ASEAN consensus on objectives of the Harmonised Regulatory Regime.**

At the first stage, the issues and problems leading to the development of the Harmonised Regulatory Regime to be recognised should be defined. A consensus on the scope of coverage and objectives that the regime will serve should also be reached. This preparatory stage is essential and provides a reference for the selection of the measures and methods to be adopted for the regime. When indicated, consultation with other related ASEAN bodies should be undertaken and support from higher levels (Senior Officers or Ministerial Meetings) within ASEAN.

### **2. Identify alternative approaches available.**

There is a wide range of optional methods for implementing regulatory measures. Each regulatory regime is unique and designed to serve identified objectives. The options may range from systems requiring premarket inspection and certifications to self-declaration. The regime may include acceptance of equivalence of measures implemented in Member States or be based on standards and regulations harmonised in ASEAN.

### **3. Examine Impact of Alternatives.**

The options selected will need to be evaluated and compared as the expected impacts on stakeholders, and the economy at a regional level. The anticipated negative and positive impacts have to be identified and quantified when feasible. Member States may conduct their own national examination of expected impact. The results of the examination of the expected impact at regional should lead to the selection of the most appropriate option and a decision to proceed with the detailed development.

### **4. Develop detail text of preferred option.**

The Working Group responsible will at this stage commence with the development of a preliminary draft text of the Harmonised Regulatory Regime. This text will be refined through consultations between AMS representatives in the Working Group.

### **5. Domestic Consultations**

Upon reaching a satisfactory level of agreement at the Working Group level, the Member States Representatives will coordinate domestic consultation and feedback the results to the Working Group.

### **6. Finalise Draft Text of the Harmonised Regulatory Regime**

The Working Group will seek to finalise the text, seeking to resolve all issues raised during the domestic consultation phase. In finalising the draft text, the Working Group will confirm that

the document addresses the objectives identified in at the first stage. This text would be forwarded to the ACCSQ and/or other responsible ASEAN Body(ies) for endorsement as appropriate.

7. Development of final text and signing of the Harmonised Regulatory Regime

The ASEAN Secretariat will coordinate the legal vetting and required processes to obtain the approvals of the higher ASEAN bodies for formal approval and ASEAN Ministers' signature.

8. Implementation of the Harmonised Regulatory Regime

The Implementation of the Harmonised Regime will commence in accordance with the provisions of the respective ASEAN agreement.

The timeline for implementation will depend on the state of readiness of the Member States in terms of infrastructure and legal changes that are required to be implemented within each Member State. It would be useful to consider phased implementation, noting the varying development levels within ASEAN.

A transparent and comprehensive monitoring mechanism should be incorporated in the regime so as to provide clarity in the progress made in implementation and avoid unnecessary disputes.