

# ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures



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## **ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures**

The ASEAN Secretariat  
Jakarta

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### **FOREWORD**

The ASEAN Policy Guideline on Standards and Conformance (APGSC) that was adopted at 26<sup>th</sup> ASEAN Consultative Committee on Standards and Quality (ACCSQ) Meeting held on 4-5 August 2005, Manila, Philippines prepared to guide all ASEAN Bodies working in the areas of standards and conformance in implementing measures on standards, technical regulations and conformity assessment procedures to facilitate ASEAN Market integration. This document, has been revised and renamed the *ASEAN Guideline on Standards, Technical Regulations and Conformity Assessment Procedures (AG STRACAP)*. The AG STRACAP updates the previous guidelines and incorporates relevant decisions and agreements concluded by the Economic Ministers and ASEAN leaders and members. This document, which shall be reviewed every 5 years or as deemed necessary by ACCSQ, is developed and managed by the Working Group 1 on Standards and Mutual Recognition Arrangements of the ACCSQ. The AG STRACAP was endorsed by the ACCSQ at its 42<sup>nd</sup> ACCSQ Meeting held in Yangon, Myanmar from 22 to 24<sup>th</sup> September 2014.

**Chair**

**ASEAN Consultative Committee on Standards and Quality, April 23<sup>rd</sup> 2015**

# ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures

## Introduction

The ASEAN Guidelines on Standards and Conformance (AG-STRACAP) applies to all ASEAN Bodies working in the areas of standards, metrology, conformity assessment, technical regulation to implement the Declaration of the ASEAN Economic Community Blueprint made by the heads of ASEAN Member States (hereinafter, Member States) on 20 November 2007. The AG-STRACAP applies to Member States and facilitates the implementation of the obligations of the ASEAN Trade in Goods Agreement (ATIGA) of 26 February 2009 towards meeting the objective of establishing an integrated single market and production base with a free flow of goods.

## Objectives

The AG-STRACAP aims at providing the guiding principles for the implementation of the individual and joint efforts of Member States in the area of standards, technical regulations, conformity assessment procedures, metrology and other related activities, both in regulated and non-regulated sectors, for enabling the economic integration of the ASEAN and realisation of the ASEAN Economic Community (AEC). The document provides guidance on ASEAN policies with regard to the harmonisation of standards, metrology<sup>1</sup>, conformity assessment, as well as the implementation of technical regulations, post market surveillance, mutual recognition arrangements and ASEAN Harmonised Regulatory Regimes.

## Terms and Definitions

The definitions for standards, technical regulations and conformity assessment procedures have the meaning given to them in Annex 1 of the WTO/TBT Agreement. Other terms concerning standardisation and conformity assessment used in this document have the meaning given to them in the definitions contained in the ISO/ IEC Guide 2 and ISO/ IEC 17000, the OIML published documents, the ASEAN Framework Agreement on MRAs and the relevant ASEAN Sectoral MRAs.

## General Provisions

1. The ASEAN activities on standards and conformance aim at creating a single market and production base, in which there is a free flow of goods and, which is fully integrated into the global economy with effective facilitation of trade.
2. National Standards Bodies in all Member States noting the reaffirmation of the WTO/TBT Agreement in Article 73 of ATIGA and obligation to accept the Code of Good Practice for the Preparation, Adoption and Application of Standards as provided in Annex 3 of WTO Agreement on Technical Barriers to Trade, shall take appropriate measures to ensure that unnecessary trade barriers are eliminated.

<sup>1</sup> Legal metrology is under the purview of ACCSQ, while scientific metrology is under the purview of the ASEAN Committee of Science and Technology (COST).

3. In order to facilitate the realisation of single market and single production base that is a *highly competitive economic region with equitable economic development and fully integrated into the global economy*, Member States, noting the provisions of Articles 74, 75, 76, 77 and 78 of ATIGA, should take any of the following possible measures or their combination to:
  - (a) Harmonise standards, technical regulations, and conformity assessment procedures;
  - (b) Develop mutual recognition of conformity assessment in regulated and non-regulated sectors;
  - (c) Enhance regulatory cooperation between Member States;
  - (d) Develop harmonised regulatory regimes; and
  - (e) Participate in relevant regional and global mutual recognition arrangements<sup>2</sup> as identified by the relevant ASEAN Bodies working in the areas of standards, metrology, conformity assessment and technical regulation.
4. Member States shall implement all the measures on standards, metrology, technical regulations, conformity assessment and post market surveillance as contained in the legal instruments as listed in Article 78(2) of the ATIGA and in any future instruments as agreed by Member States.
5. Member States recognise that the International System of Units, the SI (Système International d'Unités) that is established and maintained by the International Bureau of Weights and Measures (Bureau International des Poids et Mesures) as the reference for measurements adopted in standards, conformity assessment and technical regulation.
6. In order to support the objective of the ASEAN Free Trade Area and to ensure that the modernisation of legislation in legal metrology does not result in the introduction of new technical barriers to trade, Member States should take the following possible measures or their combination to:
  - (a) Harmonise national technical regulations through alignment with the ASEAN Guidelines on Metrology and/or OIML published documents;
  - (b) Enhance technical infrastructure and competency in laboratory testing, verification, and inspection based on OIML published documents, international/regional standards and guides.
  - (c) Develop closer cooperation amongst Legal Metrology Authorities and National Metrology Institutes (NMIs) within ASEAN to facilitate the implementation of mutual recognition or acceptance mechanisms (MRAs or MAAs) in the field of legal metrology.

### Harmonisation of Standards

7. Member States shall implement measures to harmonise their national standards with international standards to realise the obligations in Article 74 of ATIGA.

<sup>2</sup> IECEE, CIPM MRA, APLAC, PAC, ILAC, IAF.

8. National Standards Bodies of Member States shall participate in harmonisation programmes as developed by relevant ASEAN Bodies and implement decisions on harmonisation as defined in the ASEAN Guidelines for the Harmonisation of Standards.

### **Adoption of Technical Regulations**

9. Member States shall ensure that the adoption of technical regulations is consistent with the obligations of Article 75 of ATIGA and that:
  - (a) The national technical regulations adopted are consistent with existing ASEAN MRAs and ASEAN harmonised regulatory regimes in that these facilitate the recognition of conformity assessment and approvals as provided for in the relevant MRAs and in the ASEAN harmonised regulatory regimes;
  - (b) When new MRAs or harmonised regulatory regimes are agreed by relevant ASEAN Bodies, Member States shall review all existing relevant technical regulations to ensure these facilitate the recognition of conformity assessment and approvals as provided for;
  - (c) In the event that a new harmonised regulatory regime is adopted by Member States, the requirements of the regulatory regime shall be fully transposed into national technical regulations within the time frame as determined by Member States; and
  - (d) The guidance provided in the ASEAN Good Regulatory Practice Guide is fully considered and applied.

### **Conformity Assessment**

10. Member States shall ensure that the preparation, adoption and application of conformity assessment procedures and that the results of conformity assessment from designated conformity assessment bodies are accepted by other Member States as provided for in Article 76 of ATIGA.
11. Member States shall ensure that the operations of national accreditation bodies and designated conformity assessment bodies are consistent with the ASEAN Guidelines on Accreditation and Conformity Assessment.

### **Metrology**

12. Member States recognise the validity of calibration and measurement certificates issued by participating institutes under the provisions of the Mutual Recognition Arrangement of the International Committee of Weights and Measures (CIPM MRA) for the quantities and ranges specified and listed in the BIPM key comparison database (KCDB).
13. Member States shall base their relevant laws, legislation and regulations in field of legal metrology on Recommendations, Guides and other applicable publications of the International Organization of Legal Metrology (OIML) and ensure that:

- (a) Prescription of the national legal units of measurement should be based on the SI units of measurements with possible additions that may be used in certain circumstances to facilitate regional and international trade.
  - (b) The national metrological control system should ensure that measurements made for trade or regulatory purposes may be shown to traceable to the nationally recognised primary measurement standards. Whenever the uncertainty level of the system of nationally recognised primary measurement standards is not sufficient or when this system does not cover the considered quantity, Member States should obtain traceability to nationally recognised primary measurement standards of other Member States, if applicable;
  - (c) That the shared risk principle between producers and consumers are upheld. These risks are balanced in terms of measurement results in relation to its associated measurement uncertainty, appropriate permissible error limits and/or tolerable deficiency limits;
  - (d) The calibration procedure, the testing procedure, the verification procedure are harmonised to the OIML published documents, international/regional standards and guides.
14. Member States will enhance cooperation in legal metrology with the objective of facilitating the implementation of mutual recognition or acceptance mechanisms (MRAs or MAAs).

### **Post Market Surveillance**

15. Member States should ensure that appropriate Post Market Surveillance Systems are in place to complement the implementation of ASEAN Sectoral MRAs and technical regulations, in accordance with the obligations of Article 77 of ATIGA [as well as the ASEAN Guidelines on Post Market Surveillance].

### **Transparency**

16. Member States shall ensure that transparency of national standards, technical regulations and conformity assessment procedures is maintained as provided for in the WTO/TBT Agreement and in Article 11 of ATIGA.

### **Regulatory Cooperation**

17. Member States shall encourage and facilitate regulatory agencies to enhance cooperation with other Member States' agencies with a view of removing trade barriers and facilitating the free flow of goods through:
- (a) Consultation and sharing of information at a an early stage on new regulations or changes to existing regulations;
  - (b) Sharing of information on product failures and alerts; and
  - (c) Establishing mechanisms for rapid consultation when disputes between Member States arise.



These mechanisms should be applicable for sectors in which MRAs and Harmonised Regulatory schemes are absent.

### **Mutual Recognition Arrangements**

18. Member States shall undertake the development and implementation of mutual recognition arrangements as provided in Articles 76 (3) and 77 of ATIGA. The development of MRAs shall be undertaken in accordance with the ASEAN Guidelines for the Development of Mutual Recognition Arrangements.

### **Harmonisation of Technical Regulations**

19. Member States shall pursue the harmonisation of technical regulations as appropriate and agreed. The harmonisation of technical regulations shall result in one or all of the following:

- (d) Harmonisation of the technical requirements and standards for the products concerned;
- (e) Harmonisation of the conformity assessment procedures;
- (f) Harmonisation of the criteria for designation and of conformity assessment bodies;
- (g) Mutual recognition of the results from designated conformity assessment bodies;
- (h) Acceptance of the approvals granted by in one Member State by all other Member States;

20. The harmonisation of technical regulations by Member States may be achieved through the development of ASEAN Harmonised Regimes based on international standards and conformity assessment systems. .

21. Member States may, when appropriate, develop harmonised regulatory regimes. These regimes should prescribe comprehensive requirements including:

- (a) Obligations for Member States with regard to transposing the requirements into domestic legislation.
- (b) Applicable standards;
- (c) Acceptance of conformity assessment;
- (d) Post market surveillance;
- (e) Provisions for enforcement and sanctions or non-compliance;
- (f) Mechanisms for the sharing of information on approvals granted, alerts, failures, recalls, and results of post market surveillance;

- (g) Maintenance of authorised representative by suppliers to take responsibility for the product in each member state that the product is marketed in;
22. Member States may achieve harmonisation of regulations through a decision for Members States to accede to international agreements that prescribe harmonised technical regulations when this is determined to be appropriate.



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