Guidelines for the Development of Mutual Recognition Arrangements

ASEAN Consultative Committee on Standards & Quality

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Second Edition

Abbreviations

AEC	ASEAN Economic Community
ACCSQ	ASEAN Consultative Committee on Standards & Quality
AMS	ASEAN Member States
ATIGA	ASEAN Trade in Goods Agreement
CLMV	Cambodia, Lao PDR, Myanmar and Viet Nam
MRA	Mutual Recognition Arrangement
NTB	Non-Tariff Barriers
PWG	Product Working Group
SDoC	Suppliers' Declaration of Conformity
WG	Working Group

FOREWORD

ASEAN leaders have made a commitment in the ASEAN Economic Community Blueprint that necessary actions will be implemented in ASEAN towards achieving the vision of a single production base with the free movement of goods. The elimination of non-tariff barriers (NTBs) is a critical component of this target. The ASEAN Trade in Goods Agreement has tasked the ASEAN Consultative Committee on Standards & Quality (ACCSQ) to coordinate and guide its Product Working Groups towards achieving this end. These groups continue to develop and implement mutual recognition arrangements for removing a number of significant NTBs. The MRAs are one of a range of instruments available to support the establishment of the ASEAN Economic Community. These are especially useful in removing the need for multiple testing and certification for goods traded within ASEAN Member Countries. ACCSQ wishes to reiterate that the publication of these guidelines in no way diminishes the continued relevance of complementary instruments such as the harmonised regulatory regimes, harmonisation of standards and technical regulations in the removal of NTBs and establishment of an integrated ASEAN Market.

ACCSQ acknowledges and appreciates the contribution Working Group 1 on Standards and Mutual Recognition Arrangements that has overseen the development of these guidelines on the development and implementation of mutual recognition arrangements for ASEAN. ACCSQ would also record its appreciation of the support and contributions provided by the ARISE Project (ASEAN Regional Integration Support from the EU) in the development and publication of these guidelines.

These guidelines are applicable to all ASEAN Product Working Groups (PWGs) engaged in the development of MRAs. These will serve as a common reference for the PWGs developing sectoral MRAs and will aid in ensuring that the MRAs are developed in an optimum process and are effective and efficient in meeting the declared objectives of the MRAs. The Guidelines would facilitate the development of a coherent set of mutual recognition agreements that are providing a set of important instruments that underpin the establishment of the ASEAN Economic Community.

The second edition of the guidelines has been expanded and incorporates two annexes, the first containing recommended terminology for use in MRAs and the second providing guidance on the establishment of the scope of MRAs.

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Chair
ASEAN Consultative Committee on Standards & Quality
20 May, 2016

Guidelines for the Development of Mutual Recognition Arrangements

1. Introduction

1.1. Mutual Recognition Agreements (MRA) are one of the instruments utilised by ASEAN to remove non-tariff trade barriers and facilitate the free flow of goods in the region in order to realise the establishment of the ASEAN Economic Community. The MRAs are agreements between Member States that provide for mutual recognition of the results of conformity assessments conducted in one Member State by authorities in the other ASEAN Member States. MRAs typically provide an exporting party with the authority to test, inspect and/or certify products, against the regulatory requirements of the importing party, in its own territory and prior to export. These agreements facilitate trade and by enabling suppliers to confirm compliance with the requirements of the importing country with respect to mandatory inspection, testing or certification of products prior to import and sales.

1.2. The provisions of MRAs contain obligations for the recognition of inspections, tests, certifications and approvals, issued by qualified conformity assessment bodies of the exporting Member State by the importing Member State. The establishment of an MRA is independent of initiatives undertaken for harmonising standards and technical regulations. The implementation of an MRA depends on conformity assessment conducted in an exporting Member State to assess the conformity of a product to the requirements of importing Member State, which may differ from its own.

As MRAs do not generally prescribe harmonisation of technical requirements of ASEAN Member States or the recognition of their equivalence, each Member State is free to set its own regulations and standards. The parties to an MRA, however, mutually recognise the equivalence and results of conformity assessment procedures. The Member States thus must have confidence in the conformity assessment bodies of the other Member States. The recognition is usually based on confidence established through the use of international standards and guides on conformity assessment practices. These standards provide uniform criteria with regard to minimum qualifications and training requirements of the personnel engaged in conformity assessment, impartiality, independence from vested interests, technical competence to carry out certifications and tests. Each Member State must thus establish comparable and mutually acceptable systems of certification and technical infrastructure. Accreditation of conformity assessment bodies of the exporting Member State to the importing Member States' standards is the main method adopted to confirm competency of conformity assessment bodies in assessing or certifying products on behalf of the importing Member State.

1.3. The ASEAN Framework Agreement on Mutual Recognition provides a common basis for developing and implementing MRAs. This Agreement specifies general principles for developing sectoral MRAs amongst Member States and the general conditions under which each Member State shall accept or recognise the results of conformity

assessment procedures from conformity assessment bodies of other Member States. The Framework MRA Agreement does not provide for the harmonisation of technical regulations within ASEAN or the acceptance of other Member State's technical regulations as equivalent. Each Member State's Regulator retains its full authority to grant approvals based on its own domestic regulations and standards. While regional harmonisation of standards is encouraged in the MRAs, it does not amount to a mandatory obligation.

1.4. The sectoral ASEAN Mutual Recognition Agreements (MRAs) benefit industry by providing better access to conformity assessment. These agreements can also reduce the costs of conformity assessment. A parallel harmonisation of standards between Member States additionally eliminates the need for multiple tests and assessments.

2. Definitions and Terminology

The definitions and terms used in this document are as defined in **Annex 1: Definitions and Terminology recommended for use in ASEAN Mutual Recognition Arrangements.** The Annex contains terms and definitions that should be considered for adoption and use in ASEAN MRAs to ensure consistency.

3. The potential uses and limitations of MRAs in relation to the AEC Blueprint target of establishing a single market and production base

3.1 The AEC Blueprint[1] in Article 14 on the Elimination of Non-Tariff Barriers (NTBs) sets ambitious targets for:

(a) Removal of all NTBs by 2018; and
(b) Work towards, where possible, having regional rules and regulations consistent with international best practices.

3.2 Article 19 of the AEC Blueprint, on Standards and Technical Barriers to Trade, widens the options to be adopted for market integration within ASEAN. Besides the existing MRA approaches, it calls for harmonisation of standards and technical regulations and conformity assessment procedures. Alternative and supplementary approaches for eliminating technical barriers, in addition to MRAs, are recognised and encouraged. It should be noted that not all the NTBs, as envisaged in the AEC Blueprint, can be removed solely through adoption of MRAs.

3.3 The MRAs developed by ASEAN have, *inter alia*, the objective of removing technical barriers to trade through the following means:

(a) Results of testing, inspection and certification undertaken in the territory of the exporter are accepted by authorities in the importing State for regulatory purposes, when the testing, inspection and certification is performed in

[1] It is noted that the Framework Agreement on MRAs was concluded in 1996, i.e. prior to the establishment of the ASEAN Charter and the ASEAN Economic Community (AEC) Blueprint that was adopted in 2007 and has limited targets as compared to the AEC Blueprint.

accordance with the requirements of the importer, by conformity assessment bodies designated according to the requirements of the MRA; and

(b) Re-assessment of the product is no longer necessary when the technical requirements[2] for the testing, inspection, and certification are harmonised or accepted as equivalent.

3.4 The MRAs have limitations due to differences in the standards of the Member States concerned and the fact that MRAs' confine obligations for recognition[3] to recognition of results of conformity assessment and do not extend to recognition of approvals granted by regulatory authorities:

(a) When standards are not harmonised, the MRA enables suppliers to utilise testing, inspection and certification services of bodies located in their own territory or in any other Member States in addition to those in the importing Member State. Suppliers will still need to design products to comply with the standards of each member State in which they intend to market the product and subject these to tests prescribed in the standard of the importing Member State; and

(b) Suppliers need to individually obtain approvals from each authority responsible in every Member State that the product is to be marketed in. ASEAN MRAs that are based on the Framework MRA specify that each Member State retains full regulatory authority and that any approval granted is only valid in the particular Member State.

(c) Additional or alternative actions are thus necessary if technical barriers are to be eliminated more comprehensively so as to lead to a situation where testing or certification is only to one standard and a single regulatory approval is valid across the region.

3.5 Several alternative instruments are available to ASEAN Member States in achieving the objectives of removing technical trade barriers when applied individually or in combination:

(a) Harmonising standards that are referenced in technical regulations of Member States;

(b) Relying on Suppliers' Declarations of Conformity (SDoC) as regulatory instruments. This eliminates the need for premarket approval. It is applicable in situations where risk is evaluated to be low and enforcement through post market surveillance is deemed to be adequate; and

(c) Establishing harmonised regulatory regimes that oblige Member States to adopt harmonised regulations. This will include harmonisation of all standards that are referenced in the particular technical regulation.

[2] The technical requirements are normally specified in standards. In some cases the technical requirements could be directly specified in the applicable technical regulations.

[3] Regulatory aapproval usually involves administrative measures, in addition to acceptance of the results of conformity assessment.

4. Pre-conditions and preparatory processes for developing MRAs

4.1. Preliminary identification of sectors for MRA development.

The sectors identified for the development of MRAs should include the sectors that are within the twelve priority integration sectors[4] and that have been identified for accelerated economic integration in the AEC Blueprint. Other sectors may be included when supported by decisions of the ASEAN Economic Ministers towards achieving the overall ASEAN economic integration targets set by ASEAN leaders.

Article 3(6) of the Framework MRA Agreement and the associated interpretative notes provide more specific guidance on the identification of sectors. This document serves as a concise reference to guide ASEAN Working Groups on the preliminary considerations for the development of an MRA.

Article 3(6), ASEAN Framework Agreement on MRAs	**Article 3(6), Interpretative Notes**
6. Member States shall identify sectors for developing MRAs based on the following criteria: (a) with special focus on, but not limited to, the list of 20 priority product groups identified for harmonization of standards; (b) the volume of intra-ASEAN trade affected; (c) the existence and extent of technical barriers to trade; (d) the readiness of technical infrastructure in the majority of Member States, which shall include the existence of Conformity Assessment Bodies that satisfy the procedures and criteria stated in Article 6, clause 1; and (e) the interest of the majority of Member States.	(1) All the criteria should be considered before developing an MRA for a particular sector; (2) The identification of sectors for MRAs should be a continuing process. The preparatory stages of Sectoral MRAs include the identification of appropriate sectors, consultation with relevant regulatory bodies and reaching an agreement among Member States; (3)Statistics on the volume of intra-ASEAN trade affected should be considered; () Technical barriers to trade experienced by Member States should be considered; (5) Member States should be requested to formally indicate their interest in developing an MRA in a particular sector; and (6) The majority of Member States means that more than half of the existing Members of ASEAN.

The continuing relevance of item 6a) should be critically reviewed by the responsible product working groups, as the decision to harmonise standards for the 20 product groups[5] was taken in 1997 and the elapsed time has changed the trade and industry

[4] ASEAN has identified 12 priority sectors: Health care products; Automotives; Rubber-based Products; Wood-based products; Textiles; Agro-based Products; Fisheries; Electronics and Electricals; Healthcare; Air-travel; Tourism and Logistics.

[5] The 20 product groups are: Air-conditioners, Refrigerators, Monitor & Keyboard, Motors and Generators, Inductors, Loudspeakers, Video Apparatus, Telephones, Radio, Television, Part of TV and Radio, Capacitors, Resistors, Printed Circuits, Switches, Cathode Ray Tubes, Diodes, Mounted Piezo-electric crystal, Rubber Condoms and Medical rubber gloves.

profile of the region and the importance of the standards concerned with market integration.

4.2. Conducting impact assessment to identify benefits; comparing alternative approaches and identifying risks.

The successful development and conclusion of an MRA requires a substantial investment in time and energy by the Member States. It is thus recommended that a demonstrable justification of the benefits is established prior to commencement of the development. The justification should be based on an investigation of the impact, costs and benefits to be derived from the intended MRAs. Such an investigation should include comparison of alternative approaches, including that of maintaining the existing status.

MRAs should be considered in the circumstances in which a majority of ASEAN Member States:

(a) prescribe mandatory product testing or certification as requirements for placing products in the market;

(b) there is an institutional infrastructure for conformity assessment and technical regulation in most Member States in the particular sector to support implementation of the MRA;

(c) relevant legislation is available in Member States to support the adoption of the MRA; and

(d) intra-ASEAN trade is sufficient to justify the efforts and that the expected cost savings of the MRA are significant.

MRAs may also be considered for sectors where there is a demonstrable potential to vastly increase trade in a sectors where existing technical barriers to trade are removed or reduced.

On making a preliminary decision for an MRA, an investigation should be initiated by the relevant working group and the results documented. It is recommended that the working group also ensures that there is no objection from any Member State and that the MRA is conducive to the long term integration of the whole ASEAN region. It should, however, be noted that the Framework MRA Agreement prescribes that ASEAN Member States may proceed to develop an MRA based on the interest of the majority and a consensus decision of all ten Member States.

4.3. Establishing agreement on the scope of the MRA, its guiding principles and objectives

It is recommended that the development of the draft text of the MRA be deferred until the Member States have reached a consensus on the scope, guiding principles and objectives of the MRA. The premature development of draft prior to agreement on the scope, principles and objectives could lead to inefficiency in the negotiations between Member States. The absence of an agreement in principle between Member States on the scope and expected objectives of the MRA provides no common ground for the negotiations on the text of the MRA to proceed in an effective manner. The scope should define the applicable products or sectors that the MRA addresses, the principles should outline the approaches to be adopted and the objectives be defined in terms of the direct impact on trade.

Additional detailed guidance is provided in **Annex 2**: **Guidance on Determining the Scope of MRAs.** This Annex identifies the issues that should be considered in defining the scope of applicability of a Sectoral MRA and provides guidance to the Sectoral Bodies responsible for developing MRAs.

4.4. Impact of differences in regulatory requirements on the development of MRAs

The impact of the differences in regulations should be considered in developing MRAs. The different situations encountered may include situations in which:

(a) Sectors or products that are subject to an MRA are regulated in one ASEAN Member State but are not regulated in one or more of the other ASEAN Member States. In this situation, the MRA has no impact on the exports into the particular Member States that does not regulate. As the exports from this country will need to comply with the regulations other Member States, such Member State should be encouraged to participate in the MRA and its support should be sought even if it decides not to be a party to the MRA;

(b) Member countries having major differences in technical regulations. Examples include situations in which one or more Member States have less rigorous regulation, such as the requirement for registration, and/or require self-declaration of conformity (SDoC) and another Member State requires premarket approval of products and regular surveillance. In this case, the MRA will have small or no impact on exports to the AMS with light touch regulation. It will, however, have an impact on the exports from this AMS. As in the case (i) above, the AMS concerned should be encouraged to participate in the MRA and its support should be sought even if it decides not to be a party to the MRA.

(c) A majority of Member States have light touch regulations such a product registration, SDoC or type approval. In such cases, there will be no significant benefits from the development of the MRA. Member States should seek alternative methods of removing the trade barriers that continue to exist in the other Members and negotiate agreements for harmonised light touch regulations and for harmonised standards.

5. MRA Development Processes

5.1. The recommended development process stages are elaborated in the table below:

Stage	Description
Preliminary Proposal for an MRA	The proposal may be initiated by any Member State or by the ASEAN Secretariat. Agreement to proceed would be by consensus of the concerned Working Group (WG).
Impact Assessment	The WG concerned would decide on the scope and method for conducting the assessment. Funding for the assessment will be identified and implementation coordinated by the WG responsible with the support of the ASEAN Secretariat.
Confirmation of Scope and Objectives	The WG concerned will review the results of the impact assessment and decide on the proceeding and on a positive decision; the WG will decide on the scope and

	objectives of the proposed MRA.
Preparation of Working Draft the MRA	A working draft will be prepared. The WG may request a Member State, the ASEAN Secretariat or any external party for this.
Deliberation of the Working Draft by WG Members Leading to the Development of a Draft for Member States' Consultation	The "draft for consultation" is a preliminary draft and does not bind Member States. It should reflect the general principles and may include alternative texts for sections in which there is no agreement. It is a document to facilitate Member States to conduct consultation with stakeholders in each Member State.
Consultation with Stakeholders within Each Member State	The consultation process is undertaken independently by each Member State. Each Member Sate will use the results of the consultation to formulate its position in preparation for deliberations of the MRA with other Member States.
Development of a Final WG Draft	The WG concerned will reconvene deliberations, taking note of the results of consultations. The negotiations will continue till the objective of Member States reaching agreement on the content of the MRA is achieved. On completion, the draft MRA is submitted to the ASEAN Consultative Committee on Standards & Quality (ACCSQ) or other body responsible for the WG as appropriate.
Finalisation	The finalisation will include legal vetting and approval by the appropriate ASEAN body. This will be coordinated by ASEAN Secretariat. The WG responsible will be informed of progress.

5.2. Standards Referenced in MRAs

MRAs developed by ASEAN can be developed independently of the initiatives for harmonisation of standards in the sector. In cases that there is a need to reference a particular standard in the MRA, the standards referenced should be those that are harmonised[6]. Suitable standards may be required to define the criteria for recognition of conformity assessment results and in special cases, for defining product characteristics. In case the required standards to be selected are not harmonised, these should be forwarded to Working Group 1 of ACCSQ to be included in the list of ASEAN harmonised standards. Only standards that are referenced in the MRA should be those that comply with ASEAN guidelines for harmonisation of standards.

5.3. Existing ASEAN Agreements

The development of the text of any MRA should commence with an examination of all existing relevant agreements on trade, standards, conformity assessment and technical regulation concluded between ASEAN Member States. The Declaration of the AEC Blueprint by ASEAN leaders, the AEC Blueprint and ASEAN Trade in Goods Agreement (ATIGA) should be key reference for all MRAs. As the MRA will not automatically override the existing agreements, it should be ensured that the

[6] The harmonisation of standards is overseen by Working Group 1 of ACCSQ under its guidelines.

commitments and obligations in the MRA are consistent with these. Repetition of previously agreed provisions should generally be avoided and a cross reference be made in its place.

5.4. Relationship with International and Regional Agreements

ASEAN Members States are Members of the World Trade Organisation and thus obliged to comply with the provisions of the General Agreement on Tariffs and Trade (GATT) and other agreements on goods trade. The Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade are significant to the development of MRAs and should be utilised as a references in the same manner as the ATIGA and the AEC Blueprint are used.

5.5. Special Considerations for CLMV

The development of MRAs should take into consideration the special provisions that ASEAN has agreed for CLMV. Reference should be made to the relevant provisions of the AEC Blueprint and ATIGA to guide the special considerations that the working group responsible may decide for CLMV.

6. Implementation and maintenance of MRAs

6.1. The ASEAN Committee responsible for implementing the MRA should be defined in the MRA and its functions should include the following items:

(a) Ensuring compatibility with Member State legislation to ensure that there is no legal obstacle to compliance with the obligations contained in the MRA;
(b) Issues of non-participation and terminating participation are defined;
(c) Issues dealing with the special considerations for Cambodia, Lao PDR, Myanmar and Vietnam are provided for; and
(d) Guidance is provided on the maintenance of the MRA, including making amendments and responding to other changes.

Annex 1: Definitions and Terminology recommended for use in ASEAN Mutual Recognition Arrangements

	Term	**Recommended Definition**	**Source**
1	Accreditation	a statement issued by an independent body conveying confirmation of a **conformity assessment body's** competence to carry out specific **conformity assessment** tasks	ISO/IEC 17000: 2004
2	Official Accreditation	the procedure by which a government agency having jurisdiction formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services. **Note:** This term is adopted from Codex and for use in the food sector, where recognition of competence is a responsibility of government authorities.	Codex Standard: CAC/ GL 47
3	Accreditation Body	authoritative body that performs **accreditation**	ISO/IEC 17000
4	Conformity Assessment	demonstration that specified requirements relating to a product process, system, person or body are fulfilled **Note 1**: The subject field of conformity assessment includes activities, such as testing, inspection and certification, as well as the accreditation of conformity assessment bodies. **Note 2**: The expression "object of conformity assessment" or "object" encompasses any particular material, product, installation, process, system, person or body to which conformity assessment is applied. The term "product" includes services.	ISO/IEC 17000
5	Conformity Assessment Body	body that performs conformity assessment services **Note 1**: An accreditation body is not a conformity assessment body. **Note 2:** Following the definition of conformity assessment, this includes bodies performing all forms of conformity assessment within the public and private sectors	ISO/IEC 17000
6	Conformity Assessment Procedure (CAP)	any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are	WTO/TBT Agreement

	Term	Recommended Definition	Source
		fulfilled Note 1: Conformity assessment procedures include, inter alia, procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combinations Note 2: It should be noted that the definition for CAP is defers from the definition of conformity assessment and additionally includes registration and approval.	
7a	Certification (1) ISO/IEC 1700	a procedure by which a third party gives written or other assurance that a product, process or service conforms to specified requirements	ISO/IEC 17000
7b	Certification (2) (Codex)	the procedure by which official certification bodies and officially recognized bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products	Codex Standard: CAC/GL 20
8	Certification System	official and officially recognized certification systems.	CAC/ GL 34
9	i. Equivalence (of certification and inspection systems) ii. Equivalence (of conformity assessment results) iii. Equivalence (of technical regulations)	i. the capability of different inspection and certification systems to meet the same objectives. ii. sufficiency of different conformity assessment results to provide the same level of assurance of conformity with regard to the same specified requirements iii. recognition that a technical regulation in one Member State has the same regulatory objective as that in the other, and the two sets of regulations both fulfil the same objectives Note: the definition of equivalence should be selected in accordance to the context in which it is applicable.	CAC/ GL 36 ISO/IEC 17000
10a	Inspection (general application)	examination of a product design, product,	ISO/IEC 17000

	Term	Recommended Definition	Source
		process or installation and determination of its conformity with specific requirements or, on the basis of professional judgement, with general requirements	
10b	Inspection (food Sector)	Inspection is the examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, in order to verify that they conform to requirements. Note: the special definition for the food sector is to ensure consistency with the concepts used in Codex documents, in which inspections are of a regulatory nature.	Codex Standard: CAC GL/20
11	ASEAN Harmonised Regulatory Regime	the harmonised regulatory requirements for a particular sector as defined in an agreement between ASEAN Member States and implemented by ASEAN Member States pursuant to the agreement.	ASEAN
12	Harmonised standards (for ASEAN):	Standards on the same subject, adopted by different ASEAN Member States, that are identical in technical content and structure. Note: Technical deviations are not permitted. Editorial changes that do not alter the technical content may however be present.	ASEAN
13	Placed on the Market	the first making available of a product on the market of one or more ASEAN Member States.	adapted from EU Directive 765
14	Market Surveillance/Post Market Surveillance	the activities carried out and measures taken by public authorities to ensure that products in the market do not endanger health, safety or any other aspect of public interest and that they comply with the requirements set out in relevant legislation.	adapted from EU Directive 765
15	Market Surveillance Authority/Post Market Surveillance Authority	an authority of a Member State responsible for carrying out market surveillance on its territory. Note: the authority is a body that is	ASEAN

	Term	Recommended Definition	Source
		mandated by way of legislation that specifies penalties for non-compliance and provides enforcement powers to the authority.	
16	Mutual Recognition Arrangement/Agreement) (MRA)	an arrangement that establishes an agreement for the mutual recognition of the equivalence of inspections, certification, certification systems, technical regulations or results of conformity assessment. Note: except when the MRA is for the recognition of equivalence of technical regulations, it does not lead to mutual recognition of regulatory approval.	ASEAN
17	Technical Barriers To Trade (TBTs)	barriers to trade arising out of the implementation of regulations, standards, testing and certification procedures to achieve policy objectives, such as the protection of human health and safety, or the environment. Note: the term "Non-Tariff Barriers (NTBs)" is often used alternately and this term additionally includes barriers due to other administrative restrictions requirements such as licensing and quotas.	adapted from WTO publications.
18	Standard	document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not 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 Note : This is adopted from the WTO/TBT Agreement. Standards are defined as voluntary documents and are differentiated from technical regulations which are mandatory. The definition also covers documents that are not based on consensus.	WTO/TBT Agreement
19	Suppliers Declaration of Conformity (SDoC)	procedure by which a supplier gives written assurance that a product, process	ISO/IEC Guide 2: 1996

	Term	Recommended Definition	Source
		or service conforms to specified requirements. Note: A Suppliers' Declaration of Conformity' is based on an assessment by the manufacturer himself.	
20	Type Approval	procedure by an authority to grant approval of a product to be marketed or used for stated purposes or under stated conditions through an evaluation of a representative sample.	adapted from ISO/IEC Guide 2
21	Technical Regulations	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.	WTO/TBT Agreement
22	Designation	governmental authorization of a conformity assessment body to perform specified conformity assessment activities. Note: Designation implies government authorisation and is based on confirmation of competency	ISO/IEC 17000
23	Designating Authority or Designating Body	body established within government or empowered by government to designate conformity assessment bodies, suspend or withdraw their designation or remove their suspension from designation	ISO/IEC 17000
24	Recognition of conformity assessment results	acknowledgement of the validity of a conformity assessment result provided by another person or body	ISO/IEC 17000
25	Acceptance of conformity assessment results	use of a conformity assessment result provided by another person or body Note: The acceptance of conformity assessment results does not, by itself, imply that regulatory approval granted by one Member State's authority is recognised by the other Member State's authorities.	ISO/IEC 17000
26	Regulatory Authority	an entity that has been granted a legal right to control the import, use or sale of	ASEAN Framework MRA Agreement

	Term	Recommended Definition	Source
		products within a Member State's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements	
28	Competent Authority	means the official government agency having jurisdiction over designated functions. Note: the definition for Competent-Authority refers to an organization that has the legal mandate over a function.	Adapted from Codex Standards

Annex 2: Guidance on Determining the Scope of MRAs

Background

The development of Mutual Recognition Arrangements (MRAs) is recognised in ATIGA[7] as one of the means to eliminate unnecessary Technical Barriers to trade. The ASEAN FRAMEWORK AGREEMENT ON MUTUAL RECOGNITION ARRANGEMENTS that has been developed provides a model for the development of sectoral recognition agreements. A number of sectoral recognition arrangements have been developed and a number of others are under development.

The objectives of MRAs, as provided in the Framework Agreement, are "*to stipulate the general conditions under which each Member State shall accept or recognise the results of conformity assessment procedures, produced by Conformity Assessment bodies of other member States*--".

The scope of application for each ASEAN MRA is determined by the Sectoral ASEAN Body that is responsible for the development of a particular MRA. Questions have been posed by a number of Working Groups on defining the scope of a MRA. It is intended that this document provides guidance to the Working Groups in defining the scope of the MRA with respect to the sectors and products covered and the origin of the products. The ASEAN Trade in Goods Agreement (ATIGA) and the World Trade (WTO) Agreements on Technical Barriers to Trade (TBT) and on Sanitary and Phytosanitary Measures (SPS) have been referenced to ensure consistency with relevant existing obligations contained in these agreements.

This guidance is applicable to MRAs as defined in this document and does not apply to harmonised regulatory regimes that are adopted by ASEAN. The harmonisation of regulatory regimes includes consideration of additional administrative issues that will require alternative guidance.

Definitions:

The definitions of the terms "Technical regulation", "Standards" and "Conformity assessment procedures are as per definitions in the WTO/TBT Agreement.

Issues

1. Differing technical regulation and the differences in referenced standards and applicable conformity assessment procedures between ASEAN Member States lead to technical barriers to intra-ASEAN Trade in goods. MRAs are instruments that provide for the mutual recognition of the results of conformity assessment conducted in one Member State by other Member States. The recognition reduces technical barriers by removing the need for repeated testing, certification or inspections especially if standards are also harmonised. Additionally, the MRA provides that the products covered under the MRA may be assessed by any mutually accepted conformity assessment body within ASEAN.
2. The ASEAN Trade in Goods Agreement (ATIGA), as the principle instrument that defines the path to the realisation of the ASEAN Economic Community, provides the main reference for determining the scope of a Sectoral ASEAN MRA. Noting that all ASEAN Member states are members of WTO and that the fact that ATIGA has reaffirmed ASEAN Member States' rights and obligations to the WTO/TBT Agreement in Article 73 and the WTO/SPS Agreement in Article 81, the provisions of these two agreements apply. The

[7] **ATIGA Article 73**: 2. Member States shall take any of the following possible measures or their combinations to mitigate, if not totally eliminate, unnecessary technical barriers to trade:
(c) develop and implement ASEAN Sectoral Mutual Recognition Arrangements and develop ASEAN Harmonised Regulatory Regimes in the regulated areas where applicable;

scope of ASEAN MRAs should thus be guided by the provisions of WTO/TBT that deals with standards, technical regulations and conformity assessment procedures and the provisions of the WTO/SPS Agreement that deals with sanitary and phytosanitary measures. The provisions of Article 6 of WTO/TBT agreement elaborate on the obligations for recognition of conformity assessment procedures.

3. The objective of MRAs, as stated in the ASEAN Framework Agreement on MRAs, is the recognition of the results conformity assessments procedures between Members States. The recognition is in turn, dependent upon the validity and confidence of the results. The Agreement thus provides criteria and the procedures for determining the competence of conformity assessment bodies. These criteria are based on internationally recognised standards and guides.

4. Article 2.1[8] and 5.1.1 of the WTO/TBT Agreement requires WTO Members not to discriminate on the basis of the origin of the products with regard to technical regulation and application of conformity assessment procedures. The WTO/ SPS Agreement, in Articles 5 and 6 provide for sanitary and phytosanitary measures to be based on risk assessment and adapted to regional conditions.

5. International standards and guides for accreditation and conformity assessment do not permit conformity assessment bodies to discriminate on the basis of the origin of the product. Accredited conformity assessment bodies listed in the MRAs are thus required to undertake tests or certification for all products, irrespective of the origin of the product.

6. Global and regional recognition arrangements for conformity assessment such as the Asia-Pacific Laboratory Accreditation Cooperation/International Laboratory Cooperation MRA (APLAC/ILAC MRA), the Pacific Accreditation Cooperation Multilateral Recognition Arrangement/International Accreditation Forum (PAC/IAF MLA) and the IEC CB Scheme underpin the ASEAN MRAs by providing a basis for acceptance of the results of conformity assessment. These agreements have a wide coverage that extends globally, well beyond the territories of ASEAN Member States.

7. The sectoral working groups, developing mutual recognition arrangements, define the coverage of the arrangement in terms of the product types or categories. Since any MRA is dependent upon the availability of conformity assessment infrastructure, the MRA should take into consideration the infrastructure development gap. It is a reasonable expectation that non-availability of the required conformity assessment infrastructure in ASEAN Member States be factored in when determining the scope of coverage in terms of product types or categories. Specific provisions may be considered to provide for this gap.

8. Regulatory approval of a particular product is based on a range of requirements and in addition to requirements for results of conformity assessment procedures. Technical Regulations of ASEAN Member States contain other administrative and technical requirements in addition to those for conformity assessment. Harmonised Regulatory Regimes will contain provisions for these other requirements that are additional to provisions for conformity assessment.

[8] TBT Agreement, Article 2.1 Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

Guidance

1. The Guidance should be read together with the ASEAN Framework Agreement on Mutual Recognition Agreements.
2. Noting that MRAs are instruments that facilitate the reduction and/or removal of technical barriers to trade, the scope of an MRA should cover product types and categories that are subject to technical barriers to imports in majority of the Member States.
3. In event that implementation is to be phased by product categories, it will be useful for the MRA to define the scope of coverage broadly and reference the specific product types covered at any one time in an Annex. This can provide for flexibility during implementation in a phased manner if provision is made for amendments to the Annex through agreement of the parties through administrative means.
4. At the 45th Meeting of the ACCSQ, the meeting agreed that the key elements of the mutual acceptance of conformity assessment results and key elements are as below:
    a. If a Conformity Assessment Body (CAB), whether it is locally owned or foreign CAB located in an AMS (with legal entity), as long as it is accredited by an Accreditation Body that is signatory to a regional or international MRA, the CAB should be accepted.
    b. If a CAB is accredited for the scope under the regulatory regime, and carries out relevant conformity assessment procedure according to the requirements of the regulatory regime of importing countries, it should be accepted.
5. The meeting also noted the sample phrasing of the text from MRA on BE Study Report as follows:

    "The objective of this Sectoral MRA is to enable the mutual recognition of [BE Study Reports of generic medicinal products] issued by Listed [BE Centres] located in the territory of Member States in order to facilitate the movement of [generic medicinal products] within ASEAN."
6. At the SEOM 3/46 Meeting, SEOM discussed on the on-going deliberation on whether the MRA shall be for products manufactured in ASEAN or for products traded in ASEAN, SEOM gave guidance that the MRAs shall be as trade facilitating as possible.
7. At the SEOM 3/47 Meeting, the SEOM concurred with the "Silent Approach" of the MRA and provided flexibility on the implementation of the silent approach taken into consideration the nature of the product involved. The SEOM 3/47 report states as follows:

    "47. The Meeting also noted the ACCSQ decision to proceed with the finalisation of the MRA on Type Approval for Automotive Products and MRA on Inspection and Certification System for Food Hygiene by taking the approach on MRA on BE Study report where the MRA is silent on the "manufactured and traded in ASEAN". The Meeting noted that some AMS have concerns and issues on its implementation issues which may occur when these MRAs come into effect. The Meeting noted that some AMSs could interpret differently the scope of those MRAs using the "silent approach" as it would be based on their own risk assessment applied to particular covered products. Nevertheless, the Meeting agreed for ACCSQ to resort to the "silent approach" to move forward the conclusion of the pending MRAs, although ACCSQ could still specify the scope as manufactured and traded in ASEAN taking into account

the needs of each product working group (PWG) for the completion of the additional guidelines on MRA."

To ensure common understanding on SEOMs guidance in the development and implementation of sectoral MRAs, in particular on the scope and objective of the MRA, the silent approach will be considered as a default. However, should a sectoral body for a product sector finds that there is a reasonable ground for the acceptance of conformity assessment results to a particular scope of products manufactured and/or traded in ASEAN under its respective MRA, the sectoral body may propose to specify the scope as manufactured and/or traded in ASEAN with justifications to ACCSQ outlining the reasons to apply the flexibility on the scope of the MRA for ACCSQ's consideration.

8. A Sectoral Mutual Recognition Arrangement which is silent with regard to the origin of the products in its scope statement will result in the acceptance of conformity assessment results that are from any "listed or recognised conformity assessment body" a that is recognised under the MRA.
9. Member States regulations may contain additional administrative requirements for imports of certain types of products. These could include i registration of suppliers, import licencing, provision of product information and labelling. These conditions for imported products are normally not within the scope of MRAs on conformity assessment. The removal or mitigation of the additional trade barriers should be addressed through harmonised regulatory regimes.

Recommendations

1. It is recommended the Sectoral MRAs follow the ASEAN Framework Agreement on Mutual Recognition Agreements. In addition, it should make reference to Article 73 of ATIGA to reaffirm the rights and obligations of the WTO TBT Agreement and to develop and implement ASEAN Sectoral MRA to eliminate unnecessary barrier to trade.

2. It is noted that the ASEAN Framework Agreement on MRA, states that Member States to the Sectoral MRAs shall accept or recognise the conformity assessment results, which have been issued in accordance with the provisions in the Sectoral MRAs, by the listed CAB of other Member States to the Sectoral MRAs. In this regard, para 4(a) above provides greater clarity that the listed CAB is a locally owned or foreign CAB located in an AMS (with legal entity). With regard to para 4(b), it is consistent with the ASEAN Framework Agreement on MRA where the results of conformity assessment procedures should be accepted when a CAB is accredited for the scope of the regulation and the conformity assessment procedure used is in accordance to the requirements of the importing Member State.