

ERIA Research Project Report 2015, No. 15

# **Harmonization of Standards and Mutual Recognition Agreements on Conformity Assessment in Indonesia, Malaysia, Thailand, and Viet Nam**

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November 2016



Economic Research Institute for ASEAN and East Asia

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ERIA Research Project FY2015 No.15

Published in November 2016

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## LIST OF ABBREVIATIONS

AANZFTA	ASEAN-Australia-New Zealand Free Trade Agreement
ACCSQ	ASEAN Consultative Committee on Standards and Quality
ACD	ASEAN Cosmetic Directive
AHCRS	ASEAN Harmonized Cosmetic Regulatory Scheme
AHEEERR	ASEAN Harmonized Electrical and Electronic Equipment Regulatory Regime
AEC	ASEAN Economic Community
AFIC	ASEAN Furniture Industry Council
AMDD	ASEAN Medical Device Directive
APWG	Automotive Product Working Group
ARISE	ASEAN Regional Integration Support from the EU
ARL	ASEAN Reference Laboratory
ATIGA	ASEAN Trade in Goods Agreement
ASEAN	Association of Southeast Asian Nations
ASEAN EE MRA	ASEAN Electrical and Electronic Mutual Recognition Arrangement
BSN	Badan Standardisasi Nasional (National Standardization Agency of Indonesia)
CAB	conformity assessment body
ECWP	Economic Cooperation Work Program
EEE	electrical and electronic equipment
ISO	International Organization for Standardization
JSC EEE	Joint Sectoral Committee on EEE
MRA	mutual recognition arrangement
PTB	Physikalisch-Technische Bundesanstalt (National Metrology Institute of Germany)
PWG	product working group
SMEs	small and medium-sized enterprises
SNI	Standar Nasional Indonesia (Indonesian National Standard)
STAMEQ	Directorate for Standards, Metrology and Quality of Viet Nam
TATF	Technical Assistance and Training Facility
TBT	technical barrier to trade
TC	technical committee
TISI	Thai Industrial Standards Institute

UNECE	United Nations Economic Commission for Europe
USAID	US Agency for International Development
WG	working group
WTO	World Trade Organization

## 1. Introduction

Standards serve an important function in facilitating international trade as these promote interoperability and ensure product safety. However, overly burdensome measures can increase the cost of trade and reduce competition. Overly burdensome measures can become technical barriers to trade (TBTs) especially when domestic regulators impose mandatory technical regulations or voluntary standards that define specific characteristics and production methods of a product. By extension, conformity assessment procedures – encompassing product testing, inspection, and certification activities to check whether a product complies with these requirements – also represent a TBT.

The significance of TBTs has increased considerably as tariff barriers gradually decline by way of free trade agreements or through unilateral reductions in most-favoured nation tariff rates, which lead governments to introduce regulatory requirements to alter the terms of trade in favour of domestic producers. While TBTs may fulfil a legitimate public policy objective – such as protecting human health and safety or the environment, adjusting products and production processes, and completing conformity assessment procedures to comply with requirements in different markets – these can create challenges and raise certain issues for exporters with limited resources. This situation may increase costs and restrict market access to the detriment of the goals of promoting trade.

Eliminating TBTs and harmonising standards can enhance trade competitiveness, promote market access, and decrease unnecessary trade costs. This effort is imperative for members of the Association of Southeast Asian Nations (ASEAN) to achieve a single market and production base as envisioned under the ASEAN Economic Community (AEC) Blueprint by 31 December 2015. Following its implementation, ASEAN expects simple, harmonised, and streamlined trade and customs documentation and procedures that will facilitate trade in the region. On standards and conformance, ASEAN acknowledges in the AEC Blueprint that ‘systems of standards, quality assurance, accreditation, and measurement are crucial to promote greater efficiency and enhance cost effectiveness of production of intra-regional imports/exports.’

This paper examines the basis of developments surrounding the ASEAN standards and conformance efforts, focusing on the following six sectors: (i) automotive, (ii) cosmetics, (iii) electrical and electronic equipment, (iv) medical devices, (v) rubber-based products, and (vi) wood-based products. This paper also reviews the implementation of such ASEAN initiatives in four selected ASEAN member states – Indonesia, Malaysia, Thailand, and Viet Nam – and identifies public support measures and capacity-building initiatives that the ASEAN or specific member states have received from third parties, including the European Union, the United States (US), Australia, New Zealand, and Germany. Lastly, this paper provides recommendations on where ASEAN could target its efforts to advance its standards and conformance regime in order to meet the commitments set forth in the 2015 AEC Blueprint and the post-2015 AEC agenda.

## 2. Overview of National and International Standards

A standard is a document that sets out requirements, specifications, guidelines, or characteristics that help ensure that materials, products, processes, and services are fit for their purpose. According to the International Organization for Standardization (ISO), standards help to harmonise technical specifications of products and services, make the industry more efficient, and break down barriers to international trade. Conformity to international standards helps reassure consumers that products are safe, efficient, and good for the environment (ISO, 2014). While standards can serve legitimate commercial and policy objectives, overly burdensome or discriminatory standards-related measures can become a barrier to trade.

The World Trade Organization (WTO) Agreement on Technical Barriers to Trade ('the TBT Agreement') is the principal agreement establishing multilateral rules to ensure that regulations, standards, testing, and certification procedures do not create unnecessary obstacles to trade.<sup>1</sup> One of the goals of the TBT Agreement is to ensure that standards serve a genuine purpose, rather than an arbitrary one, or a front for protectionism. The TBT Agreement contains detailed provisions to clarify the entire process of preparing, adopting, and applying standards-related measures, while encouraging the use of international standards and requiring transparency throughout the process.

Within the ASEAN process, standards-related measures imposed by ASEAN member states are subject to the ASEAN Trade in Goods Agreement (ATIGA),<sup>2</sup> specifically Chapter 7 covering Standards, Technical Regulations, and Conformity Assessment Procedures. The Parties reaffirm their commitments under the TBT Agreement and agree to additional provisions under Article 73(2), as follows:

- i. Harmonise national standards with relevant international standards and practices,
- ii. Promote mutual recognition of conformity assessment results among member states,

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<sup>1</sup>Binding on all WTO members, the TBT Agreement entered into force on 1 January 1995. The TBT Agreement distinguishes the three categories of measures, as follows: (i) **Technical regulations** are documents that lay down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. These may also include or deal exclusively with terminology, symbols, packaging, marking, or labelling requirements as they apply to a product, process, or production method; (ii) **Standards** are documents approved by a recognized body that provide, for common and repeated use, rules, guidelines, or characteristics for products or related processes and production methods, with which compliance is not mandatory. These may also include or deal exclusively with terminology, symbols, packaging, marking, or labelling requirements as they apply to a product, process, or production method; and (iii) **Conformity assessment procedures** are any procedures used – directly or indirectly – to determine that relevant requirements in technical regulations or standards are fulfilled.

<sup>2</sup> The ATIGA entered into force on 17 May 2010 among Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Viet Nam.

- iii. Develop and implement ASEAN Sectoral Mutual Recognition Arrangements and develop ASEAN Harmonized Regulatory Regimes in regulated areas where applicable, and
- iv. Encourage cooperation among national accreditation bodies and national metrology institutes, including relevant legal metrology authorities in the ASEAN to facilitate the implementation of mutual recognition arrangements (MRAs) in regulated and non-regulated sectors.

In addition, under the AEC Blueprint, the ASEAN acknowledges that harmonised standards, technical regulations, and conformity assessment procedures are vital to promote greater efficiency and lower the cost of intra-regional trade.<sup>3</sup>The ASEAN Policy Guideline on Standards and Conformance<sup>4</sup> ('the Guideline') guides the implementation of the AEC Blueprint concerning standards-related measures. The Guideline aims to provide 'the guiding principles for the implementation of joint efforts of ASEAN Member [States] in the area of standards and conformance both in regulated and non-regulated sectors as one of the measures for accelerating economic integration towards the AEC.' Nonetheless, the AEC Blueprint cautions that the 'identification of standards, technical regulations and conformity assessment procedures to be harmonised or for sectoral MRAs to be developed, must take into consideration the impact on ASEAN trade, the complexity of the regulatory system, the technical infrastructure as well as the feedback from stakeholders.'

Based on this high-level guidance, ASEAN member states seek to prioritise the harmonization of standards and adoption of MRAs where possible, which may culminate in a single regulatory regime, such as those in the cosmetics and electrical and electronic equipment sectors. The basic principle of the harmonization process in the ASEAN is that national standards bodies would need to adopt regionally agreed international standards. If they do not adopt any of the identified international standards as their national standards, then the national standards bodies would accept the direct use of these international standards, meaning that the international standard would be directly applied and utilised in the national context.<sup>5</sup>

The ASEAN Framework Agreement on Mutual Recognition Arrangements provides the general principles for developing sectoral MRAs among ASEAN member states, and the general conditions under which a member state will accept or recognise the results of conformity assessment procedures produced by the conformity assessment body (CAB) of another

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<sup>3</sup>ASEAN adopted the Declaration on the AEC Blueprint on 20 November 2007.

<sup>4</sup> ASEAN adopted the ASEAN Policy Guideline on Standards and Conformance on 5 August 2005.

<sup>5</sup>The adoption of international standards results in the establishment of national standards that are (i) equivalent to the international standard but may have editorial differences as to appearance, use of symbols and measurement units, substitution of a point for a comma as the decimal marker, or (ii) modified from the international standard due to differences resulting from governmental regulations or industry-specific requirements caused by fundamental climatic, geographical, technological, or infrastructural factors, or the stringency of safety requirements that a national standard body considers appropriate.



member state.<sup>6</sup>To ensure confidence in the CAB's competency and to take into account the different national systems of ASEAN member states, the Framework Agreement on Mutual Recognition Arrangements states that CABs need to meet one of the following criteria to demonstrate technical competence:

- Accreditation by a body that is a signatory to a regional or international MRA, which is conducted in conformance with the relevant ISO/International Electrotechnical Commission (IEC) standards and/or guides (e.g. Asia Pacific Laboratory Accreditation Cooperation, International Laboratory Accreditation Cooperation, Pacific Accreditation Cooperation, International Accreditation Forum); or
- Participation in regional and/or international MRAs for testing and certification bodies, which are conducted in conformance with the relevant ISO/IEC standards and guides; or
- Regular peer evaluations, conducted in conformance with ISO/IEC guides.

The ATIGA also recognises that the role of the ASEAN Consultative Committee on Standards and Quality (ACCSQ), which was originally established in 1992, is to monitor the implementation of ATIGA with respect to standards, technical regulations, and conformity assessment procedures. The ACCSQ – which reports to the Senior Economic Official Meeting and ultimately to the ASEAN Economic Ministers – currently oversees three cross-cutting working groups (WGs), as follows:

- (i) Working Group on Standards and MRAs (WG1),
- (ii) Working Group on Accreditation and Conformity Assessment (WG2), and
- (iii) Working Group on Legal Metrology (WG3).

The working structure of ACCSQ also involves the activities of eight product working groups (PWGs) with specific sectoral jurisdictions, as follows:

- Automotive – Automotive Product Working Group (APWG)
- Cosmetics – ASEAN Cosmetic Committee (ACC)
- Electrical and electronic equipment – Joint Sectoral Committee for ASEAN Electrical and Electronic Equipment (JSC EEE)
- Medical devices – Medical Device Product Working Group (MDPWG)
- Pharmaceuticals – Pharmaceutical Product Working Group (PPWG)
- Prepared foodstuff – Prepared Foodstuff Product Working Group (PFPWG)

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<sup>6</sup>ASEAN member states signed the ASEAN Framework Agreement on Mutual Recognition Arrangements on 16 December 1998; it entered into force on 31 December 2002.

- Rubber-based products – Rubber-based Product Working Group (RBPWG)
- Traditional medicine and health supplements – Traditional Medicine & Health Supplement Product Working Group (TMHSPWG)

Under WG1, there are two task force groups – one is on building and construction (Task Force on Building and Construction [TFBC]), and the other is on wood-based products (Task Force on Wood-based Products [TFWBP]).

A Product Working Group (PWG) and a Task Force (TF) are substantially the same since they are able to achieve the same goals of discussing the harmonization of sectoral standards and establishment of MRAs. Their difference is that a PWG has reached the level of support and investment from ASEAN member states that warrants the independence of a dedicated body, while a TF usually means that the subject under its purview has yet to achieve a critical level of interest (see Appendix A for the ASEAN structure for standards and conformance, and Appendix B for a summary of the WGs and PWGs, and the responsibilities of each entity).

### **3. The Harmonization of Standards in the ASEAN**

The ASEAN does not formulate its own standards. To ensure economic integration within the ASEAN, and the compatibility of ASEAN-origin products with international markets, the member states agree to adopt certain international standards for products of interest as national standards. Through this approach, the ASEAN aims to avoid conflict in the national standards among all member states, such that these do not become an impediment to trade.

During the harmonization exercise, the national standards bodies in ASEAN or appointed standards development agencies would need to adopt agreed upon international standards (ISO, IEC, etc.) as national standards. In the event they do not adopt any of the identified international standards as their national standards, they would then accept the direct use of these international standards. Harmonising existing national standards and adopting international standards into new national standards is based on the ISO/IEC Guide21 'Adoption of International Standards as Regional or National Standards' or its latest edition (ASEAN, 2005b).

Harmonising the standards to international standards, with standards being essentially voluntary, may be considered relatively easier to undertake than harmonizing the technical regulations, which are mandatory in nature, unless the standards become part of technical regulations. However, if an ASEAN member state needs to modify an international standard prior to adopting it, such member states should ensure that the modification is not prepared and adopted with a view to or with the effect of creating unnecessary TBTs, and should not be more restrictive than necessary to fulfil legitimate objectives. The member state would also endeavour to ensure an easy comparison of the content and structure of its national standards with the referenced international standards and to provide information to explain the reason for such modifications (ASEAN, 2005b).

On conformity assessment procedures, ASEAN member states agreed under the ATIGA to adopt procedures that are consistent with international standards and practices. In instances where they cannot achieve such procedures due to differences in legitimate public policy objectives such as the protection of health, safety, or the environment, ASEAN member states agree to minimise the differences of conformity assessment procedures as far as possible. Conformity assessment procedures imposed by an ASEAN member state should also not be more stringent on suppliers of products originating in the territories of other member states than those on domestic suppliers of similar products. For MRAs, ASEAN member states should accept the results of conformity assessment produced by CABs 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.

Notably, the harmonization of standards and development of MRAs are focused on ASEAN's 11 Priority Integration Sectors as identified in the ASEAN Framework Agreement for the Integration of Priority Sectors, namely (i) agro-based products, (ii) air travel, (iii) automotive, (iv) e-ASEAN, (v) electronics, (vi) fisheries, (vii) healthcare, (viii) rubber-based products, (ix) textiles and apparels, (x) tourism, and (xi) wood-based products.<sup>7</sup>This focus is in line with provisions in the ASEAN Policy Guideline on Standards and Conformance that ASEAN member states should give special attention to implement all standards, technical regulations, and conformity assessment measures as stated in the Bali Concord II, the Recommendation of the High-Level Task Force on ASEAN Economic Integration, and the documents for fast-track integration of the priority sectors, including the ASEAN Framework Agreement for the Integration of Priority Sectors, its protocols, and road maps.

According to discussions with national standards body representatives, the process to identify certain standards for harmonization within each Priority Integration Sectors is based on several criteria, namely (i) the volume of intra-ASEAN trade affected, (ii) the existence and extent of TBTs, (iii) the readiness of technical infrastructure in the majority of ASEAN member states, and (iv) the interest of the majority of ASEAN member states. The discussion to adopt a standard for harmonization generally begins at the PWG level, after which the relevant PWG will forward its decision to the ACCSQ for endorsement prior to submission to the Senior Economic Official Meeting or to the ASEAN Economic Ministers for adoption.

More crucially, the adoption of international standards is equally critical for ASEAN's external trade as it is for intra-ASEAN trade so that the products could compete at an international level. As international standards define the characteristics that products and services have to meet in export markets, these help developing countries take part fairly and competitively in international trade. Demonstrating compliance with such standards and achieving certification would be useful in establishing the credibility and reputation of ASEAN exports in the international market. As ASEAN industries continue to grow and develop, these can use

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<sup>7</sup>ASEAN member states signed the ASEAN Framework Agreement for the Integration of Priority Sectors on 29 November 2004.

international standards as basis for developing new products and services, supporting their acceptance in new markets, or even creating new markets (ISO, 2014).

#### 4. Evaluating Sector-Specific Developments

This paper examines the regional framework and developments for the following six sectors: (i) automotive, (ii) cosmetics, (iii) electrical and electronic equipment, (iv) medical devices, (v) rubber-based products, and (vi) wood-based products. This is followed by a review of their implementation in Indonesia, Malaysia, Thailand, and Viet Nam. The results are based on comparisons between publicly available information and interviews with national standards bodies – the National Standardization Agency of Indonesia (BSN), the Department of Standards Malaysia, the Thai Industrial Standards Institute (TISI), and the Directorate for Standards, Metrology and Quality of Viet Nam (STAMEQ) and the Viet Nam Standard and Quality Institute.<sup>8</sup>

##### Automotive Sector

For *standards harmonization* within ASEAN, the Automotive Product Working Group (APWG) has undertaken the harmonization of automotive products by agreeing to align national standards or technical requirements with the United Nations Economic Commission for Europe (UNECE) Regulations of the 1958 Agreement.<sup>9</sup> Under the AEC 2015 implementation schedule, the ASEAN has adopted 19 UNECE regulations for harmonization (Table 1). In addition, the APWG has undertaken initial work towards the alignment and/or adoption of 32 additional UNECE regulations during the post-2015 period following the process undertaken for the 19 UNECE regulations. In this regard, the APWG is analysing the suitability of M1, N1, and L categories of vehicles<sup>10</sup> for the 32 UNECE regulations in the ASEAN.

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<sup>8</sup> This paper omits information deemed sensitive or not yet made public by the ASEAN or its member states and does not directly attribute information to a certain body or its representative. Moreover, the purpose of this paper is not to elaborate on the main objectives of each of the PWGs, but rather to provide information on recent sectoral developments and the policy basis behind them.

<sup>9</sup> The purpose of the 1958 Agreement, signed on 20 March 1958, is the adoption of uniform technical prescriptions for wheeled vehicles, equipment, and parts that can be fitted and/or used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions.

<sup>10</sup> Category M1 refers to vehicles designed and constructed for carrying passengers, comprising no more than eight seats in addition to the driver's seat; Category N1 refers to vehicles designed and constructed for carrying goods and have a maximum mass not exceeding 3.5 tons; Category L refers to mopeds, motorcycles, motor tricycles, and quadricycles.

**Table 1: UNECE Regulations for Harmonization in the ASEAN**

Regulation	Description
ECE R13	Heavy-vehicle braking
ECE R13H	Braking of passenger cars
ECE R14	Safety-belt anchorages
ECE R16	Safety belts
ECE R17	Strength of seats, their anchorages, and head restraints
ECE R25	Head restraints (headrests)
ECE R28	Audible warning device
ECE R30	Tires for passenger cars and their trailers
ECE R39	Speedometer
ECE R40	Exhaust emission
ECE R41	Noise emission (L category)
ECE R43	Safety glass
ECE R46	Devices for indirect vision (rear-view mirror)
ECE R49	Diesel emission
ECE R51	Noise emission of M and N vehicle categories
ECE R54	Tires for commercial vehicles and their trailers
ECE R75	Tires for motorcycles and/or mopeds
ECE R79	Steering equipment
ECE R83	Exhaust emission of M1 and N1 vehicle

UNECE = United Nations Economic Commission for Europe.

Source: Adopted from AMCHAM Thailand.

The implementation progress of the 19 priority UNECE regulations is as follows:

- **Indonesia** has adopted the priority 19 UNECE regulations.
- **Malaysia** has adopted the priority 19 UNECE regulations.
- **Thailand** has adopted 16 UNECE regulations. The remaining three are undergoing domestic implementation process, including legal scrubbing by the Council of State and verification of notifications for publication in the *Royal Government Gazette*. TISI expects to complete these procedures in mid-2016.
- **Viet Nam** has adopted 16 UNECE regulations in a non-equivalent manner. The government reportedly plans to use the UNECE regulations as reference standards only instead of fully adopting them. Moreover, the government does not have a plan to improve the degree of correspondence in the near future due to its interest in protecting the domestic automotive industry. On the three remaining regulations, Viet Nam adopted these prior to the promulgation of the Law on Standards and Technical Regulations that took effect on 1 January 2007. STAMEQ, however, indicated that these three standards have become invalid as they were not converted into official Viet Nam standards under the Law on Standards and Technical Regulations.

On **conformity assessment procedures**, the UNECE regulations serve as the basis for the forthcoming ASEAN MRA for Type Approval of Automotive Products. According to the 11th draft of the MRA published on 6 May 2014 by the Philippine Department of Trade and Industry,

ASEAN member states agree to recognise the conformity assessment results issued by a Listed Technical Service (accredited under ISO/IEC17025, ISO/IEC 17021 and/or ISO/IEC 17020 as applicable), which demonstrate conformity of subject automotive products with the mandatory requirements under the corresponding UNECE regulations. As such, member states would commit to ensure that no re-testing is required for components and systems that are already compliant with UNECE regulations according to the requirements of the MRA, even if a vehicle incorporates such components and/or systems. It may be noted that the MRA only covers 'ASEAN Automotive Products' and does not cover whole vehicle type approval, as the latter is not a component of the 1958 Agreement that underpins the ASEAN MRA.<sup>11</sup>The MRA also only covers new automotive products, not used automotive products, i.e. refurbished, reconditioned or remanufactured. ASEAN member states aim to sign the MRA by the end of 2015, which the ASEAN has designated as a deliverable under the final Scorecard for the AEC 2015.<sup>12</sup> ASEAN member states will also establish an ASEAN Automotive Committee to implement and monitor the MRA.

### **Cosmetics Sector**

The cosmetics sector is subject to a **single regulatory regime** under the ASEAN Harmonized Cosmetic Regulatory Scheme (AHCRS).<sup>13</sup>This scheme comprises (i) the ASEAN MRA of Product Registration Approvals for Cosmetics under Schedule A, and (ii) the ASEAN Cosmetic Directive (ACD) under Schedule B. The ASEAN introduced the MRA as a preparatory stage prior to transitioning to the ACD.<sup>14</sup>Subsequently, the ACD superseded the MRA beginning 1 January 2008.

The ACD comprises five primary components as follows: (i) the definition and scope of cosmetic products, (ii) ingredients listing, (iii) labelling, (iv) product claims, and (v) cosmetic good manufacturing practice. Under the ACD, a product produced or marketed in any signatory country and meets the requirements of the AHCRS would be able to enter other signatory countries without additional requirements. The most significant aspect of the ACD is that the ASEAN moved from the traditional approach of pre-market approval to the new approach of post-market surveillance for cosmetic products. This change in procedure means that the manufacturer or the person responsible for placing cosmetic products in the market

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<sup>11</sup> The agreed scope of 'ASEAN Automotive Products' tentatively refers to automotive products manufactured by a manufacturer incorporated and operating within the boundary of ASEAN that carries out manufacturing activities and is responsible for the safety, quality, and environmental protection of the product concerned.

<sup>12</sup> The Scorecard is a compliance tool created by the ASEAN, which reports the progress of implementing the various AEC measures, identifies implementation gaps and challenges, and tracks the realization of the AEC by 2015.

<sup>13</sup> ASEAN member states signed the AHCRS during the 35th ASEAN Economic Ministers Meeting on 2 September 2003.

<sup>14</sup> Under the MRA, ASEAN member states will recognize the product registration approval of any signatory in accordance with agreed rules and procedures (i.e. the ASEAN Cosmetic Labelling Requirements, the ASEAN Cosmetic Claims Guidelines, and the ASEAN Guidelines for Cosmetic Good Manufacturing Practices).

will notify the cosmetic regulatory authority of each member state where the product will be marketed, of the place of manufacture, or of the initial importation of the cosmetic product before it is placed on the ASEAN market. The product can only be marketed after notification has been sent to the regulatory authority and acknowledgement has been received. This Product Notification System also replaced the Product Registration System under the previous MRA, such that it now involves upfront declaration of compliance by the company responsible for the product.

Following the submission of the required forms to the regulatory body, the regulatory body will then conduct spot checks at random, i.e. post-market sampling, to check whether a particular cosmetic product complies with the agreed-upon technical regulations and standards. The regulatory body will then send these samples to the relevant testing body. One key determinant in the process is the risk level (the risk classification) of a particular cosmetic product (e.g. certain safety concerns, harmful elements, etc.), and whether the particular risk level warrants additional scrutiny and investigation. For products that fail to meet the technical regulations or standards, ASEAN member states have developed tracking mechanisms to trace down errant products to the batch level.

To implement the ACD, ASEAN member states committed to adopt five aspects of the AHCRS into their national regulatory framework, as follows:

- ASEAN Definition of Cosmetics and Illustrative List by Category of Cosmetic Products
- ASEAN Cosmetic Ingredient Listings and ASEAN Handbook of Cosmetic Ingredients
- ASEAN Cosmetic Labeling Requirements
- ASEAN Cosmetic Claims Guidelines
- ASEAN Guidelines for Cosmetic Good Manufacturing Practice

The implementation progress of the ACD is summarised as follows:

- **Indonesia** transposed the ACD into its national regulatory regime on 1 January 2011.
- **Malaysia** transposed the ACD into its national regulatory regime on 1 January 2008
- **Thailand** transposed the ACD into its national regulatory regime on 1 March 2008. In addition, Thailand introduced an additional notification number to trace back any post-market surveillance activity and to urge businesses to notify their products.
- **Viet Nam** transposed the ACD into national regulatory regime by way of Circular No. 6/2011/TT-BYT dated 25 January 2011.

Even so, the key operational challenge of ACD is the limited resources of cosmetic regulatory authorities to conduct effective post-market surveillance, and to effectively disseminate relevant information to consumers and cosmetics producers. The sheer market size and the involvement of small and medium-sized enterprises (SMEs) cosmetics operators (e.g. over 4,000 such operators in Thailand) illustrates this challenge. The lack of adequate supporting infrastructure, such as testing equipment, has also been a challenge. Other constraints include

personnel and staffing limitations in the industry with individuals unaware of the ACD, or an understanding of how it works and affects the industry (Prasetya and Intal Jr., 2015).

### **Electrical and Electronic Equipment Sector**

The ASEAN oversees the trade of electrical and electronic equipment (EEE) under a *single regulatory regime*, which comprises (i) the Agreement on the ASEAN Harmonized Electrical and Electronic Equipment Regulatory Regime (AHEEERR),<sup>15</sup> and (ii) the ASEAN Sectoral MRA for Electrical and Electronic Equipment.<sup>16</sup> Efforts for the EEE sector are the most advanced in the ASEAN given its high share of intra-ASEAN commodity trade. ASEAN's initial efforts towards standards harmonization under the 1993 ASEAN Free Trade Area Agreement (AFTA), the precursor of the ATIGA, involved almost all products in the EEE sector – 139 out of 142 harmonised standards (Prasetya and Intal Jr., 2015). The EEE sector is also the first in which ASEAN succeeded in establishing agreements not only on standards, but also in the form of MRAs.

On *standards harmonization* under the AHEEERR, the ASEAN agreed to adopt harmonised technical regulations based on the ASEAN Essential Requirements for EEE as provided under Appendix B of the AHEEERR.<sup>17</sup> The Joint Sectoral Committee on EEE (JSC EEE) identifies and reaches consensus on the list of relevant international standards for use in demonstrating the compliance of an EEE to the ASEAN Essential Requirements. Relevant regional or national standards (in this order) may be used in the absence of international standards. If necessary, the JSC EEE may supplement the listed standards with mutually agreed harmonised regulatory requirements.

In this regard, sources indicate that the ASEAN agreed to adopt 121 IEC product standards that meet the Essential Requirements of AHEEERR. ASEAN member states need to harmonise their national standards with these IEC standards to support the implementation of the ASEAN Electrical and Electronic Mutual Recognition Arrangement (ASEAN EE MRA) and the AHEEERR. **Table 2** summarises the adoption rate of these standards.

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<sup>15</sup> ASEAN member states signed the AHEEERR on 9 December 2005.

<sup>16</sup> ASEAN member states signed the MRA on 5 April 2002.

<sup>17</sup> The ASEAN Essential Requirements state that (i) Any regulated EEE placed on the market shall not cause any danger to human health and safety or damage to property when applied under normal use or reasonably foreseeable conditions of misuse, taking account, in particular, of the product's presentation, marking, instructions for its use and disposal, warning statements, and any other indication or information provided by the manufacturer or the authorized agent or by any other person responsible for placing the product in the market; (ii) An EEE placed in the marketplace must not cause damage or deterioration of the environment under reasonable conditions. There are situations where the desired improvement of the environment and prudent and rational utilization of natural resources call for the establishment and enforcement of additional technical regulations; and (iii) The EEE shall be so constructed so that the electromagnetic disturbances it generates does not exceed a level that introduces intolerable electromagnetic disturbances to anything in that environment, and shall allow radio and telecommunication equipment or other EEE to operate as intended. In addition, the EEE shall have an adequate level of intrinsic immunity to electromagnetic disturbances to enable it to operate as intended.



**Table 2: Adoption of Harmonised EEE Standards**

Country	Identical	Modified	Direct Use	Unclear*
Indonesia	101	1	-	19
Malaysia	84	5	24	8
Thailand	11	10	-	100
Viet Nam	80	-	41	-

EEE = electrical and electronic equipment.

\*Unable to verify existence of national standard in the national standards database or the direct use of the international standard.

Source: Author's comparison based on review of national standards.

To implement harmonised **conformity assessment procedures** to ensure compliance with the ASEAN Essential Requirements, Appendix C of the AHEEERR stipulates that ASEAN member states agreed to adopt the ISO Certification System 1 or the ISO Certification System 5. As to certification procedures, member states will follow (i) ISO/IEC Guide 67: 2004 'Conformity Assessment – Fundamentals of Product Certifications', (ii) ISO/IEC Guide 53: 2005 'Conformity Assessment – Guidance on the use of an organization's quality management system in product certification', and (iii) ISO/IEC Guide 28: 2004 'Conformity Assessment – Guidance on a Third Party Certification System for Product'. Subsequently, ASEAN member states will designate CABs that meet these aforementioned requirements, such that they will mutually recognise test reports and certificates of conformity issued by listed CABs in accordance with the MRA. All ASEAN member states currently participate in the recognition of test reports and recognition of certificates under the ASEAN EE MRA (see Appendix D for a partial list of bodies based on publicly available information). According to information obtained from ASEAN standards bodies, CABs participating in the MRA include a total of 16 testing laboratories (5 in Indonesia, 1 in Malaysia, 1 in the Philippines, 3 in Singapore, 4 in Thailand, and 2 in Viet Nam); and six certification bodies (3 in Indonesia, 1 in Malaysia, 1 in Singapore, and 1 in Viet Nam).

Test reports and certificates of conformity issued by CABs located outside the ASEAN in compliance with the requirements of the AHEEERR may be accepted, provided that the ASEAN enters into an MRA with the country or countries where the said CABs are situated. For an EEE produced outside the ASEAN, its test reports and certificate of conformity issued by the listed CABs may be recognised by arrangements between concerned participating ASEAN member states.

Today, all ASEAN member states have ratified the AHEEERR. However, Indonesia and Thailand have yet to transpose the AHEEERR into their respective national regulations, while Malaysia and Viet Nam have transposed the AHEEERR into their national regulations (Prasetya and Intal Jr., 2015). It must be noted that the AHEEERR does not oblige ASEAN member states that do not have an EEE regulatory regime to develop one.

## Medical Device Sector

ASEAN member states signed the ASEAN Medical Device Directive (AMDD) on 21 November 2014. All ASEAN member states are currently undertaking internal processes to transpose the AMDD into their national legislation and to initiate the ratification process. Nevertheless, the AMDD entered into force on 1 January 2015 but will only be effective for countries that have ratified it.

To align standard procedures in medical device registrations across ASEAN member states, the AMDD lays out basic requirements for a harmonised classification system, medical device safety and performance, conformity assessments, and a Common Submission Dossier Template. The AMDD uses a four-tier, risk-based classification system of medical devices that can determine differentiated fees, processing times, and clinical requirements. It also adopts the Post-Market Alerts System for information and appropriate action on complaints and adverse events such as death or serious deterioration of the health of patients.

The implementation progress of the AMDD is summarised as follows:

- **Indonesia** is in the process of implementation; no official target date.
- **Malaysia** has aligned its Medical Device Act 2012 with the AMDD, which took effect on 1 July 2013
- **Thailand** is in the process of drafting domestic regulations to be in line with the AMDD.
- **Viet Nam** is drafting a decree on Medical Device Management based on the AMDD, which is still undergoing discussion between the National Assembly and the government as of October 2015.

On **standards harmonization**, ASEAN member states have also adopted certain ISO standards applicable to the medical device sector as the basis for harmonised standards across the region. There are 14 'first priority' and two 'second priority' standards adopted for harmonization (**Table 3**). The implementation progress is summarised in **Table 4**.

**Table 3: Medical Device Standards for Harmonization in the ASEAN**

First Priority		
No.	Title of Standard	Reference
1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	IEC 60601-1:2005 Third edition
2	Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies	ISO/IEC 17011
3	Medical devices – Quality management systems – Requirements for regulatory purposes	ISO 13485:2003
4	Medical devices – Quality management systems – Guidance on the application of ISO 13485: 2003	ISO/TR 14969:2004
5	Medical devices – Application of risk management to medical devices	ISO 14971:2007
6	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements	ISO 15223-1:2007
7	Sterilisation of healthcare products – Ethylene oxide – Part 1: Requirements for the development, validation, and routine control of a sterilisation process for medical devices	ISO 11135-1:2007
8	Sterilisation of healthcare products – Radiation – Part 1: Requirements for the development, validation, and routine control of a sterilisation process for medical devices	ISO 11137-1:2006
9	Medical laboratories – Requirements for safety	ISO 15190:2003
10	Packaging for terminally sterilised medical devices – Part 2: Validation requirements for the forming, sealing, and assembly processes	ISO 11607-2:2006
11	Clinical Investigation of Medical Devices for Human Subjects	ISO 14155-1:2003 ISO 14155-2:2003
12	Biological Evaluation of Medical Devices	ISO 10993-1 to -18
13	Contact Lens	ISO 14729-2001
14	Contact Lens Substances	ISO 14730-2000

Second Priority		
No.	Title of Standard	Reference
1	Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type	ISO 81060-1:2007
2	Medical electrical equipment – Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	IEC 60601-2-19:2009 Second edition

Source: ASEAN Secretariat.

**Table 4: Adoption of Medical Device Standards**

Country	Identical	Modified	Original	Direct Use	*Unclear
Indonesia	11	-	-	-	5
Malaysia	14	-	1	-	1
Thailand	10	-	-	2	4
Viet Nam	14	-	-	-	2

\*Unable to verify existence of national standard in the national standards database or the direct use of the international standard.

Source: Author's comparison based on review of national standards.

For Thailand, the Food and Drug Administration is in the process of amending certain domestic regulations, which will enable Thailand to harmonise standards in this sector. Once completed, the Food and Drug Administration and the TISI will jointly commence the process of ratifying the ASEAN harmonization of medical device standards, which will require parliamentary approval. The TISI expects to complete the ratification process in late 2016 subject to the schedule of the National Legislative Assembly.

### **Rubber-Based Product Sector**

The Product Working Group for Rubber-Based Products aims to (i) strengthen and enhance networking and exchange of information among ASEAN member states on standards, quality, and regulations of rubber-based products; (ii) enhance joint actions and approaches on international issues; and (iii) adopt common positions in relevant international organisations, agreements, and arrangements.

For **standards harmonization**, the ASEAN has reportedly agreed to harmonise 46 rubber-based product standards, which encompass 34 ISO Test Methods Standards, 1 Specification, and 11 ISO Standards (six for hoses and five for non-UNECE automotive rubber-based products). **Table 4** summarises the implementation progress.

**Table 4: Adoption of Rubber-Based Product Standards**

Country	Identical	Modified	Original	Direct Use	Unclear*
Indonesia	26	-	-	-	20
Malaysia	37	2	-	-	7
Thailand	-	-	-	-	-
Viet Nam	26	-	-	-	20

\*Unable to verify existence of national standard in the national standards database or the direct use of the international standard.

Source: Author's comparison based on review of national standards.

Thailand has not implemented any rubber-based product ISO standards. According to sources, Thailand is in the process of implementing the harmonised standards, although these standards must go through domestic legal procedures, including a legal scrubbing procedure by the Council of State, and verification of the notifications for publication in the *Royal Government Gazette*. As these standards are not mandatory, TISI indicated that there is no definite timeline to complete the harmonization process.

On **conformity assessment procedures**, ASEAN member states have developed a directory of accredited laboratories for rubber-based products. The directory of accredited testing laboratories for rubber products is reportedly available online,<sup>18</sup> although the information only provides links to the national standards bodies and the number of testing laboratories in each country. Nonetheless, sources have disclosed that the roster comprises 61 accredited testing laboratories across ASEAN member states and that the ASEAN intends to publish updated information online by the end of 2015. The Product Working Group for Rubber-Based Products has also endorsed the work program to proceed with the establishment and drafting of the Guidelines for ASEAN Rubber Reference Laboratory. It is likely that the ASEAN Regional Integration Support from the EU (ARISE) program will provide technical assistance and capacity building in the drafting process of the ASEAN Rubber Reference Laboratory, including assistance in developing the eventual MRA based on the Guidelines for the Development of Mutual Recognition Arrangements, currently used as a reference tool for all WGs and PWGs.

The directory of accredited laboratories for rubber-based products simply serves as a consolidated list of laboratories, accredited domestically, to undertake testing activities based on national standards. There is no MRA for the rubber-based product sector.

The ASEAN Reference Laboratory (ARL) refers to a government laboratory selected by ASEAN member states, which serves as a reference laboratory in cases where there are disputes in analytical test results in specific areas of expertise. An ARL also provides training, technical advice, and services to relevant laboratories of ASEAN member states on the definition, selection, application of methods of analysis and sampling, and on the organisation and management of testing activities in the ASEAN. Thus, when the ASEAN Rubber Reference

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<sup>18</sup> For more information, please see [http://www.lgm.gov.my/accsq\\_rbpwg/main.pdf](http://www.lgm.gov.my/accsq_rbpwg/main.pdf)

Laboratory is finalised, it will provide the scope of activities and responsibilities for an ARL in the rubber-based products sector.

### **Wood-Based Product Sector**

The ASEAN disbanded the Wood-based Products Working Group in 2009 due to the lack of quorum by ASEAN member states. However, the Malaysian Timber Industry Board took up the initiative in 2014 to revive this PWG, which currently assumes the form of a Task Force under WG1. The Malaysian Timber Industry Board is currently engaging its relevant counterparts from other ASEAN member states to revive interest in joining the Task Force and defining its agenda. Viet Nam has signalled its support for this endeavour.

For **standards harmonization**, at a meeting of the Task Force on 3 December 2013 in Jakarta, representatives identified 34 ISO standards for harmonization, which are classified under the three following categories:

- Wood-based panels (12 standards)
- Sawn timber (10 standards)
- Flooring products (12 standards)

The Task Force agreed to gather further information from ASEAN member states on their interest in adopting the ISO standards, and to report the steps taken to align their standards with international standards. Beyond this scope, the Task Force has also identified 12 additional standards for wood-based panels for harmonization, and for most traded wood-based products with special focus on plywood and furniture. The ASEAN Furniture Industry Council (AFIC) also reportedly raised its issues with the Task Force during this meeting. The AFIC delivered a presentation on timber regulations and certification schemes in ASEAN countries, statistical data on intra-ASEAN trade, and on export–import activity between the ASEAN and the international market.

Both sides also discussed possible TBTs that may occur in furniture trade in the ASEAN, including differences of standards. On this, the AFIC informed the Task Force that it would discuss this matter internally and share its feedback through the ASEAN Secretariat. Nevertheless, the Task Force has rejected a separate AFIC proposal on potentially adopting the requirements of the United States (US) standards for furniture into the ASEAN context. The Task Force asserted that this proposal is not in line with the ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures and the ASEAN Guidelines on Harmonization of Standards, based on the adoption of ISO Standards as international standards.

## 5. Capacity-Building Measures by Third Parties

The ASEAN has received capacity-building support in the area of standards and conformance from third parties – international organisations such as the ISO, countries with which ASEAN has a free trade agreement by way of a TBT chapter in the agreement, and other interested countries and regional blocs. The ASEAN has cautiously selected its partners from which to receive capacity-building support based on their experience and expertise on standards and conformance. In this regard, the ASEAN has received support from the European Union, the US, Australia-New Zealand, and Germany. This section provides details on these capacity-building activities, insofar as they are publicly available. Detailed information is currently lacking as the ASEAN and its partners do not regularly publish them.

### European Union

The ARISE program is a technical cooperation facility with €7.5 million in financial support. Implemented over a four-year period until 2016, the purpose of ARISE is to support the implementation of the ASEAN regional economic integration initiatives and cooperation, together with the Coordinating Committee on ASEAN Trade in Goods Agreement, the Coordinating Committee on Customs, and the ACCSQ.

The recent support programs under ARISE, to the extent that they are made public, are summarised as follows:

- **ARISE Assists Myanmar on Safety Regulations for EEE**

ARISE held a two-day workshop on 10-11 March 2015 for government officials and industry representatives to discuss issues related to the updating of the electrical regulation and its impact on trade and safety in Yangon, Myanmar. ARISE has been assisting Myanmar in developing its regulations for electrical equipment safety with the twin objectives of improving safety and enabling Myanmar to remove trade barriers when trading in electrical products with other ASEAN member states. The assistance is directed at enabling Myanmar to participate in the ASEAN Sectoral MRA for Electrical and Electronic Equipment and the AHEEER.

This assistance from ARISE complements the efforts by Myanmar to improve its regulatory regime on EEE. The government enacted its Electricity Law in 2014 to replace the 1984 Electricity Law. The new law provides safety regulations of electrical equipment, which currently applies to 12 product types made in Myanmar.

- **Workshop for Lao PDR on Development of EEE Safety Regulation**

ARISE funded a workshop on the Development of Safety Regulations for Electrical & Electronic Equipment, held in Vientiane on 28–29 October 2014, for the country's policymakers, the prospective regulatory authority, government lawyers, and select representatives of Lao PDR as part of a set of capacity-development programs in

support of JSC EEE initiatives. The workshop provided an opportunity for the participants to discuss with the experts how Lao PDR can comply with the ASEAN Sectoral MRA for Electrical and Electronic Equipment and the AHEEER. The workshop resulted in recommendations for Lao PDR to develop its national regulations on EEE in a manner that will serve the twin goals of consumer safety and an enhanced integration with the ASEAN.

- **ASEAN Regulatory Agencies Deliberate on Harmonised Regulations for Cosmetics**

ARISE hosted a workshop on the AHCRS on 1–2 October 2014 in Jakarta. Workshop participants reviewed the implementation of AHCRS, considered the results of the evaluation, and developed recommendations to enhance the implementation of AHCRS. The workshop also focused on enhancing knowledge on post-market surveillance systems for cosmetic regulatory authorities in ASEAN member states.

- **Study Visit of Cosmetics Regulators to Malaysia and the Philippines**

ARISE invited regulators on 5–6 May and 8–9 May 2014 from Brunei Darussalam, Cambodia, Lao PDR, Myanmar, and Viet Nam to participate in a study visit to the National Pharmaceutical Control Bureau in Malaysia and to the Food and Drug Administration in the Philippines. The focus of these study visits was for the development of an ‘On-line Notification for the ASEAN Cosmetics Directive’. The study visits aimed to provide participants with an opportunity to study the systems that Malaysia and the Philippines have implemented for cosmetics regulators.

## **United States**

The US implements its capacity-building efforts for the ASEAN through programs by the US Agency for International Development (USAID), through its ASEAN-US Technical Assistance and Training Facility (TATF). The TATF provides a central point through which USAID works with US government entities to support the ASEAN-US Trade and Investment Framework Arrangement and cooperation on standards. The TATF is housed in the ASEAN Secretariat in Jakarta and receives funding from USAID and the US Department of State. The recent support programs under TATF, to the extent that they are made public, are summarised as follows:

- **Medical Devices Regulatory Harmonization – Region-Wide Training**

The US Department of Commerce, in collaboration with USAID, funded the ASEAN’s standards-related measures on medical devices. Upon request of the Medical Device Product Working Group in 2012, USAID developed a training program for use in the ASEAN Medical Device Multiyear Training Program. The program objective is to enhance the capabilities of ASEAN regulators and the medical device industry in the interpretation and implementation of the AMDD during 2014–2015. The Medical Devices Regulatory Harmonization – Region-Wide Training was held in Singapore on



5–6 May 2014. USAID coordinated this workshop with the ASEAN Secretariat, the Medical Device Product Working Group, and the US Department of Commerce.

- **Promoting Vehicle Fuel Efficiency in ASEAN**

USAID organised the workshop ‘US-ASEAN Vehicle Fuel Efficiency Workshop’ on 13 May 2013 in Jakarta, in collaboration with the US Department of Energy and Department of Transportation, and Indonesia’s Ministry of Energy and Mineral Resources. Of the ASEAN officials in charge of energy efficiency and conservation, 50 attended the workshop. Held in conjunction with the annual meeting of the ASEAN Energy Efficiency and Conservation Sub-Sector Network, the workshop covered a number of topics, including (i) US experience with transportation energy, (ii) removing old vehicles from US roads along with fuel efficiency standards for new vehicles, (iii) present and projected transportation energy demands in the ASEAN, and (iv) presentations by government officials on existing and planned vehicle fuel efficiency programs in ASEAN member states.

- **US Government Supports Improving Appliance Safety in the ASEAN**

USAID, in collaboration with ASEAN and Underwriters’ Laboratories (UL), jointly held on 29 May 2012 in Cambodia the workshop ‘Applied Safety Science and Engineering Techniques (ASSET)’. Fifty ASEAN electrical safety regulators attended the workshop in an effort to boost safety standards for EEE manufacturing in the ASEAN. The technical knowledge learned from the workshop is expected to benefit manufacturers, product designers, and representatives from conformity assessment bodies and national standards bodies who are directly involved in the design, manufacture, and testing of EEE.

- **ASEAN and US Promote Energy Efficiency for Everyday Appliances**

USAID and the US Department of Energy cooperated to assist ASEAN energy regulators in establishing energy efficiency standards and labelling programs. These programs were designed to improve energy efficiency without degrading performance, quality, and safety and without increasing cost. On 13–15 December 2010, the US-ASEAN Energy Efficiency Standards and Labeling Workshop took place in Ha Noi to develop, improve, and implement energy efficiency programs. The workshop was organised by the US Department of Energy, USAID, and the US Department of State in collaboration with the ASEAN Secretariat and the Ministry of Industry and Trade of Viet Nam.

### **Australia and New Zealand**

The ASEAN-Australia-New Zealand Free Trade Agreement (AANZFTA) provides for the Economic Cooperation Work Program (ECWP), which involves proposals submitted to the Working Group of Economic Cooperation. The ECWP outlines the assistance provided by Australia and New Zealand to AANZFTA Parties in eight components linked to different aspects of the AANZFTA. Among the eight components, the ECWP (i) supports joint efforts in the fields

of standards, technical regulation, conformity assessment procedures; (ii) assists in promoting mutual understanding of each party's Standards, Technical Regulations and Conformity Assessment Procedures (STRACAP) measures; and (iii) strengthens information exchange and cooperation among the Parties. Under this component, experts from Australia and New Zealand, and in some cases, certain ASEAN Parties, will conduct the requisite workshops, seminars, and other training procedures; as well as develop other capacity-building activities. While all Parties will benefit from their cooperation on STRACAP, ASEAN Parties currently with less developed systems, e.g. Cambodia, Lao PDR, and Myanmar, will gain major benefit.

- **Australia Hosts AANZFTA Workshop**

On 19 February 2013, Standards Australia hosted a two-day workshop on International Standards Development Best Practices under the ECWP of the AANZFTA. Australian Standards provided a benchmark for technology, safety, interoperability, and trade. According to Australian special negotiator Michael Mugliston, Australia has a key role to play through AANZFTA in contributing towards capacity building and institutional strengthening across the region.

## **Germany**

As one of ASEAN's development partners, Germany is helping ASEAN member states address the challenge of harmonization especially on strengthening ASEAN's quality infrastructure on areas concerning standards and technical regulations, metrology, testing, quality assessment, certification, and accreditation. In this context, Physikalisch-Technische Bundesanstalt (PTB), the National Metrology Institute of Germany, supports ASEAN's regional economic integration efforts towards harmonising the technical rules and standards and thus reducing TBTs. The Federal Ministry of Economic Cooperation and Development of Germany finances the PTB projects.

- **PTB Assists the ASEAN on Regional and National Quality Infrastructure**

PTB assists the ASEAN in implementing the quality infrastructure project. The project, which runs from 2015 to 2018, marks the second phase of cooperation between PTB and ACCSQ. The project supports the ASEAN in facilitating the harmonization of national standards and in the integration process of standards, the enhancement of conformance, and in the implementation of MRAs on conformity assessment. The project aims to enhance national quality infrastructure, which includes accreditation bodies and conformity assessment bodies in each ASEAN member state, while enhancing the ASEAN regional integration process in standards and conformance.

## 6. Key Recommendations

The review of domestic implementation of standards and conformance efforts in Indonesia, Malaysia, Thailand, and Viet Nam suggests that challenges persist, including resource constraints at the government level, particularly on the timely preparation and promulgation of standards. Another challenge is the overall technical capacity of CABs and industry players, particularly SMEs, as they account for the bulk of industry in the ASEAN region. On CABs, some national standards bodies may not have the necessary manpower or logistical support to implement standards and conformance effectively, particularly in cases where a standard must be promulgated in the local language or in cases where the jurisdiction over a particular sector is spread across multiple ministries or government agencies. Challenges with SMEs broadly include the lack of qualified CABs, as well constraints among local businesses that are unable to meet the identified standards owing to a lack of current expertise, advanced technology, and/or know-how.

In this regard, the key recommendations to support the domestic implementation of ASEAN standards and conformance initiatives are as follows:

- **Improve technical capacity.** Donors and other facilitators should tailor capacity-building programs specifically for the intended audience – whether for government officials involved in the standardisation process, companies that actively utilise standards on a regular basis, and SMEs with little exposure or understanding of even the basic principles of standardisation and conformance. Oftentimes, there may be a tendency to mismatch the type of information and training provided to the intended audience, creating unnecessary confusion or misunderstanding as to the basics of standardisation, its importance to the industry, and its overall benefits. In the case of SMEs, technical capacity challenges include, among others, access to and dissemination of basic information on standardisation and conformance, human resource and cost constraints to apply or adhere to a particular standard or to gain access to a testing laboratory or accreditation facility, and lack of infrastructure and financing to participate in the standardisation process.
- **Expand private sector participation.** In standards-related discussions and during information-sharing sessions, the participation of the private sector is crucial to ensure the sustainability of standards-related efforts, as these would be meaningless without uptake from relevant users. Private sector participation in technical committees and industry standards committees during the standards formulation process is necessary to provide technical inputs and to support industry advancement. However, non-participating firms may feel isolated from the process and lose interest in standards and conformance activities. Government bodies and trade associations can both play a role in developing programs to increase the awareness and usage of standards. The critical goal in this process is to build connections among all members of a sector such that standards-related matters become a whole-of-industry approach.

- ***Design specific and tailor-made capacity-building programs.*** Engagement should be (i) at the national level if targeted at a specific weakness of a country; or (ii) at the regional level if it is a regional issue. The program should be specific and the solution is tailored to the challenge and audience. In addition, language should be simple and accessible to newcomers, regardless of whether this is addressed to private or public sectors. Based on interviews with the national standards bodies, parties interested in designing capacity-building programs for the ASEAN or its member states often misunderstand the national or regional levels of authority and process of decision making. As a result, such proposed programs often miss their intended targets or face likely rejection from the recipient country. In addition, due to the differences in economic development and maturity of regulatory regimes across ASEAN member states, the technical content used in capacity-building programs suitable to a more developed member state may not be appropriate to another less developed member state. Program organisers should be fully aware of the existing knowledge of their intended audience and tailor the content and language of the program accordingly.
- ***Improve the CABs.*** ASEAN governments should allocate more resources to spur the development of qualified and competent CABs. They should understand that the lack of qualified CABs obstructs local businesses, especially SMEs, from expanding across the ASEAN market under the sectoral harmonised standards and MRAs. A notable example that supports this recommendation is Malaysia's national budget for 2016 in which the government will provide incentives for the establishment of CABs. The fact that Malaysia has allotted a specific budget to this area highlights an unmistakable fact that the resources of ASEAN's partners are limited, financial or otherwise. It is ultimately the responsibility of a country to take ownership over lagging areas of a policy area and to dedicate time and resources to address the issue.
- ***Publish online all information relating to standardisation and conformance.*** This could include appropriate portals, such as the ASEAN Trade Repository, where the list of all harmonised standards and listed CABs are published. The information should also include updated progress in the implementation of ASEAN standards and conformance initiatives, such as the adoption level of the harmonised standards. Providing such information in a clear and transparent manner – even if presented first in the national language of each ASEAN member state with the ultimate aim of eventually using English – would allow businesses to obtain the necessary information to prepare their strategies that will expand the reach of their products and services across the ASEAN. It must be noted that the ASEAN is reportedly taking steps to publish all information by the end of 2015. The speed and timeliness in which information is available is also crucial for business growth across the ASEAN. The business sector has noted the lack of up-to-date information that inhibits companies or enterprises from developing strategies for their market access to grow in the region. While they may contact their national standards body for information, this method of information gathering may take time as government representatives have to research the information and issue a response. Given the general lack of manpower at the

national standards bodies, this approach may not be an effective use of time and resources. In this regard, publishing all information online and providing a contact person for further inquiries could be an ideal solution.

- ***Enhance technical infrastructure and competency in laboratory testing, certification, accreditation, and calibration.*** Internationally accepted procedures and guidelines should form the basis of this process. This constant focus on improvement and pursuit of world-class practices will ensure that ASEAN-origin businesses or foreign businesses seeking to leverage the harmonised sectoral standards and MRAs in the region can expect a consistent and predictable business environment.
- ***Encourage ASEAN member states to share with each other the use of conformity assessment facilities*** when such facilities do not exist in a particular member state. Financial resources may not be sufficient in cases where a country has to develop facilities and personnel to conduct conformity assessment procedures. These efforts may also take a long time to complete. The sharing of such facilities could temporarily alleviate these resource constraints and even serve as an approach to limit redundancies.

## **7. Conclusion**

The implementation of standard and conformance measures under the AEC Blueprint has not been without challenges, and the reality is that full implementation of all measures by the end of 2015 is unlikely. The formal target of establishing the AEC by 31 December 2015 is, therefore, not an end goal but an initial milestone for ASEAN economic integration. In that respect, the post-2015 agenda, i.e. AEC 2025, would prioritise any unfinished work from AEC 2015, while expanding the coverage of sectors under standards and conformance beyond the priority integration sectors. While ASEAN member states are taking steps towards implementation, there needs to be a greater appreciation that standards and conformance form the technical foundation for the free flow of goods in a true single market and production base envisioned under the AEC Blueprint. This paradigm shift is arguably not achievable in the short term either in a country or as a region. However, the ASEAN has the opportunity to focus attention to this lagging area during the AEC 2025 implementation period by inculcating values and adjusting attitudes to achieve the foundation necessary for greater standards and conformance activities in the region.

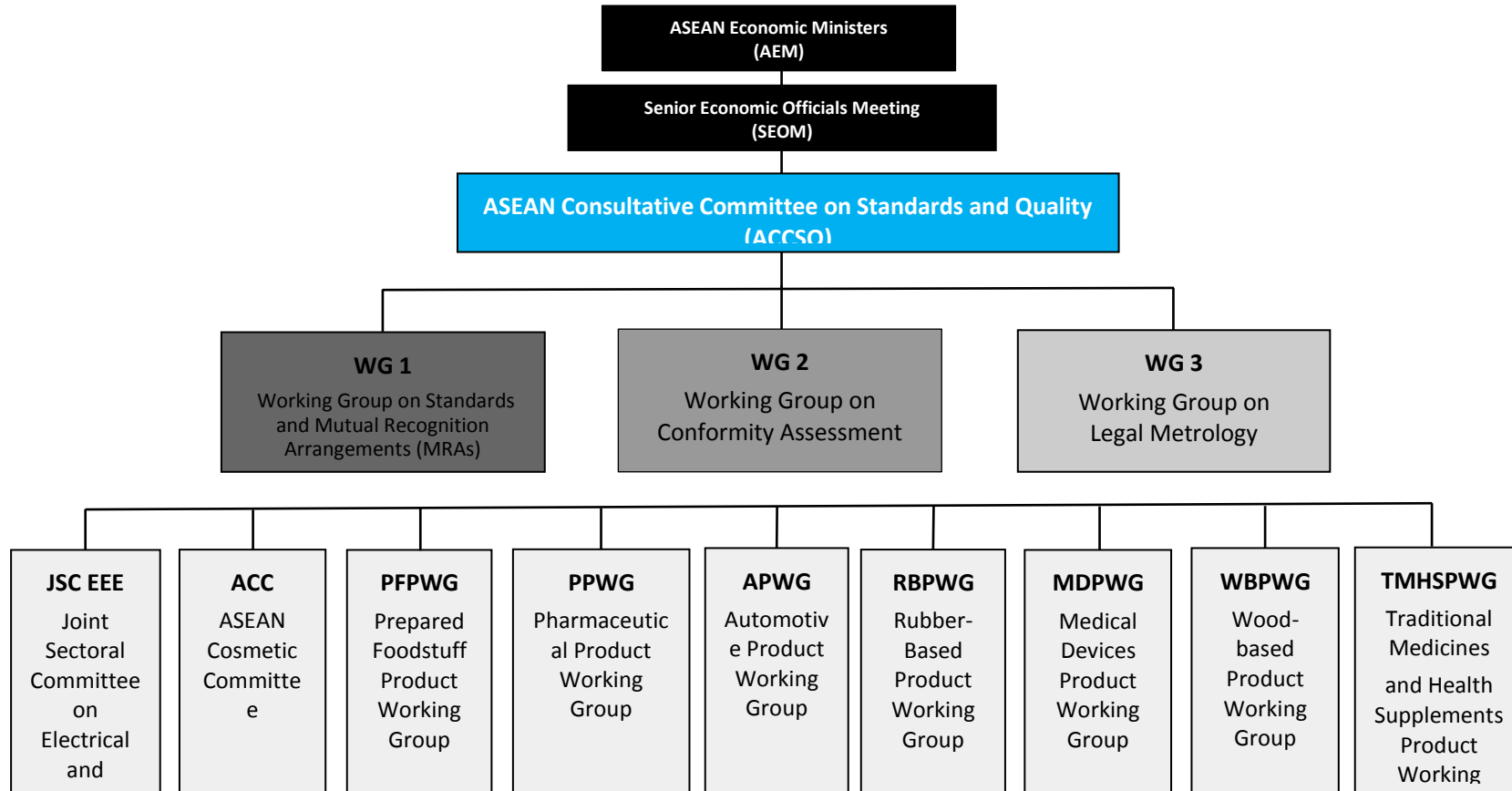
## References

- Association of Southeast Asian Nations (ASEAN) (1998), *ASEAN Framework Agreement on Mutual Recognition Arrangements*. <http://www.asean.org/communities/asean-economic-community/item/asean-framework-agreement-on-mutual-recognition-arrangements-2> (accessed 2 July 2015).
- Association of Southeast Asian Nations (ASEAN) (2002), *ASEAN Sectoral Mutual Recognition Agreement for Electrical and Electronic Equipment*. <http://www.asean.org/communities/asean-economic-community/item/asean-sectoral-mutual-recognition-arrangement-for-electrical-and-electronic-equipment-preamble> (accessed 2 July 2015).
- Association of Southeast Asian Nations (ASEAN) (2003), *ASEAN Harmonized Cosmetics Regulatory Scheme*. [http://www.hsa.gov.sg/content/dam/HSA/HPRG/Cosmetic\\_Products/AGREEMENT%20ON%20ASEAN%20HARMONIZED%20COSMETIC%20REGULATORY%20SCHEME.pdf](http://www.hsa.gov.sg/content/dam/HSA/HPRG/Cosmetic_Products/AGREEMENT%20ON%20ASEAN%20HARMONIZED%20COSMETIC%20REGULATORY%20SCHEME.pdf) (accessed 15 July 2015).
- Association of Southeast Asian Nations (ASEAN) (2004), *ASEAN Framework Agreement for the Integration of Priority Sectors*. <http://www.asean.org/news/item/asean-framework-agreement-for-the-integration-of-priority-sectors-vientiane-29th-november-2004> (accessed 4 August 2015).
- Association of Southeast Asian Nations (ASEAN) (2005a), *ASEAN Harmonized Electrical and Electronic Equipment Regulatory Regime*. <http://www.asean.org/communities/asean-economic-community/item/agreement-on-the-asean-harmonized-electrical-and-electronic-equipment-eee-regulatory-regime-kuala-lumpur-9-december-2005-2> (accessed 2 July 2015).
- Association of Southeast Asian Nations (ASEAN) (2005b), *ASEAN Policy Guideline and Standards and Conformance*. <http://www.asean.org/archive/20531.pdf> (accessed 7 July 2015).
- Association of Southeast Asian Nations (ASEAN) (2007), *Declaration on the ASEAN Economic Community Blueprint*. <http://www.asean.org/archive/5187-10.pdf> (accessed 7 July 2015).
- Association of Southeast Asian Nations (ASEAN) (2008), *ASEAN Economic Community Blueprint*. Jakarta: ASEAN Secretariat.
- Association of Southeast Asian Nations (ASEAN) (2010), *Trade in Goods Agreement*. <http://www.asean.org/communities/asean-economic-community/category/asean-trade-in-goods-agreement> (accessed 7 July 2015).
- ASEAN Regional Integration Support from the EU 2013-2016 (ARISE) (n.d.). <http://arise.asean.org/> (accessed 21 May 2015).

- Department of Foreign Affairs and Trade, Australia (n.d.), *Agreement Establishing the ASEAN-Australia-New Zealand Free Trade Area (AANZFTA) Economic Co-Operation Work Programme*. <http://dfat.gov.au/trade/agreements/aanzfta/pages/agreement-establishing-the-asean-australia-new-zealand-free-trade-area-aanzfta-economic-co-operation-work-programme.aspx#comp3> (accessed 22 May 2015).
- Department of Standards Malaysia (2009), *Guide to the Malaysian Standards System*. <http://www.jsm.gov.my/documents/10180/86670/Microsoft+Word+-+MS+System+Handbook.pdf/3ca67aa7-f449-4b1b-b458-fecaa5346c5c> (accessed 5 October 2015).
- International Standards Organization (ISO) (2014), *Economic Benefits of Standards*. Geneva: ISO.
- Ministry of Health, Malaysia (2013), *Cosmetic Product Notification*. Presentation by National Pharmaceutical Control Bureau.
- Philippine Department of Trade and Industry (2014), *11th Draft ASEAN Mutual Recognition Arrangement on Type Approval for Automotive Products*. [http://www.bps.dti.gov.ph/index.php?option=com\\_docman&task=doc\\_download&gid=5298&Itemid=77](http://www.bps.dti.gov.ph/index.php?option=com_docman&task=doc_download&gid=5298&Itemid=77) (accessed 20 August 2015).
- Physikalisch-Technische Bundesanstalt (PTB)(n.d.). <https://www.ptb.de/cms/> (accessed 22 May 2015).
- Prasetya, R. and P. S. Intal Jr., (2015), 'AEC Blueprint Implementation Performance and Challenges: Standards and Conformance', *ERIA Discussion Paper* No. 2015-42, Jakarta: ERIA.
- UN Economic Commission for Europe (UNECE) (1995), *Agreement concerning the Adoption of Uniform Technical Prescriptions*. <http://www.unece.org/trans/main/wp29/wp29regs.html> (accessed 7 July 2015).
- United States Mission to ASEAN (n.d.). <http://asean.usmission.gov/mission/index.html> (accessed 21 May 2015).
- World Trade Organization (WTO) (1995), *Agreement on Technical Barriers to Trade*. [https://www.wto.org/english/docs\\_e/legal\\_e/17-tbt\\_e.htm](https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm) (accessed 7 July 2015).

## Appendix A

### ASEAN Structure for Standards and Conformance





## Appendix B

### Activity Scope of the ASEAN Consultative Committee on Standards and Quality Working Groups

Working Groups	Scope of Activities
<b>Horizontal function</b>	
<b>WG1</b> – Working Group on Standards and MRAs	<ul style="list-style-type: none"> <li>• Monitor the implementation of the sectoral MRAs in the ASEAN.</li> <li>• Establish an ASEAN Guide to MRAs.</li> <li>• Harmonise national standards to international standards.</li> <li>• Assist in promoting good regulatory practice (GRP) concept to regulators.</li> <li>• Undertake confidence building among regulators in the use of harmonised standards.</li> <li>• Promote the transparency of technical regulations.</li> <li>• Explore new areas for the development of MRAs and standards harmonization in the ASEAN.</li> <li>• Develop a mechanism for cooperation between standards bodies and regulatory agencies.</li> <li>• Recommend to the ACCSQ proposals, activities, or issues for ASEAN cooperation in relevant international and regional organisations, such as ISO, IEC, APEC, and ASEM.</li> </ul>
<b>WG2</b> – Working Group on Accreditation and Conformity Assessment	<ul style="list-style-type: none"> <li>• Enhance the capability of accreditation bodies in ASEAN member countries to achieve regional and/or international recognition.</li> <li>• Enhance the competence of conformity assessment bodies in ASEAN member countries to facilitate the implementation of mutual recognition of test reports and certifications.</li> <li>• Assist new member countries in accreditation and conformity assessment.</li> <li>• Monitor the certification bodies within the ASEAN.</li> </ul>
<b>WG3</b> – Working Group on Legal Metrology	<ul style="list-style-type: none"> <li>• To align legal metrology in the ASEAN to support the objectives of the ASEAN Free Trade Area (AFTA) and to ensure that the modernisation of legislation in legal metrology by ASEAN member countries will not result in the introduction of new technical barriers to trade.</li> <li>• To establish ASEAN cooperation in the area of legal metrology and to improve the national legal metrology systems through cooperation in technology, human resources, and management expertise,</li> <li>• To hold discussions and promote ASEAN interest in legal metrology with other national, regional, and international organisations.</li> </ul>

**Appendix B (continued)**

**Activity Scope of the ASEAN Consultative Committee  
on Standards and Quality Product Working Groups**

<b>Product Working Groups (PWGs)</b>	
<b>JSC EEE</b> – Joint Sectoral Committee for Electrical and Electronic Equipment	<ul style="list-style-type: none"> <li>• Undertake listing, suspension, removal, and verification of testing laboratories and/or certification bodies in accordance with the ASEAN EE MRA.</li> <li>• Provide a forum for the discussion of issues that may arise concerning the implementation of the ASEAN EE MRA.</li> <li>• Review and propose amendments to the scope and coverage of the ASEAN EE MRA.</li> <li>• Consider ways to enhance the operation of the ASEAN EE MRA, such as developing outreach program for capacity building.</li> <li>• Consider ways to a Good Regulatory Practice on electrical and electronic products.</li> </ul>
<b>ACC</b> – ASEAN Cosmetic Committee	<ul style="list-style-type: none"> <li>• Coordinate, review, and monitor the implementation of the Agreement on ASEAN Harmonized Cosmetic Regulatory Scheme, including the ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetics, and the ASEAN Cosmetic Directive.</li> <li>• Monitor the implementation of the following technical documents and review and update these documents when necessary:               <ul style="list-style-type: none"> <li>– ASEAN Definition of Cosmetics and Illustrative List by Category of Cosmetic Products,</li> <li>– ASEAN Cosmetic Ingredient Listings and ASEAN Handbook of Cosmetic Ingredients,</li> <li>– ASEAN Cosmetic Labelling Requirements,</li> <li>– ASEAN Cosmetic Claims Guideline,</li> <li>– ASEAN Cosmetic Product Registration Requirements,</li> <li>– ASEAN Cosmetic Imports/Export Requirements, and</li> <li>– ASEAN Guidelines for Cosmetic Good Manufacturing Practice.</li> </ul> </li> <li>• Provide a forum for the discussion of issues that may arise concerning the implementation of the Agreement.</li> <li>• Consider measures to enhance the operation of the Agreement.</li> </ul>
<b>PPWG</b> – Pharmaceutical Product Working Group	<ul style="list-style-type: none"> <li>• Undertake an exchange of information on the existing pharmaceutical requirements and regulations implemented by each ASEAN member country.</li> <li>• Review and prepare a comparative study of the requirements and regulations.</li> </ul>

	<ul style="list-style-type: none"> <li>• Study the harmonised procedures and regulatory system on pharmaceutical trade currently being implemented in other regions.</li> <li>• Develop harmonised technical procedures and requirements, including appropriate MRAs (full harmonization equivalence of conformance, equivalence of results and/or acceptance of test procedures) that are applicable to the ASEAN pharmaceutical industry, taking into account other regional and international developments on pharmaceuticals.</li> </ul>
<b>PFPWG</b> – Prepared Foodstuff Product Working Group	<ul style="list-style-type: none"> <li>• Undertake an exchange of information on standards, regulations, procedures, and mandatory requirements in member countries related to prepared foodstuff.</li> <li>• Review and analyse the comparative study of regulatory regimes among ASEAN member countries.</li> <li>• Identify areas for possible harmonization and MRAs.</li> <li>• Develop, implement, and monitor the sectoral MRAs.</li> <li>• Identify the technical infrastructure needs and build mutual confidence in testing and conformity assessment.</li> </ul>
<b>APWG</b> – Automotive Product Working Group	<ul style="list-style-type: none"> <li>• Undertake an exchange of information on standards, rules, regulations, procedures, and mandatory requirements related to the automotive sector among ASEAN member countries.</li> <li>• Review and analyse the comparative study of regulatory regimes among ASEAN member countries.</li> <li>• Identify areas for possible harmonization and MRAs, with focus on the harmonization of ASEAN automotive safety and emission standards based on UNECE regulations.</li> <li>• Develop sectoral MRAs.</li> <li>• Identify the technical infrastructure needs and build mutual confidence in conformity assessment.</li> </ul>
<b>TMHSPWG</b> – Traditional Medicines and Health Supplements Product Working Group	<ul style="list-style-type: none"> <li>• Exchange, review, and analyse information on the existing regulatory framework and/or regime, including standard definition, terminologies, and technical infrastructure in ASEAN member countries.</li> <li>• Study the existing regulatory frameworks and/or regime of selected countries and internationally accepted technical guidelines.</li> <li>• Enhance the technical infrastructure including mutual confidence in testing and conformity assessment.</li> <li>• Identify areas for possible harmonization and MRAs.</li> </ul>
<b>MDPWG</b> – Medical Device Product Working Group	<ul style="list-style-type: none"> <li>• Develop a common submission dossier template for product approval in the ASEAN.</li> <li>• Explore the feasibility of an abridged approval process for medical devices, which regulators of benchmarked countries or recognised regulators have approved.</li> </ul>

	<ul style="list-style-type: none"> <li>• Explore the feasibility of adopting a harmonised system of placement of medical devices into the ASEAN markets, based on a common product approval process.</li> <li>• Formalise a post-marketing alert system for defective or unsafe medical devices.</li> <li>• Ensure that all ASEAN member countries consider joining the Asian Harmonization Working Party and work in parallel with the Global Harmonization Task Force on technical harmonization efforts.</li> </ul>
<b>RBPWG – Rubber-Based Product Working Group</b>	<ul style="list-style-type: none"> <li>• To enhance cooperation in conformity assessment, development, and implementation of standards and technical regulations for rubber-based products among ASEAN member countries.</li> <li>• To strengthen and enhance networking and exchange of information among ASEAN member countries on standards, quality, and regulations of rubber-based products, with the view of facilitating cooperative undertakings in this area.</li> <li>• To identify standards for rubber-based products for ASEAN to harmonise with international standards and quality.</li> <li>• To enhance joint actions and approaches on international issues and adopt common positions in relevant international organisations, agreements, and arrangements.</li> <li>• To identify fields of cooperation among related ASEAN member countries and third-party countries and organisations in order to promote the development of standards for rubber-based products.</li> <li>• To strengthen human resource development in the area of standards and quality for rubber products.</li> <li>• To share equal responsibility to the tasks and activities agreed at meetings.</li> </ul>
<b>TFWBP – Task Force on Wood-Based Product</b>	<ul style="list-style-type: none"> <li>• This currently exists under the WG1.</li> </ul>

ACCSQ = ASEAN Consultative Committee on Standards and Quality, AHEEERR = ASEAN Harmonized Electrical and Electronic Equipment Regulatory Regime, APEC = Asia-Pacific Economic Cooperation, ASEAN = Association of Southeast Asian Nations, ASEAN EE MRA = ASEAN Electrical and Electronic Mutual Recognition Arrangement, ASEM = Asia–Europe Meeting, IEC = International Electrotechnical Commission, ISO = International Organization for Standardization, MRAs = mutual recognition arrangements, UNECE = United Nations Economic Commission for Europe, WG = working group.

Source: ASEAN Secretariat.

## **Appendix C**

### **National Process of Standards and Conformance**

#### **Indonesia**

The National Standardization Agency of Indonesia (Badan Standardisasi Nasional or BSN), was established in 1997 under Presidential Decree No. 13/1997 and was improved with a new mandate under Presidential Decree No. 166/2000. BSN is a government institution, but not a department or a ministry, having the responsibility to develop and promote national standardisation in Indonesia. Separately, the National Accreditation Body of Indonesia was established in 2000 under Presidential Decree No. 166/2000 to become the accreditation body in Indonesia. Its main function is to establish an accreditation system and to grant accreditation in certain fields, including testing and calibration laboratories, certification bodies, and inspection bodies.

The Indonesian National Standard (Standar Nasional Indonesia or SNI) applies to certain designated goods, services, systems, and processes in Indonesia and businesses responsible for such items may choose to conform to its requirement to obtain SNI certifications. Relevant technical committees formulate SNIs in accordance with the nationally agreed mechanism of standard formulation and generally align SNIs with international standards whenever possible. The affixing of the SNI mark on the product or service is an indication that it meets the standard requirements. While SNIs are primarily voluntary, those related to safety, security, health, and environment conservation may be mandatory. As of August 2015, the BSN database states that there are 8,631 voluntary SNIs in force, which comprises 2,435 for materials, 1,783 for the agriculture sector, and 1,382 for the engineering technology. There are 78 mandatory SNIs in force.

The issuance of SNIs as mandatory standards falls under the authority of government ministries, such as the Ministry of Trade, the Ministry of Industry, and the Ministry of Agriculture, as well as certain agencies that function to regulate their respective responsibilities including the Agency for Drug and Food Control. Once a ministry promulgates an SNI as mandatory, the standard becomes a requirement of the market. It may be noted that mandatory SNIs take effect in a non-discriminatory manner – they are applicable for both foreign and domestic goods.

#### **Malaysia**

The Department of Standards Malaysia (or 'Standards Malaysia'), under the Ministry of Science, Technology and Innovation, is mandated by the Government of Malaysia to function as the national standards body and as the national accreditation body through the Standards of Malaysia Act, 1996 (Act 549). As provided for by Act 549, Standards Malaysia has also appointed SIRIM Berhad as the sole national agency to coordinate standards development activities in Malaysia and to represent Malaysia in international standardisation activities. SIRIM Berhad has, in turn, appointed other organisations and associations as Standards

Writing Organizations to assist in the task of developing standards for specifically defined scopes, such as the Construction Industry Development Board for construction practices, and the Malaysian Palm Oil Board for palm oil products.

At the policy level, the Malaysian Cabinet approved the National Standards Strategy and Action Plan in 2004 to further enhance Malaysia's standardisation activities. This document provides the blueprint that charts the strategies and directions of Malaysia's standardisation activities, both at national and international levels. In 2004, as one of the steps to encourage the active participation of the private sector in standardisation activities, the government – through the Amendment to Section 34(6) (m) of Akta Cukai Pendapatan 1967 – provided for tax deduction to be given for expenditure incurred by private sector participation in international standardisation activities.

To protect Malaysia's trading interest and increase the competitiveness of Malaysian products and services in the global market, Malaysia needs to maintain its influence on international standardisation activities to ensure the continued alignment of national standards to international standards. This has resulted in Standards Malaysia's active participation in regional and international standardisation, including the International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), ASEAN Consultative Committee on Standards and Quality (ACCSQ), Asia-Pacific Economic Cooperation Sub-Committee on Standards and Conformance, Pacific Area Standards Congress, and the Asian Europe Meeting/Trade Facilitation Action Plan on Standards and Conformance.

Presently, Standards Malaysia is implementing the National Standards Compliance Programme to bridge all initiatives and information on standard compliance in the country. Standards Malaysia envisions this programme to result in better acceptance of local products and services in domestic and foreign markets, and increase national competitiveness through the industry's adoption of standards. To that end, the National Standards Compliance Programme provides a one-stop centre that consolidates information on standards compliance knowledge, initiatives, assistance, and support available. The NSCP also focuses on providing technical support for the government's implementing agencies, such as SME Corp. Malaysia, with the intention to increase their awareness, knowledge, and technical know-how on standards compliance. Through this approach, Standards Malaysia seeks to strengthen the technical competence of government bodies on standards matters, such that industries under their purview will also be more prepared to undertake standards compliance activities.

## **Thailand**

Thailand's standards and conformance regime is governed by the Industrial Product Standards Act B.E. 2511. Section 15 of this Act empowers the Industry Minister to impose, amend, and revoke standards for industrial standards in accordance with the recommendation of the Industrial Product Standards Council. Notifications on imposition, amendment, and revocation of the standards must be published in the *Royal Government Gazette* through a royal decree.

The Government of Thailand recognises the importance of standards and conformance and assigns the Thai Industrial Standards Institute (TISI) to be the leading agency in charge of the standards and conformance regime in Thailand. Besides ASEAN, the TISI participates actively in international and regional standardising bodies, including the WTO Agreement on Technical Barrier to Trade, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures, and in various APEC cooperation efforts on standards and conformance. In addition, Thailand is an active member of the ISO, the IEC, the Codex General Standard for Food Additives (Codex Alimentarius), the International Plant Protection Commission, and the World Organization for Animal Health.

The TISI organises a unified system of standard and conformance to be in line with the internationally acceptable system, while at the same time improves the acceptance of other countries' standards and conformance system through an accreditation system. According to the TISI, Thailand aims to align its national standards to international standards to the maximum extent possible. Currently, more than 1,000 Thai industrial standards are aligned with relevant international standards.

According to the TISI, necessary mechanisms for conformity assessment include separate bodies to carry out testing, inspection, certification, and accreditation activities, which must also operate in compliance with international standards to generate confidence and gain acceptance. The TISI cited that the key factor to the successful operation of all standardisation activities is the adequacy and capacity of testing and calibration laboratories. This remains the key challenge to the Thai standardisation system as Thailand needs to increase both the number and capability of its testing and calibration laboratory facilities to support the country's standards development and conformity assessment activities.

Standard efforts are mainly driven by the Industry Product Standards Council (or 'the Council') established under Section 7 of the Industrial Product Standards Act. The Council consists of the following members: a Permanent Secretary for Industry as chairman, while other council members include the (i) Director-General of the Department of Industrial Works;(ii) Director-General of the Department of Industrial Promotion;(iii) a representative of the Ministry of Agriculture and Cooperatives;(iv) a representative of the Ministry of Interior;(v) a representative of the Ministry of Commerce;(vi) a representative of the Ministry of Science, Technology and Energy; (vii) a representative of the Ministry of Public Health; (viii) a representative of the Customs Department; (ix) a representative of the Thailand Institute of Scientific and Technological Research; (x) a representative of the Office of the Board of Investment; (xi) a representative of the Office of the National Economic and Social Development Board; and (xii) not more than six qualified individuals from the private sector or academia.

In addition, the Council has the authority to govern a technical committee (TC), which was established under Section 13 of the Industrial Product Standards Act to develop, draft, amend, or revoke industrial standards. The TC will then submit its decision to the Council for final endorsement. In this regard, the TC may appoint subcommittees to assist in carrying out the activities or to consider matters assigned by the TC. According to the TISI, the TC has

established subcommittees for each key industry to assist in developing and drafting standards. Most subcommittee members are industry experts from the private sector and academia. Their inputs are highly valued and largely determine the standards development.

## **Viet Nam**

The Ministry of Science and Technology manages the issuance of the Vietnamese national standards or *Tiêu chuẩn Việt Nam*. With this authorisation, the ministry assigns almost all of the standardisation works to its agency, the Directorate for Standards, Metrology and Quality of Viet Nam (STAMEQ). STAMEQ is responsible for the management of standardisation activities in Viet Nam, including preparing, guiding, and monitoring the implementation of legislative documents on standardisation. Within STAMEQ, its subsidiary, the Vietnam Standards and Quality Institute oversees the organisation of national technical committee activities.

Until 2014, Viet Nam had issued approximately 8,100 national standards in 98 industries, 43 percent of which are in line with international standards. Notably, the government has consistently reaffirmed the need to improve the economic integration and implement relevant commitments, including those for ASEAN, as both the motivation and direction for the development of standards in Viet Nam. Vietnamese national standards are usually not mandatory, however, under Article 23.1 of the Law on Standards and Technical Regulations, these become mandatory when regulated in a legal document or technical regulation. In this case, the standards become the basis for establishing the technical regulations.

Under Article 3.1 of Decree No.127/2007/ND-CP, the budget for developing national standards comes from the annual state budget for activities of science and technology. Under Article 49.1 of the Law on Science and Technology, the annual state budget expenditure for the activities of science and technology is 2 percent of the total annual state budget expenditure. According to the 2014–2015 state budget figures provided by the Ministry of Finance, the state budget expenditure in 2014 was VND107.0 trillion, while the state budget expenditure in 2015 is expected to be VND114.7 trillion. However, the budget allocates most of the funding to regular expenses incurred during the operation of the relevant agencies, while dedicating only 10 percent of the said 2 percent for the development of standards.

As most enterprises in Viet Nam tend to be micro, small, and medium-sized enterprises, the government generally assumes the leadership role in the development of standards and conformance. Viet Nam's enterprises mainly support this effort by providing their comments to the draft standards as requested by the government. Nonetheless, most of Viet Nam's enterprises may not be able to comply with international standards due to their lack of access to advanced technology or expertise to implement the standards in their organisations. In addition, most Vietnamese enterprises generally still conduct business with the mindset of short-term benefits and do not have long-term plans for investment and development. These two factors aggravate the lack of interest in and adoption of international standards, which



may complicate efforts by the government to encourage industrial development towards world-class products and services.

## Appendix D

### Listed Testing Laboratories and Certification Bodies under the ASEAN Sectoral MRA for Electrical and Electronic Equipment

Country	Name of Listed Body	Type
Indonesia	PT HIT, Indonesia	Testing laboratory
	Sucofindo International Certification Services (SICS)	Certification body
	TUV Rheinland Indonesia	Certification body
	PT. Panasonic Manufacturing Indonesia	Testing laboratory
Malaysia	SIRIM QAS International Sdn. Bhd, Malaysia	Testing laboratory
	SIRIM QAS International Sdn. Bhd, Malaysia	Certification body
Thailand	Intertek Testing Services (Thailand) Ltd. (ITS Thailand-1)	Testing laboratory
	TUV SUD PSB (Thailand) Limited	Testing laboratory
	Electrical and Electronics Institute, Foundation for Industrial Development (EEI Thailand)	Testing laboratory
	Electrical and Electronic Products Testing Center (National Science and Technology Development Agency)	Testing laboratory
	Pro Application Testing Lab Listing	Testing laboratory
Viet Nam	Quality Assurance and Testing Center (QUATEST), Viet Nam	Testing laboratory
	Vietnam Certification Center (QUACERT), Viet Nam	Certification body

Source: ASEAN Secretariat.