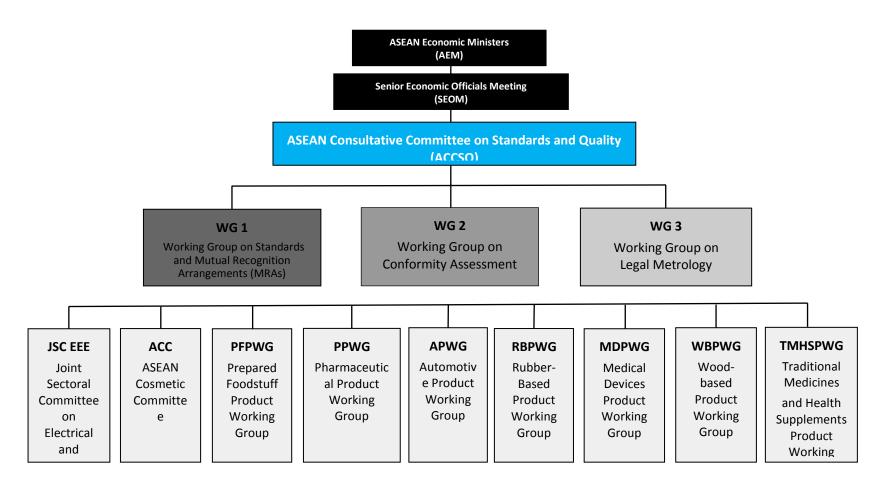
Appendix A

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	
Horizontal function		
WG1 – Working Group on Standards and MRAs	 Monitor the implementation of the sectoral MRAs in the ASEAN. Establish an ASEAN Guide to MRAs. Harmonise national standards to international standards. Assist in promoting good regulatory practice (GRP) concept to regulators. Undertake confidence building among regulators in the use of harmonised standards. Promote the transparency of technical regulations. Explore new areas for the development of MRAs and standards harmonization in the ASEAN. Develop a mechanism for cooperation between standards bodies and regulatory agencies. Recommend to the ACCSQ proposals, activities, or issues for 	
	ASEAN cooperation in relevant international and regional organisations, such as ISO, IEC, APEC, and ASEM.	
WG2 – Working Group on Accreditation and Conformity Assessment	 Enhance the capability of accreditation bodies in ASEAN member countries to achieve regional and/or international recognition. Enhance the competence of conformity assessment bodies in ASEAN member countries to facilitate the implementation of mutual recognition of test reports and certifications. Assist new member countries in accreditation and conformity 	
	assessment. Monitor the certification bodies within the ASEAN.	
WG3 – Working Group on Legal Metrology	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.	
	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,	
	To hold discussions and promote ASEAN interest in legal metrology with other national, regional, and international organisations.	

Appendix B (continued)

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

Product Working Groups (PWGs)			
JSC EEE – Joint Sectoral Committee for Electrical and Electronic Equipment	 Undertake listing, suspension, removal, and verification of testing laboratories and/or certification bodies in accordance with the ASEAN EE MRA. 		
	Provide a forum for the discussion of issues that may arise concerning the implementation of the ASEAN EE MRA.		
	Review and propose amendments to the scope and coverage of the ASEAN EE MRA.		
	Consider ways to enhance the operation of the ASEAN EE MRA, such as developing outreach program for capacity building.		
	Consider ways to a Good Regulatory Practice on electrical and electronic products.		
ACC – ASEAN Cosmetic Committee	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.		
	Monitor the implementation of the following technical documents and review and update these documents when necessary:		
	 ASEAN Definition of Cosmetics and Illustrative List by Category of Cosmetic Products, 		
	 ASEAN Cosmetic Ingredient Listings and ASEAN Handbook of Cosmetic Ingredients, 		
	 ASEAN Cosmetic Labelling Requirements, 		
	 ASEAN Cosmetic Claims Guideline, 		
	 ASEAN Cosmetic Product Registration Requirements, 		
	 ASEAN Cosmetic Imports/Export Requirements, and 		
	 ASEAN Guidelines for Cosmetic Good Manufacturing Practice. 		
	Provide a forum for the discussion of issues that may arise concerning the implementation of the Agreement.		
	Consider measures to enhance the operation of the Agreement.		
PPWG – Pharmaceutical Product Working Group	Undertake an exchange of information on the existing pharmaceutical requirements and regulations implemented by each ASEAN member country.		
	Review and prepare a comparative study of the requirements and regulations.		

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	 Study the harmonised procedures and regulatory system on pharmaceutical trade currently being implemented in other regions. 	
	 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. 	
PFPWG – Prepared Foodstuff Product Working Group	Undertake an exchange of information on standards, regulations, procedures, and mandatory requirements in member countries related to prepared foodstuff.	
	 Review and analyse the comparative study of regulatory regimes among ASEAN member countries. 	
	• Identify areas for possible harmonization and MRAs.	
	• Develop, implement, and monitor the sectoral MRAs.	
	 Identify the technical infrastructure needs and build mutual confidence in testing and conformity assessment. 	
APWG – Automotive Product Working Group	Undertake an exchange of information on standards, rules, regulations, procedures, and mandatory requirements related to the automotive sector among ASEAN member countries.	
	 Review and analyse the comparative study of regulatory regimes among ASEAN member countries. 	
	 Identify areas for possible harmonization and MRAs, with focus on the harmonization of ASEAN automotive safety and emission standards based on UNECE regulations. 	
	Develop sectoral MRAs.	
	 Identify the technical infrastructure needs and build mutual confidence in conformity assessment. 	
TMHSPWG – Traditional Medicines and Health Supplements Product Working Group	Exchange, review, and analyse information on the existing regulatory framework and/or regime, including standard definition, terminologies, and technical infrastructure in ASEAN member countries.	
	 Study the existing regulatory frameworks and/or regime of selected countries and internationally accepted technical guidelines. 	
	 Enhance the technical infrastructure including mutual confidence in testing and conformity assessment. 	
	• Identify areas for possible harmonization and MRAs.	
MDPWG – Medical Device Product Working	Develop a common submission dossier template for product approval in the ASEAN.	
Group	 Explore the feasibility of an abridged approval process for medical devices, which regulators of benchmarked countries or recognised regulators have approved. 	

	 Explore the feasibility of adopting a harmonised system of placement of medical devices into the ASEAN markets, based on a common product approval process.
	• Formalise a post-marketing alert system for defective or unsafe medical devices.
	 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.
RBPWG – Rubber-Based Product Working Group	To enhance cooperation in conformity assessment, development, and implementation of standards and technical regulations for rubber-based products among ASEAN member countries.
	 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.
	 To identify standards for rubber-based products for ASEAN to harmonise with international standards and quality.
	 To enhance joint actions and approaches on international issues and adopt common positions in relevant international organisations, agreements, and arrangements.
	 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.
	 To strengthen human resource development in the area of standards and quality for rubber products.
	• To share equal responsibility to the tasks and activities agreed at meetings.
TFWBP – Task Force on Wood-Based Product	This currently exists under the WG1.

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 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 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 *Tiêuchuẩn 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 2014–21015 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-terms 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	Туре
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.