Chapter 4

Evaluating Sector-Specific Developments

November 2016

This chapter should be cited as

ERIA (2016), 'Evaluating Sector-Specific Developments', in Scoles, S.D (ed.), *Harmonization of Standards and Mutual Recognition Agreements on Conformity Assessment in Indonesia, Malaysia, Thailand, and Viet Nam*. ERIA Research Project Report 2015-14, Available at: http://www.eria.org/RPR_FY2015_No.15_Chapter_4.pdf, pp.7-17

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.[8]

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.[9]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[10] for the 32 UNECE regulations in the ASEAN.

[8] 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.

[9] 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.

[10] 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 modpeds, 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 16UNECE 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.[11]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.[12] 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).[13]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.[14]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

[11] 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.

[12] 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.

[13] ASEAN member states signed the AHCRS during the 35th ASEAN Economic Ministers Meeting on 2 September 2003.

[14] 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 on1 January2011.
- **Malaysia** transposed the ACD into its national regulatory regime on1 January 2008
- **Thailand** transposed the ACD into its national regulatory regimeon1 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 (Prassetya 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),[15] and (ii) the ASEAN Sectoral MRA for Electrical and Electronic Equipment.[16] 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 (Prassetya 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.[17]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.

[15] ASEAN member states signed the AHEEERR on 9 December 2005.

[16] ASEAN member states signed the MRA on 5 April 2002.

[17] 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 (Prassetya 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,[18] 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

[18] For more information, please see 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.