

ASEAN STANDARDS AND CONFORMANCE STRATEGIC PLAN 2016 -2025

**“FORGING AHEAD TOGETHER: ENSURING
QUALITY & BUILDING CONFIDENCE”**

Introduction

1. The ASEAN Leaders at their Summit in Kuala Lumpur in December 1997 decided to transform ASEAN into a stable, prosperous, and highly competitive region with equitable economic development, and reduced poverty and socio-economic disparities (ASEAN Vision 2020). At the Bali Summit in October 2003, ASEAN Leaders declared that the ASEAN Economic Community (AEC) shall be the goal of regional economic integration (Bali Concord II) by 2020. At the 12th ASEAN Summit in January 2007 in Cebu City, Philippines, the Leaders affirmed their strong commitment to accelerate the establishment of an ASEAN Community by 2015 as envisioned in the ASEAN Vision 2020 and the ASEAN Concord II, and signed the Cebu Declaration on the 'Acceleration of the Establishment of an ASEAN Community by 2015'. In particular, the Leaders agreed to hasten the establishment of the ASEAN Economic Community by 2015 and to transform ASEAN into a region with free movement of goods, services, investment, skilled labour, and freer flow of capital.
2. The Kuala Lumpur Declaration on The Establishment of The ASEAN Community was announced by ASEAN Leaders during 27th ASEAN Summit on 22 November 2015, to formally establish ASEAN Community on 31 December 2015. Following that, the ASEAN Community Vision 2025 was adopted which consisted of the ASEAN Political Security Community Blueprint 2025, the ASEAN Economic Community Blueprint 2025 and the ASEAN Socio-Cultural Community Blueprint 2025.
3. The AEC 2025 is envisioned to be (i) a Highly Integrated and Cohesive Economy; (ii) a Competitive, Innovative, and Dynamic ASEAN; (iii) Enhanced Connectivity and Sectoral Cooperation; (iv) A Resilient, Inclusive, People-Oriented, and People-Centred ASEAN; and (v) a Global ASEAN.
4. The ASEAN Consultative Committee for Standards and Quality (ACCSQ) was established by the ASEAN Economic Ministers at their 24th Meeting held on 22- 23 October 1992 in Manila, Philippines with the aim of removing technical barriers to trade in order to facilitate the implementation of the Common Effective Preferential Tariff (CEPT) Agreement to realize the ASEAN Free Trade Area (AFTA). Furthermore, at the 4th Senior Economic Officials Meeting (SEOM) held in Medan, Indonesia on 8-10 September 1997, the SEOM approved the revised TOR of the ACCSQ, which among others, authorized the ACCSQ to involve regulatory bodies in the ACCSQ in order to achieve its mandate of eliminating technical barriers to trade.
5. To achieve its mandate, the ACCSQ further formed its working groups/product working groups, in order to eliminate technical barrier and facilitate trade among ASEAN Member

States, through harmonisation of standards, technical regulations and conformity assessment procedures. As of 2015, numbers of instruments have been established by ACCSQ and its WGs/PWGs. The achievements include development of policy documents, harmonisation of standards and technical requirements, MRAs, and harmonisation of technical regulations. Details of achievement as appears as ANNEX 1.

6. Immediate priorities for ACCSQ is to complete its continuing commitments of eliminating technical barriers to trade. These are incorporated in the ASEAN Standards and Conformance Strategic Plan 2016 – 2025.
7. With the global economy that is constantly evolving, ASEAN has to continually review its strategies to meet the new challenges and opportunities, in line with the AEC Blueprint 2025. Therefore, the ASEAN Standards and Conformance Strategic Plan 2016-2025 will enhance the contribution of ACCSQ in ensuring quality and building confidence for ASEAN products and services.

Vision

The ASEAN Economic Community (AEC) 2015 ushers in a new era of cooperation and business opportunities among the grouping's ten members. The AEC has defined the region as one that:

- 1) operates as a single market and production base;
- 2) is a highly competitive economic region;
- 3) promotes equitable economic development; and
- 4) is fully integrated into the global economy.

The ASEAN Economic Ministers have at their 47th Meeting held on August 22, 2015 defined the ASEAN's targets for 2025 in the following statement:

"ASEAN has made good progress in putting in place key frameworks and other fundamentals that are imperative for the effective functioning of the economic community. AEC 2025 will follow through on these achievements and early gains, while taking into consideration the evolving global context and other mega-trends. By 2025, the AEC is envisioned to be highly integrated and cohesive; competitive, innovative and dynamic; with enhanced economic connectivity as well as integration and cooperation across sectors; while fostering a more resilient, inclusive, and people-oriented, people centred community that is integrated into the global economy."

Noting the mandate granted to ACCSQ in shaping the market integration of ASEAN in trade in goods through the provisions of ASEAN Trade in Goods Agreement, ACCSQ will play a key role in guiding ASEAN to achieve the targets set by the Economic Ministers.

Vision Statement for ACCSQ:

ACCSQ's vision is to have an integrated internationally recognised, people-oriented and sustainable regime in ASEAN for standards, technical regulations and conformity assessment procedures to enable the free flow of goods and services, and ensure safety, health and protection of the environment throughout ASEAN.

ACCSQ's Mission for the period from 2016 to 2025:

ACCSQ shall establish comprehensive policies relating to standards, technical regulations and conformity assessment procedures (STRACAP)¹, and support the development of associated quality infrastructure for the purpose of creating a highly integrated and cohesive ASEAN economy. ACCSQ, in collaboration with other relevant ASEAN sectoral bodies, shall establish sectoral and regulatory mechanisms in all priority sectors based on these policies to eliminate technical barriers to trade through measures such as harmonised standards and technical

¹ The term STRACAP refers to standards, technical regulations, conformity assessment procedures, accreditation, scientific and legal metrology, market surveillance.

regulations, mutual recognition of conformity assessment results and acceptance of equivalence² of technical regulations.

STRATEGIC PLAN

To realise its post 2015 vision ACCSQ has adopted six strategic thrusts which are as follows:

- 1. Enhance the standards and conformance infrastructure through development of policies and initiatives to meet the present and future needs of ASEAN.**
- 2. Achieve a highly integrated and cohesive ASEAN economy through a comprehensive and progressive reduction of technical barriers to trade related to STRACAP.**
- 3. Strengthen joint ASEAN approaches on issues related to STRACAP for effective representation and participation in international and Asia-Pacific bodies and associated recognition arrangements.**
- 4. Strengthen private sector participation in standards and conformity assessment to accelerated development and enhance availability of services to industry and businesses.**
- 5. Enhance the effectiveness of ACCSQ, its Working Groups and its collaboration with other relevant ASEAN sectoral bodies.**
- 6. Support the capacity building and human capital development of Member States for the implementation of ASEAN initiatives and policies related to STRACAP.**

The six strategic thrusts are elaborated in the following section. The strategic thrusts are designed to further elaborate policies, identify and support the review of existing agreements, the development of new agreements and related mechanisms that will support the further removal of remaining technical barriers to trade. Emphasis is placed on enhanced cooperation with other sectoral bodies and committees that have related interests. The external trade perspective has been included to ensure that ASEAN integration efforts enhance its linkages with global organisations in standards, accreditation, metrology and technical regulation, so as to support continued openness to global trade.

² The term of “equivalence” refers to article 2.7 of WTO TBT Agreement

Strategic Thrust 1: To enhance the standards and conformance infrastructure through development of policies and initiatives to meet the present and future needs of ASEAN.

Rationale:

The market integration will be realised through the removal of technical trade barriers. This in turn is dependent on mutual confidence of the results of conformity assessment and regulatory approvals between the authorities in Member States. The establishment of a framework of policies and initiatives sets the basis for the establishment of standards and conformance infrastructure in Member States upon which harmonisation of standards and technical regulations can be pursued and mutual confidence established. It is through such policies and initiatives that ASEAN can ensure the development towards a coherent standards and conformance ecosystem. In defining these policies and initiatives it is recognised that different levels of development among ASEAN Member States exist and that actions to narrow the gaps are an essential element.

The development of framework of policies and initiatives for the quality infrastructure needs to be expanded from the existing ASEAN guidelines for STRACAP to cover additional areas and actions to enable and facilitate their adoption.

Activity Programmes Outcomes and Key Performance Indicators (KPIs)

| Activity Programme |
|--|
| 1. Strengthening the framework for cooperation in standards development to ensure relevant harmonised standards are available to support market integration, building upon the ASEAN Guidelines for Harmonisation of Standards. |
| 2. Support and contribute to the development of an ASEAN roadmap for serving scientific and legal metrology needs. This will be undertaken by joint work between ASEAN bodies engaged in legal and scientific metrology. This will lead to the development of a mechanism for regular cooperation between the national metrology institutes and legal metrology authorities and will leverage on the existing cooperation in APMP and APLMF and not duplicate any of the existing initiatives. |
| 3. Enhance the framework for cooperation in accreditation, building upon the ASEAN Guidelines for Accreditation and Conformity Assessment. This will include structured cooperation between National Accreditation Bodies (NAB) and National Accreditation Focal Points (NAFP) for capacity building, development of accreditation schemes, and delivery of services and sharing of personnel and resources. The enhanced framework should build upon the existing cooperation in APLAC and PAC and not duplicate any of the existing initiatives. |
| 4. Develop a generic guidance for sector groups for establishing harmonised regulatory regimes, extending the ASEAN Guidelines for Developing MRAs that has been previously developed. This guidance will identify factors to be considered, elaborate on approaches and methods of harmonisation and consider the relationship with existing international harmonisation agreements and initiatives required for implementation. |

5. Enhance the implementation of regional rapid alert systems and adopt common approaches on risk assessment methodologies and market surveillance systems in ASEAN Member States.

Strategic Thrust 2: Achieve a highly integrated and cohesive ASEAN economy through a comprehensive and progressive reduction of technical barriers to trade related to

Rationale

In the last decade, much has been achieved and easier trade in goods, have been facilitated within the region. But full market economic integration that creates a true single market environment is yet to be realized. Significant technical trade barriers remain even in sectors that have implemented mutual recognition arrangements. Evaluations undertaken have revealed that mutual recognition arrangements and harmonisation of standards do not remove the technical trade barriers comprehensively. Differences in technical regulations lead to other barriers that will have to be removed to enable the targeted intended free flow of goods. Further it is noted that the focus on the removal of technical barriers to trade has been limited only on the 12 priority sectors and this focus will be reviewed with a view to expansion to other sectors. Enhancements to existing initiatives and new approaches are needed to overcome the observed limitations.

Activity Programmes Outcomes and Key Performance Indicators (KPIs)

| Activity Programme |
|---|
| 1. Review and accelerate ongoing market integration initiatives which covers existing ACCSQ mutual recognition arrangements and harmonised regulatory regimes with a view to enhancing effectiveness in removing technical barriers to trade. |
| 2. Deepen regional implementation of trade-facilitative STRACAP initiatives in existing and new areas including addressing the needs of MSMEs. |
| 3. Promote and facilitate the ASEAN Good Regulatory Practice Guide (GRP) in the preparation and implementation of harmonised regulations in ASEAN as well as the Guidelines for Regulatory Impact Assessment (RIA) and Regulatory Impact Statement (RIS). |

Strategic Thrust 3: Strengthen joint ASEAN approaches on issues related to STRACAP for effective representation and participation in international and Asia-Pacific bodies and associated recognition arrangements

Rationale

The international and the Asia Pacific regional standards and conformance bodies have an established key role in trade facilitation and operate within the rules of WTO TBT and SPS Agreements. These bodies have established platforms for the development of international standards, and have developed mutual recognition arrangements for accreditation, metrology and conformity assessment. These initiatives facilitate and support global trade. In order to maintain market access to global markets, exporters from ASEAN need to comply with international standards and in many instances additionally require certification, test and inspection reports issued under these regional and global recognition arrangements. Participation by ASEAN counterpart bodies in the international bodies and their recognition arrangements serves to ensure that the interests of the region are reflected. Participation also facilitates the availability of the required conformity assessment services in the region. National counterpart bodies in ASEAN Member States keep up to date with changing global developments in these areas through participation.

Noting the initiatives developed internationally, it is logical that ASEAN's work builds upon, rather than duplicates, the work undertaken by regional and international bodies. ASEAN will be able, where appropriate, draw upon the expertise and the experience of these international and Asia Pacific regional bodies.

Activity Programmes Outcomes and Key Performance Indicators (KPIs)

| Activity Programme |
|--|
| 1. Enhance effective participation in, and coordination for, a common regional position in the identified international standards organisations ³ with a view to safeguard and promote regional interests and to utilise the platforms for the development of standards and related conformance matters relevant to the region. |
| 2. Coordinate and cooperate with regard to representation on new and developing issues in international and in Asia Pacific regional organisations. ⁴ |

³ ISO and IEC

⁴ ILAC, IAF, BIPM, OIML, APEC, PASC, APLAC, PAC, APMP, APLMF

3. Support ASEAN initiatives in the negotiation and implementation of technical barriers to trade (TBT) Chapters of ASEAN + 1 FTAs, and future economic partnership and free trade agreements, including coordination of inputs to the WTO TBT committee.

4. Adopt a concerted approach to identify and participate in global organisations⁵ and other bodies in standards, conformity assessment, metrology, and technical regulation.

⁵Including, but not limited to ICH, IMDRF, PIC/S, UN/ECE WP 29 and the 1958 Agreement, OECD's Mutual Acceptance of Data, and European Pharmacopeia Commission

Strategic Thrust 4: Strengthen private sector participation in standards and conformity assessment to accelerate development and enhance availability of services to industry and businesses.

Rationale

With the growth of global trade in the last few decades, the use of international standards is becoming more important as it opens doors for businesses. The development of standards at the international level has been largely market-driven. Companies that meet export requirements through adoption of relevant standards are able to gain greater trade and market opportunities as it assures customers that their products or services are safe and reliable.

Standards help Micro, Small and Medium Enterprises (MSMEs) to enhance their capabilities and differentiate themselves from their competitors. Furthermore, involvement in the development of standards enables companies to keep abreast of regional and international developments as well as to market their innovations across borders.

Similarly, conformity assessment has also become an equally important part of doing business in the global marketplace. Conformity assessment involves the process of demonstrating that products, services, systems or people meet the specifications of a relevant standard. It supports the enforcement of regulation to ensure national health, safety and environmental legislation, and also facilitates business transactions by assisting buyers and sellers to verify the quality of products and the credibility of the suppliers.

The development of market-relevant standards by ASEAN member States is primarily undertaken by government bodies with the involvement of different stakeholders such as industry, relevant conformity assessment bodies, research institutions, academia, consumer associations and other stakeholders. The private sector being one of the major stakeholders, is a beneficiary and an affected party. Governments have a role in enabling active participation of the private sector in standards development as well as in ensuring the structured development of conformity assessment systems. The partnership between government and the private sector will help to overcome the capacity constraints that ASEAN Member States face in developing the standards and conformity assessment infrastructure as well as permit faster adoption of new initiatives for economic integration by leveraging more on private sector conformity assessment services.

Activity Programmes Outcomes and Key Performance Indicators (KPIs)

| Activity Programme |
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| 1. Support and encourage working groups / product working groups to engage with trade and other relevant associations to consult on development and to review trade related implementation issues on standards, conformity assessment and technical regulation. |

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| 2. Establish common approaches to the use of conformity assessment activities implemented to support technical regulation. Enable and support the increased use of services provided by the private sector whenever feasible. |
| 3. Collaborate to enhance the delivery of information on standards and conformity assessment in ASEAN to industry and businesses with a special focus on MSMEs. |

Strategic Thrust 5: Enhance the effectiveness of ACCSQ, its Working Groups/ Product Working Groups, and its collaboration with other relevant ASEAN sectoral bodies

Rationale

ACCSQ, as the body mandated by the Economic Ministers of ASEAN, has the responsibility of setting the direction and defining the activities for ASEAN Bodies and the related institutions in ASEAN Members States in implementing initiatives for the economic integration. -.

ASEAN Member States are in different levels of economic development and have variable legislation with differing institutional arrangements. The differences range from availability and scope of legislation, methods of implementation adopted to the level of resources allocated. This complex situation requires careful analysis to assure the choice of the most appropriate initiatives and tools for economic integration.

ACCSQ will enhance its effectiveness by ensuring that the processes adopted are comprehensive and adequate to effectively deal with this task. The work will additionally be facilitated when the working groups/product working groups have appropriate terms of reference and representation.

The cooperation and coordination with other ASEAN Bodies, will be strengthened to maximise their contributions to further ACCSQ's objectives.

Activity Programmes Outcomes and Key Performance Indicators (KPIs)

| Activity Programme |
|--|
| 1. Review existing structures, terms of reference, processes and procedures for the work undertaken by ACCSQ and its working groups/product working groups and strengthen internal monitoring, with a view to ensure effective delivery of planned actions for on-going and expected future needs. |
| 2. Establish structured mechanisms for cooperation between ACCSQ and related ASEAN bodies in areas of mutual interest. These areas include consumer protection, food safety, agriculture, health, MSMEs, science and technology (S&T) and others ⁶ . |

⁶Other areas include Information and communication technology (ICT), Energy, Environmental Protection, Services, etc.

Strategic Thrust 6: Support the capacity building and human capital development of Member States for the implementation of ASEAN initiatives and policies related to STRACAP

Rationale

The implementation of the economic integration initiatives developed under the ACCSQ'S Strategic Plans are dependent on the availability of institutional capacity and skilled human capital in Member States. Capacity building programmes implemented by ACCSQ will increase effectiveness and accelerate the implementation of its initiatives. The availability of human capital and competent institutions manned by skilled and qualified personnel are critical in ensuring mutual confidence and recognition of the result of conformity assessment, accreditation and regulatory actions among Member States.

The implementation of ACCSQ'S initiatives on STRACAP, including those on capacity building, will be enhanced through cooperation and coordination with dialogue partners and other partner development agencies.

Activity Programmes Outcomes and Key Performance Indicators (KPIs)

| Activity Programme |
|--|
| 1. Identify needs and support initiatives on standards education for the development of skilled and knowledgeable personnel needed to support the standards infrastructure in ASEAN. |
| 2. Identify needs and support initiatives for the enhancement of the human capital and institutional capacity to support the delivery of professional services in the field of standards and conformance. |
| 3. Enhance cooperation among ASEAN Member States in capacity building and promote the sharing of professional resources in the field of STRACAP. |
| 4. Strengthen and expand cooperation with dialogue partners and other external development partners to ensure these are appropriate and effective in meeting development needs of ACCSQ and its working groups/product working groups with a focus on narrowing the STRACAP development gap among AMS. |

List of Acronyms and Abbreviations

| Acronym | Details |
|------------------------------|---|
| AEC | ASEAN Economic Community |
| ACCP | ASEAN Committee on Consumer Protection |
| ACCSQ | ASEAN Consultative Committee on Standards and Quality |
| APLAC | ASIA Pacific Laboratory Cooperation |
| APLMF | Asia Pacific Legal Metrology Forum |
| APMP | Asia Pacific Metrology Programme |
| BIMP | International Bureau of Weights and Measures |
| COST | Committee on Science and Technology |
| GRP | Good Regulatory Practice |
| IAF | International Accreditation Forum |
| ICH | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| ILAC | International Laboratory Accreditation Cooperation |
| IMDRF | International Medical Device Regulators Forum |
| OECD | Organisation for Economic Cooperation and Development. |
| OIML | International Organization for Legal Metrology |
| PAC | Pacific Accreditation Cooperation |
| PIC/S | Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) |
| ACCSQ Working Groups | Working Group on Standards and MRAs (WG 1), Working Group on Conformity Assessment (WG 2), Working Group on Legal Metrology (WG 3) |
| ACCSQ Product Working Groups | ASEAN Cosmetic Committee (ACC), ASEAN Medical Device Committee (AMDC), Automotive Product Working Group (APWG), Joint Sectoral Committee on Electrical and Electronic Equipment (JSC EEE), Pharmaceutical Product Working Group (PPWG), Prepared Foodstuff Product Working Group (PFPWG), Rubber-Based Product Working Group (RBPWG), Traditional Medicines and Health Supplements Product Working Group (TMHS PWG) |

UN/ECE WP 29

UNECE World Forum for Harmonization of Vehicle Regulations
(WP.29)

1958 UN/ECE
Agreement

Agreement Concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles, Equipment and Parts which can be fitted and/or be used on Wheeled Vehicles and the Conditions for Reciprocal Recognition of Approvals Granted on the Basis of these Prescriptions

ANNEX 1

i. Policy Documents

1. ASEAN Guidelines on Standards, Technical Regulations and Conformity Assessment Procedures (STRACAP).
2. ASEAN Guideline on Accreditation and Conformity Assessment.
3. ASEAN Guidelines on Development of MRA.
4. ASEAN Guidelines on Harmonisation of Standards.

ii. Harmonization of standards and technical requirements

1. ASEAN Common Technical Dossier (ACTD) and ASEAN Common Technical Requirements (ACTR) in pharmaceuticals sector.
2. Common Submission Technical Dossier (CSDT) in medical device sector.
3. Harmonisation of all 19 technical requirements of the ASEAN Guidelines on Traditional Medicines and Health Supplements.
4. Harmonisation of 15 out of 19 technical requirements of ASEAN priority UN Regulations on automotive.
5. Harmonisation of 21 standards on electrical and electronic equipment.
6. Harmonisation of 46 ISO test methods standards on rubber.
7. ASEAN Maximum Level on Food Additives.
8. ASEAN Common Requirement for Pre-packaged Products.
9. Handbook of ASEAN Common Requirement for Pre-packaged Products.
10. ASEAN Guidelines on Non-Automatic Weighing Instrument.
11. Guidance Notes on the Agreement for Applicable Conformity Assessment Regime (ACAR) for ASEAN Regulated Electrical and Electronic Equipment.
12. ASEAN Risk Assessment Guidelines in EEE sector.
13. Post Market Surveillance Guidelines on EEE.
14. ASEAN Common Food Control Requirements (ACFCR), which include:
 - ASEAN Principles and Guidelines for National Food Control Systems;
 - ASEAN General Principles of Food Hygiene;
 - ASEAN Principles for Food Import and Export Inspection and Certification;
 - ASEAN Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems;
 - ASEAN Guidelines for Food Import Control Systems;
 - Guidelines on Inspection and Certification of Food Hygiene (previously known as Guidelines on HACCP and GMP Requirements and Inspection and Certification System).

iii. Mutual Recognition Arrangements

1. ASEAN Sectoral Mutual Recognition Arrangement (MRA) for electrical and electronic equipment (EEE).
2. ASEAN Sectoral MRA on GMP Inspection of Manufacturers on Medicinal Products.

iv. Harmonisation of Technical Regulations

1. ASEAN Harmonised Cosmetic Regulatory Scheme
2. ASEAN Harmonized Electrical and Electronic Equipment Regulatory Regime
3. ASEAN Medical Device Directive

v. Involvement in implementation and negotiation in STRACAP Chapter within ASEAN + 1 FTA and future economic partnership and free trade agreement

1. ASEAN Australia New Zealand Free Trade Agreement (AANZFTA)
2. ASEAN Japan Comprehensive Economic Partnership (AJCEP)
3. ASEAN China Free Trade Agreement (ACFTA)
4. Regional Comprehensive Economic Partnership (RCEP)
5. ASEAN - Hong Kong Free Trade Agreement (AHFTA)