Introduction to Mutual Recognition Agreements in ASEAN

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Content

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• Alternatives of MRA
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Definitions of Mutual Recognition
Cross Border Requirements

International Border Inspection
Prior entering the market e.g. at port

Post International Border Inspection – having entered the market, upon customs clearance

Compliance Technical Regulations (e.g. fumigation, food safety)

Food regulations and safety, standards
# Food Safety and Food Standards Traceability System

<table>
<thead>
<tr>
<th>Primary Products and Ingredients</th>
<th>Secondary Products and Ingredients</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Suppliers of Raw Materials</td>
<td>• Compliance to rules and standards relating to food production techniques, production methods and the end products</td>
<td>• Labelling to meet international rules and standards</td>
</tr>
<tr>
<td>• Compliance to Standards and Regulations relating to Farming Methods, Catching Methods and Product Safety</td>
<td></td>
<td>• Food nutrient and claim</td>
</tr>
<tr>
<td></td>
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<td>• Intellectual Property protected</td>
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Mutual Recognition

Reciprocity
- Exchange of equivalent promises to recognize each other regulations between two countries
- Accepts standards in other country to the one of its own

Acceptance
- Acceptance of regulatory conditions for goods and services required in one country (exporting origin/home country) as equivalent with the conditions necessary in another country (importing country/host country).
Principle in Casis de Dijon (EU)

• If a product can be sold lawfully in one jurisdiction, it can be sold freely in any other participating jurisdiction, without having to comply with the regulations of these other jurisdictions regardless of the differences in standards or other sale related regulatory requirements.

• A process of approval can be obtained domestically by the producers and exporters set by the national law based on the same requirement set by the destination country.
Characteristics

• National rules and regulations being recognized by another State
• Judicial and Political
  • Judicial mainly in the European Union eg. Casis de Dijon; German Beer cases
  • Political imposes the contractual norm = agreements
• Do not require full harmonization of rules and regulations
• Establishment of institutional mechanisms
Risks of Mutual Recognition

• Sacrifices important regulatory goals without adequate justification.
• Thus States may accept MR if they are compensated with enhanced welfare from free trade, or from other sources.
• MR established by developed countries in a way that disadvantages exports of poor countries.
• Mutual recognition can only take place to the extent that states can legitimately agree on an appropriate level of regulatory protection.
• Mutual recognition cannot be permitted to leave poor countries at a disadvantage in international trade.
How to effect Mutual Recognition

• Mutual Recognition Agreement
  • An MRA is one in which the respective regulatory authorities accept, in whole or in part, the regulatory authorizations obtained in the territory of the other party or parties to the agreement in granting their own authorization

• To agree on the methodology for recognition
  • To verify the equivalence of the level of protection provided by the product under scrutiny.
  • Collecting the necessary data
  • Verification of the equivalence of level of protection
  • Issuing the results of the assessment
  • Communicating the results to the applicants.
Alternative of MRA: Harmonisation and Standardisation

• Harmonisation:
  • The process of making different domestic laws, regulations, principles and government policies substantially or effectively the same or similar
  • Making the regulatory requirements or governmental policies of different jurisdictions identical or at least more similar
  • A process of reducing divergence or fragmentation to increasing similarity or comparability

• Standardisation is focusing on a common standard, i.e. a generally accepted and followed system of nomenclature
Comparison between harmonization and recognition

Conformity Assessment, Technical Standards

- Harmonization of standards, conformity assessment
  - Unilateral harmonization
    - Harmonization among concerned parties
  - Automatic mutual recognition
  - Managed mutual recognition

- Recognition of standards, conformity assessment
  - Unilateral recognition
    - Mutual recognition
Why not harmonization?

Difficulty to obtain full harmonization. E.g. GM products

MR would be equally appropriate to achieve economies of scale
MRA in Goods in ASEAN
ASEAN Community 2015 and ASEAN Community 2025

• Free Flow of Goods
  • Elimination of Non-tariff Barriers
  • Standards and Technical Barriers to Trade

• AEC Blueprint 2025: to minimise trade protection and compliance costs in dealing with non-tariff barriers (NTB) by working on, inter alia, Mutual Recognition Agreements (MRAs)
ASEAN Framework Agreement on MRA 1998 (see also the text)

• Use definitions in Guide 2 (1996 edition) of the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC)
• "Conformity Assessment“= systematic examination to determine the extent to which a product, process or service fulfills specified requirements;
• "Conformity Assessment Body“= a body whose activities and expertise include performance of all or any stage of the conformity assessment process except for accreditation;
• "Regulatory Authority" = an entity that exercises a legal right to control the import, use or sale of products within a Member State's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.
Conformity assessment

• Processes that are used to demonstrate that a product or a service or a management system or a person meets specified requirements.

• The specified requirements may be contained in a technical standard, a regulation or a contract

• Three levels:
  • First party (suppliers)
  • Second party (customers, e.g. private standards)
  • Third Party (independent certification body, governmental authorities)
Compliance mechanisms

- Products, materials, installations, plants, processes, work procedures and services, and report on such parameters as quality, fitness for use and continuing safety in operation.
- The overall aim is to reduce risk to the buyer, owner, user or consumer of the item being inspected.
Examples: Malaysia

Regulatory Authority  
CAB
ASEAN Consultative Committee on Standards & Conformance (ACCSQ)

• To facilitate the ASEAN Economic Integration towards a single market and production base by 2020 through elimination of technical barriers to trade posted by standards, technical regulations and conformity assessment in ASEAN Member Countries
• Harmonise standards and technical regulations through alignment with international practices;
• Develop and implement Mutual Recognition Arrangements (MRAs) on Conformity Assessment;
• Enhance the technical infrastructure and competency in laboratory testing, calibration, certification and accreditation based on internationally accepted procedures and guides; and
• Strengthen information networking on standards and technical regulations
ACCSQ Working Groups

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<tr>
<th>Standards and Conformance</th>
<th>Sectoral MRA Working Group</th>
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<tbody>
<tr>
<td>• WG on MRAs and Standards</td>
<td>• Joint Sectoral Committee on Electrical and Electronic Equipment</td>
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<td>• WG on Accreditation and Conformity Assessment</td>
<td>• ASEAN Cosmetic Committee</td>
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<td>• WG on Legal Metrology</td>
<td>• Pharmaceutical</td>
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<td></td>
<td>• Prepared Foodstuff</td>
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<td></td>
<td>• Traditional Medicines and Health Supplements</td>
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<td>• Automotive</td>
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<td>• Rubber-Based</td>
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<td>• Wood-Based</td>
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<td>• Medical Device</td>
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Policy Guideline on Standards and Conformance

• General provisions and principles specific to the harmonisation of standards, the adoption of technical regulations, conformity assessment, post-market surveillance and transparency

• National standards bodies should accept and follow the Code of Good Practice for the Preparation, Adoption and Application of Standards as provided in Annex 3 of TBT Agreement

• Put into practice MRAs in regulated areas where appropriate, using the ASEAN Framework Agreement on Mutual Recognition Arrangements as the basis;

• Encourage cooperation among National Accreditation Bodies and National Metrology Institutes in ASEAN to enable the implementation of MRAs.
Achievement

Harmonisation

• 140 standards
• Technical regulations
  • electrical and electronic equipment;
  • pharmaceuticals;
  • cosmetics;
  • medical devices;
  • traditional medicines and health supplements
  • prepared foodstuff.

MRA

• electrical and electronic equipment
• cosmetics
• Telecommunications
• Pharmaceuticals
MRA for Electrical Electronic Equipment

- Acceptance of test reports (based on APLAC MRA & IECEE CB Scheme) & certification (based on PAC MRA & IECEE CB – Full Certification Scheme)
- Signed in 2000 and implemented in 2004
- Supports implementation of AHEEER
Pharmaceutical Good Manufacturing Practice (GMP) MRA

• ASEAN MRA on GMP of Inspection of Manufacturers of medicinal products (signed in 2009 and based on PIC/S)
• Inspections can be carried out by competent local inspection bodies resulting in cost savings for manufacturers.
ASEAN Guidelines

• ASEAN Principles and Guidelines for National Food and Control System;
• ASEAN General Principles of Food Hygiene;
• ASEAN Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification System;
• ASEAN Guidelines for Food Reference Laboratories and ASEAN Principles for Food Import and Export Inspection and Certification.
Work in Progress

• MRA Model for Agriculture Best Practices

• The ASEAN Ministers of Agriculture and Forestry (AMAF), in 2006 and 2014, has endorsed the ASEAN Agricultural Best Practices (GAP, Good Animal Husbandry Practices (GAHP) and the Good Aquaculture Practices (GAqP)

• To improve quality assurance, quality of products, and minimise hazards in food safety, environmental impacts, and worker health, safety and welfare.

• Sets of separate ASEAN standards: mango, pineapple, durian, papaya, pomelo, rambutan, mandarin, lansium, guava, mangosteen and watermelon

• The MRA will define how the ASEAN standards are applied and operationalized, at the national and the regional level, by various relevant institutions at both levels, through new or existing regional institutions and mechanism such as the ASEAN Sectoral Working Groups and Experts Working Groups.

• Small farms usually lack the capability and economies of scale to have effective quality assurance and traceability systems, which may leave them out.