



# Update On Harmonisation for Health Supplements Sector

# Outline



- **ASEAN HS Harmonisation Overview**
- **ASEAN HS Harmonisation Status**
- **Implementation Challenges**

# ASEAN Economic Community At A Glance



## ASEAN Economy

A Highly Competitive Economic Region

With a combined GDP of **US\$2.6 trillion** in 2014, ASEAN economy was the **7<sup>th</sup> largest in the world** and the **3<sup>rd</sup> largest in Asia**

## ASEAN Population

A Region Fully Integrated Community

In 2014, ASEAN was the **3<sup>rd</sup> largest market in the world** with **622 million people** behind only China and India

## ASEAN Trade

A More Integrated Market

Total trade increased by nearly **US\$1 trillion** between 2007 and 2014, with **intra-ASEAN** trade comprising **the largest share** of ASEAN's total trade by partner.



## ASEAN FDI

A World Class Investment Destination

ASEAN attracted **US\$136 billion** in FDI in 2014, accounting for **11%** of global FDI inflows, up from only **5%** in 2007

## ASEAN Connectivity

A More Connected Community

Annual tourist arrivals were up from **62 million** in 2007 to **105 million** in 2014, **almost half** of which were **intra-ASEAN**

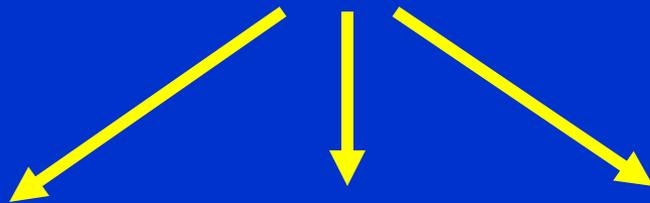
The rate of Internet subscription **more than doubled** from **11.8 per 100 inhabitants** in 2007 to **28.6** in 2014

<http://asean.org/storage/2012/05/11c-April-2016-Fact-Sheet-of-AEC.pdf>

**Euromonitor Estimates for 2016 Vits & Dietary Supplement ASEAN Sales of US\$4.4 Billion**



## 3 PILLARS Targeted for 2020



**ASEAN  
SECURITY  
COMMUNITY**

**ASEAN SOCIAL  
COMMUNITY**

**ASEAN  
ECONOMIC  
COMMUNITY**

**AEC : Accelerate to 2015**

**AEC: 11 priority sectors including health supplements**

ASEAN HS industry  
representation

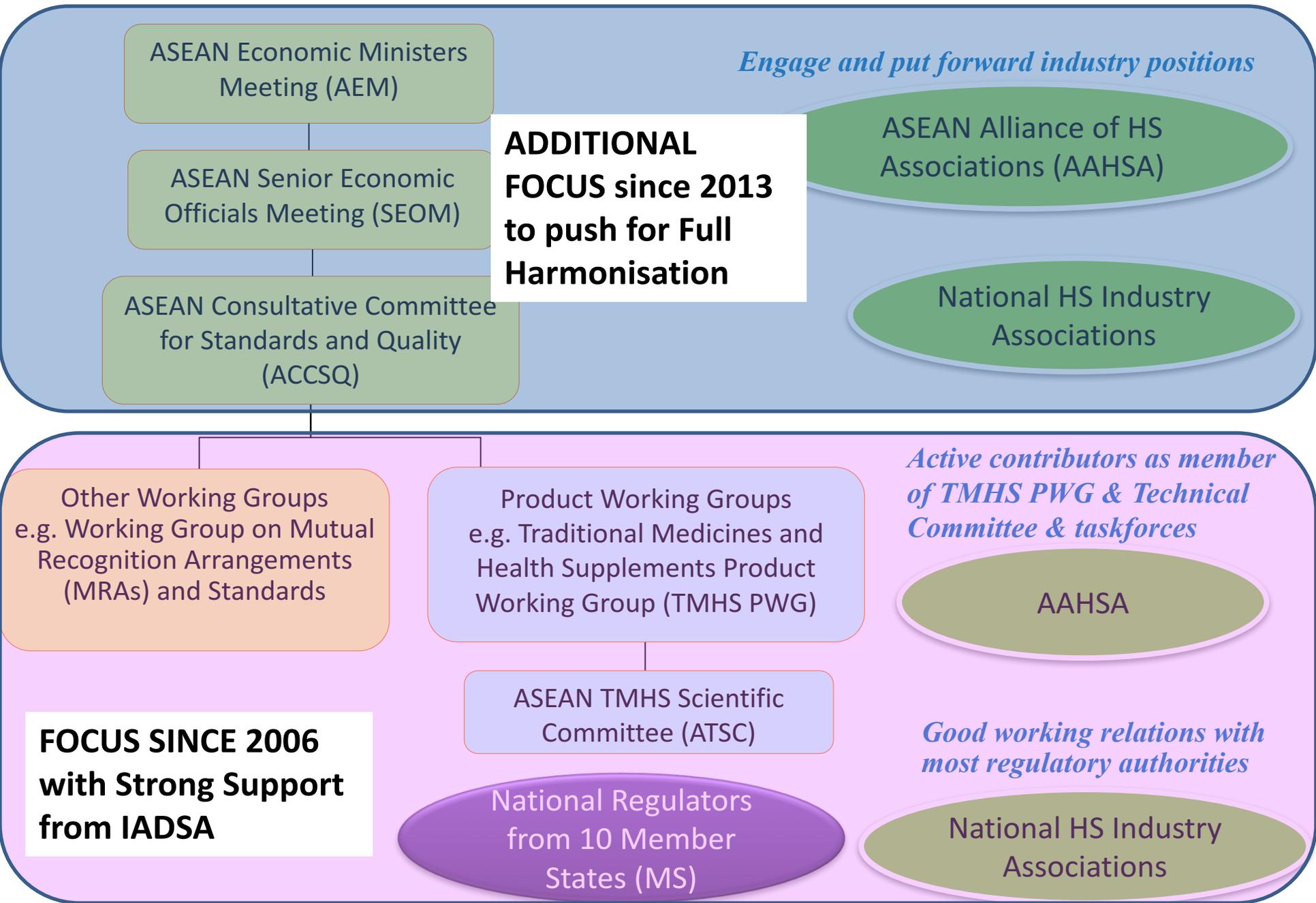
**ACCSQ**  
ASEAN Consultative  
Committee for Standards  
and Quality

**T**raditional **M**edicines /  
**H**ealth **S**upplements  
**P**roduct **W**orking **G**roup

## ILLUSTRATIVE ASEAN ORGANIZATIONAL STRUCTURE



# ASEAN TMHS Harmonization - multiple levels of work

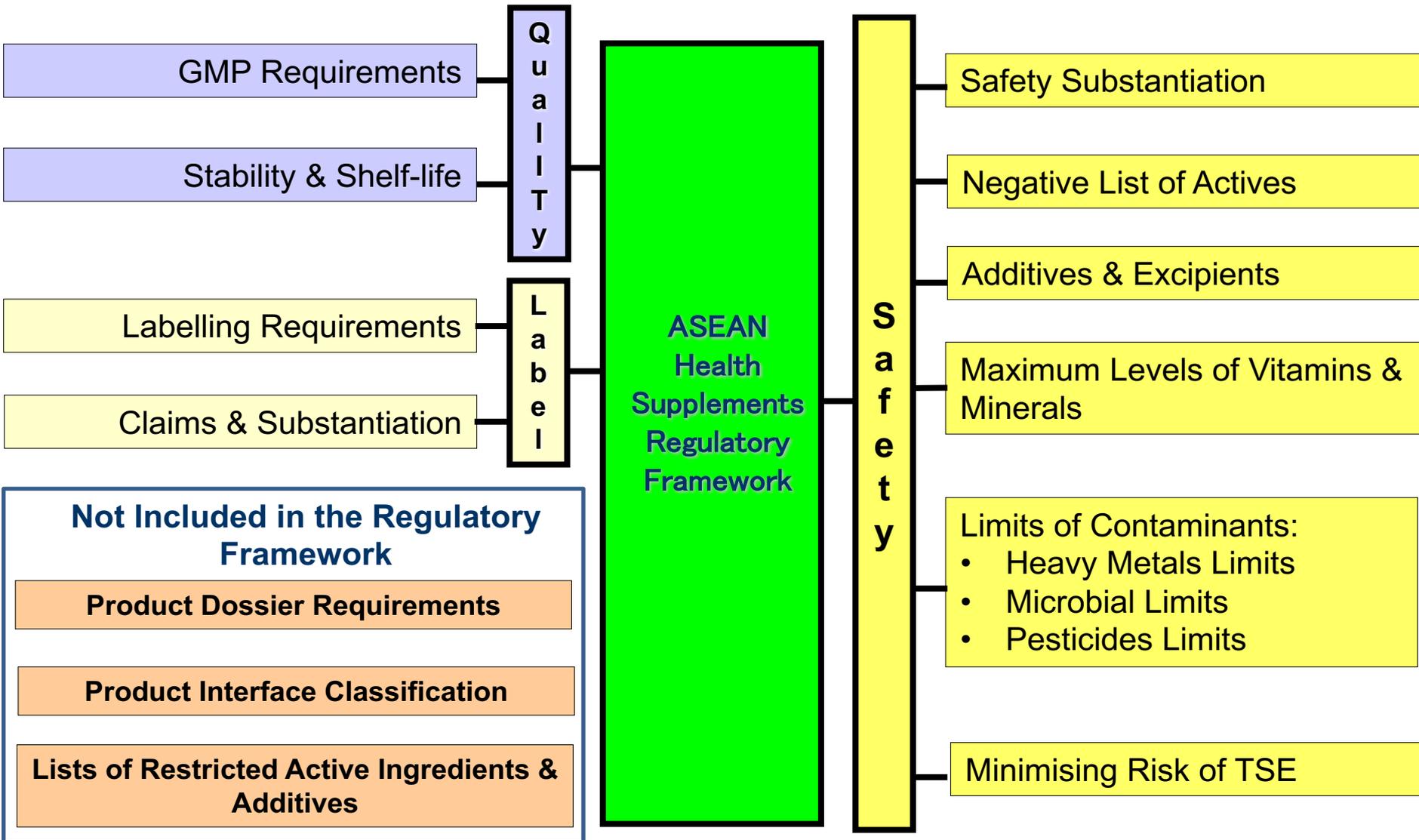


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# What are the standards and technical requirements for health supplements that will be harmonised in ASEAN?



# Key Phases of Harmonisation



Phase 1

- Finalisation of Agreement & Guidelines

Phase 2

- Final Endorsement by TMHS PWG

Phase 3

- Signing By AEM

Phase 4

- Ratification & Implementation

## Close to Competing Phase 2

- i. The TMHSPWG has agreed on the titles of the instruments: ***“ASEAN Agreement on Regulatory Framework for Traditional Medicines”*** and ***“ASEAN Agreement on Regulatory Framework for Health Supplements”***.
- ii. In order to clarify on the terms “Regulatory Framework” as used in the titles that the Agreements ***do not include the harmonisation of the regulatory regimes*** of TM and HS, a ***“Question and Answer (Q&A)”*** will be developed by TMHSPWG.

# Expected Timeline



- **August 2017** = Finalisation/Endorsement of the instrument by TMHS PWG (15 May 2017 Danang ; Vietnam)
- **August 2017** onwards = National approval procedures
- **May 2018** = Signing of the Agreement by AEMs
- **June 2018** = Enter into Force
- **June 2018 to June 2023** = Ratification, Transposition & Notification to ASEAN Secretariat
- **1 July 2023** = The Final Date for Implementation

# Some Countries Are Starting



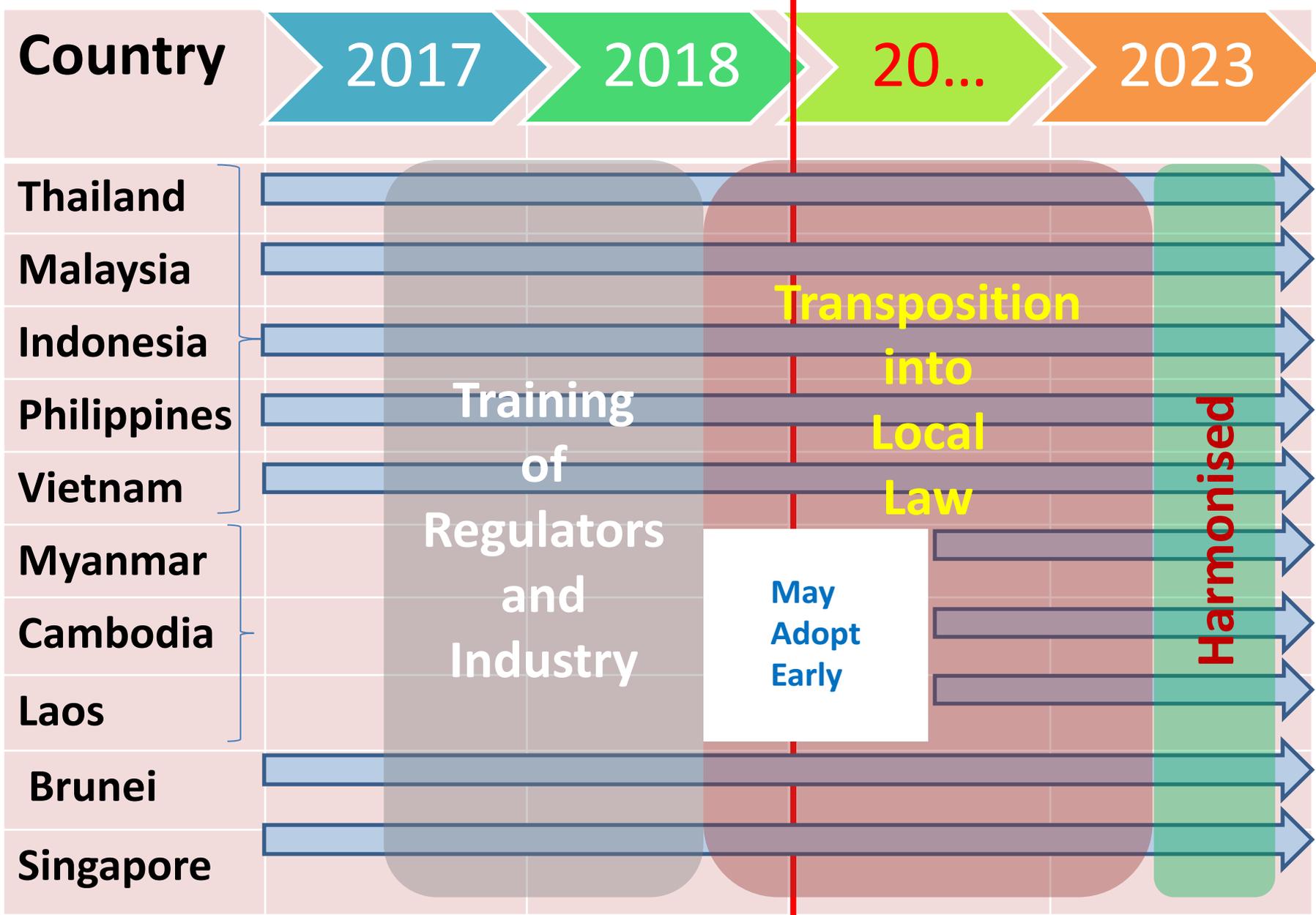
- Indonesia - GMP, Stability
- Malaysia - GMP, Stability
- Singapore - BSE
- Thailand - HS Max Levels, Claims

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- ASEAN HS Industry Overview
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# Framework Transposed in Respective Country By?



# Key Challenges in Preparation for Implementation



TRAINING

- Training Regulators & Industry

LEGAL

- Transposition into local law

TECHNICAL

- Capacity Building esp SMEs

SPECIFIC

- Reduce Country Specific Aspects

# Support For Implementation



- **Training for Regulators and Industry - major training programme is underway**
  - Stability study requirements training 4-6 October 2016
  - Safety Substantiation training 25-28 April 2017
  - GMP training 3-4 May 2017
- **Other activities will be launched if funding is available**
  - Claims Substantiation training
  - SMEs training and capacity building
- **Continued support for ASEAN harmonisation to 2018 and beyond**
  - IADSA strategic and scientific guidance/support for ASEAN TMHS Committee (ATMHSC)
  - Increased participation from National HS Associations and member companies
    - Target on minimising country specific requirements
    - Focus on consistency in guidelines applications
    - Tracking transposition to local law

# Training Started



Safety Substantiation Training for Regulators & Industry 25-28 April 2017 sponsored by US AID

# Training Started



GMP Training for Regulators & Industry 4-5 May 2017 sponsored by ASEAN Development Fund



# AEC Blueprint 2025



ASEAN Economic Community 2025				
A Highly Integrated and Cohesive Economy	A Competitive, Innovative, and Dynamic ASEAN	Enhanced Connectivity and Sectoral Cooperation	A Resilient, Inclusive and People-Oriented, People-Centred ASEAN	A Global ASEAN
<ul style="list-style-type: none"> <li>• Trade in Goods</li> </ul>	<ul style="list-style-type: none"> <li>• Effective Competition Policy</li> </ul>	<ul style="list-style-type: none"> <li>• Transport</li> </ul>	<ul style="list-style-type: none"> <li>• Strengthening the Role of Micro, Small, and Medium Enterprises</li> </ul>	<ul style="list-style-type: none"> <li>• More strategic and coherent approach towards external economic relations</li> </ul>
<ul style="list-style-type: none"> <li>• Trade in Services</li> </ul>	<ul style="list-style-type: none"> <li>• Consumer Protection</li> </ul>	<ul style="list-style-type: none"> <li>• Information and Communications Technology</li> </ul>	<ul style="list-style-type: none"> <li>• Strengthening the Role of the Private Sector</li> </ul>	<ul style="list-style-type: none"> <li>• Review existing FTAs</li> </ul>
<ul style="list-style-type: none"> <li>• Investment Environment</li> </ul>	<ul style="list-style-type: none"> <li>• Strengthening Intellectual Property Rights Cooperation</li> </ul>	<ul style="list-style-type: none"> <li>• E-commerce</li> </ul>	<ul style="list-style-type: none"> <li>• Public-Private Partnership</li> </ul>	<ul style="list-style-type: none"> <li>• Enhance economic partnerships with non-FTA Dialogue Partners by upgrading and strengthening trade and investment work programmes/plans</li> </ul>
<ul style="list-style-type: none"> <li>• Financial Integration, Financial Inclusion, and Financial Stability</li> </ul>	<ul style="list-style-type: none"> <li>• Productivity-Driven Growth, Innovation, Research and Development, and Technology Commercialisation</li> </ul>	<ul style="list-style-type: none"> <li>• Energy</li> </ul>	<ul style="list-style-type: none"> <li>• Narrowing the Development Gap</li> </ul>	<ul style="list-style-type: none"> <li>• Engage with regional and global partners</li> </ul>
<ul style="list-style-type: none"> <li>• Facilitating Movement of Skilled Labour and Business Visitors</li> </ul>	<ul style="list-style-type: none"> <li>• Taxation Cooperation</li> </ul>	<ul style="list-style-type: none"> <li>• Food, Agriculture, and Forestry</li> </ul>	<ul style="list-style-type: none"> <li>• Contribution of Stakeholders on Regional Integration Efforts</li> </ul>	<ul style="list-style-type: none"> <li>• Continue strongly supporting the multilateral trading system and actively participating in regional fora</li> </ul>
<ul style="list-style-type: none"> <li>• Enhancing Participation in Global Value Chains</li> </ul>	<ul style="list-style-type: none"> <li>• Good Governance</li> </ul>	<ul style="list-style-type: none"> <li>• Tourism</li> </ul>		<ul style="list-style-type: none"> <li>• Continue to promote engagement with global and regional institutions</li> </ul>
	<ul style="list-style-type: none"> <li>• Effective, Efficient, Coherent and Responsive Regulations, and Good Regulatory Practice</li> </ul>	<ul style="list-style-type: none"> <li>• Healthcare</li> </ul>		
	<ul style="list-style-type: none"> <li>• Sustainable Economic Development</li> </ul>	<ul style="list-style-type: none"> <li>• Minerals</li> </ul>		
	<ul style="list-style-type: none"> <li>• Global Megatrends and Emerging Trade-related Issues</li> </ul>	<ul style="list-style-type: none"> <li>• Science and Technology</li> </ul>		



**End of Presentation  
Thank You for  
Your Attention**