



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 **7th largest in the world** and the **3rd largest in Asia**

ASEAN Population

A Region Fully Integrated Community

In 2014, ASEAN was the **3rd 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**

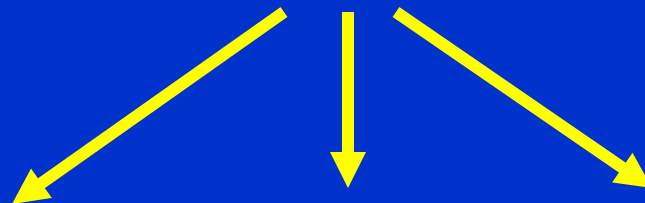
The rate of Internet subscription **more than doubled** from **11.8 per 100 inhabitants** in 2007 to **28.6** in 2014

<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

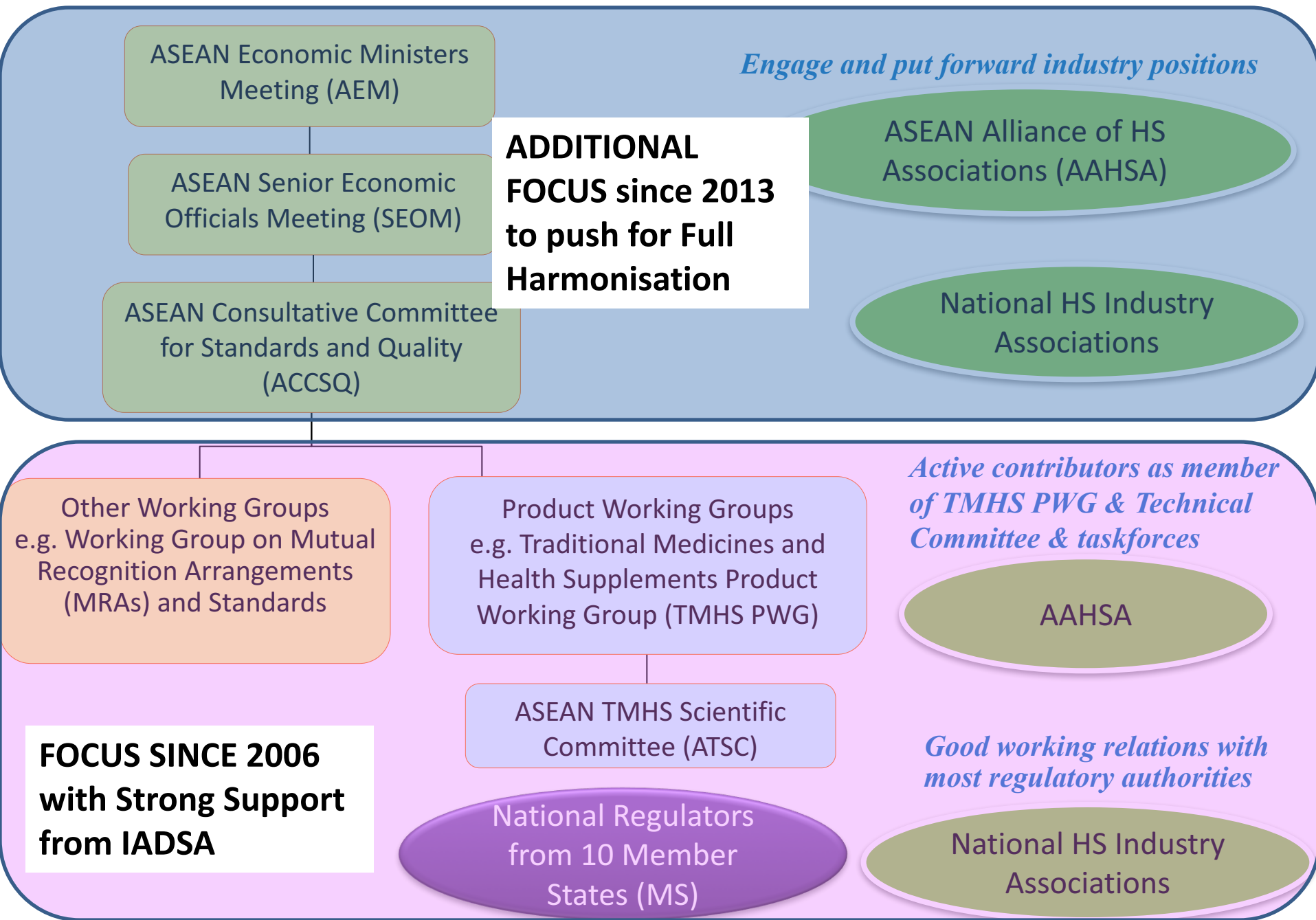
**ASEAN Consultative
Committee for Standards
and Quality**

Traditional **M**edicines /
Health **S**upplements
Product **W**orking **G**roup

ILLUSTRATIVE ASEAN ORGANIZATIONAL STRUCTURE



ASEAN TMHS Harmonization - multiple levels of work

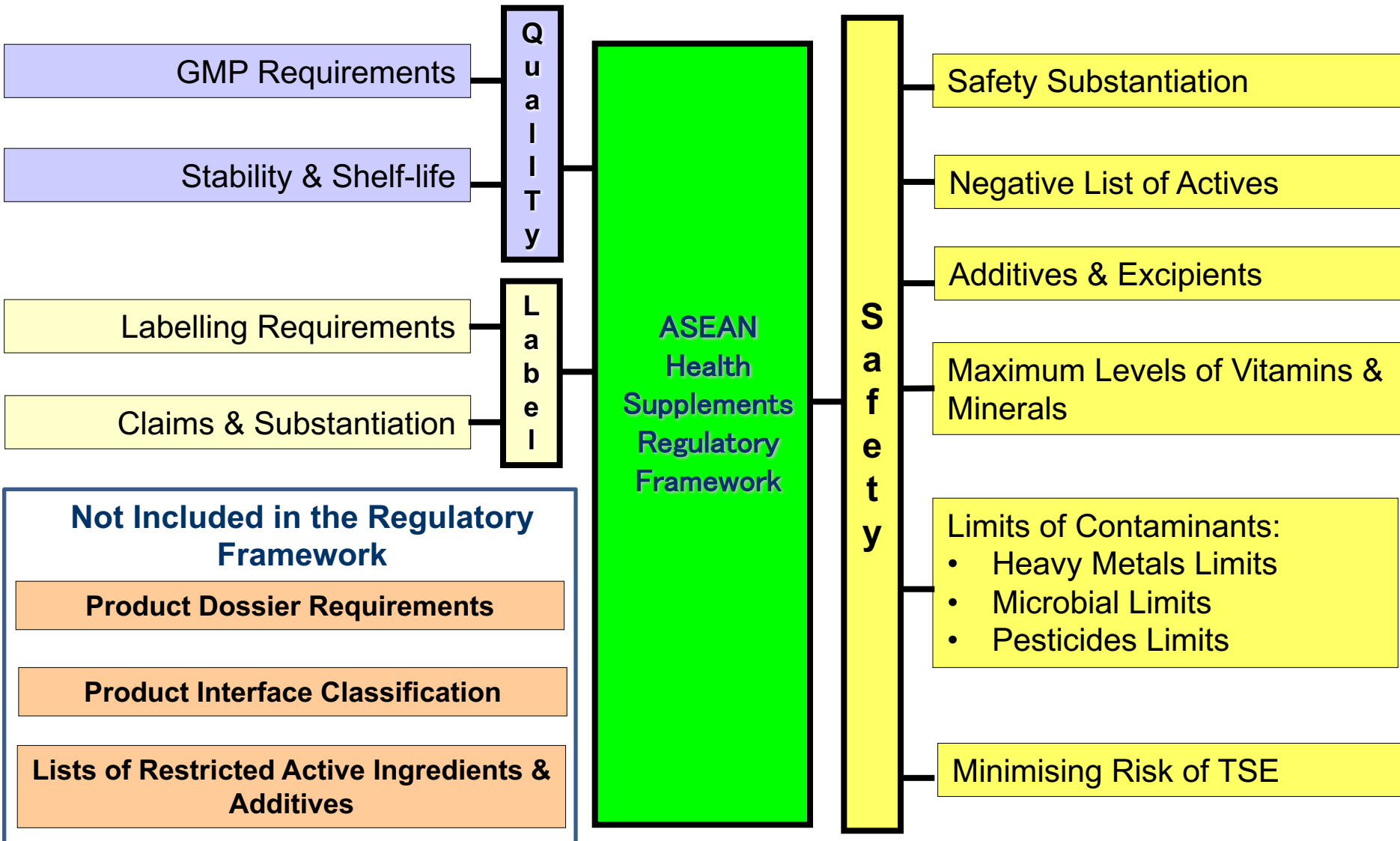


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What are the standards and technical requirements for health supplements that will be harmonised in ASEAN?



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



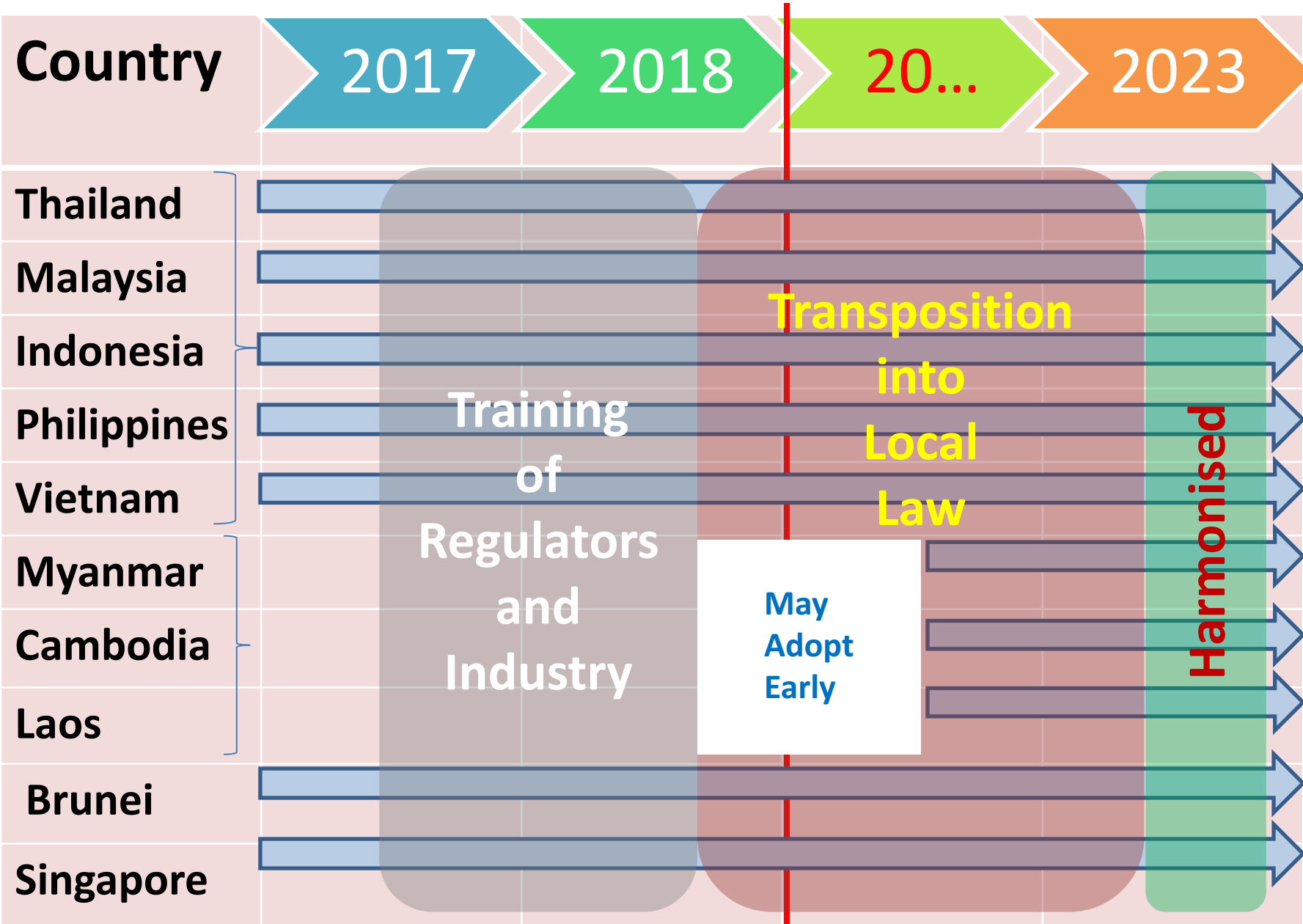
- Indonesia - GMP, Stability
- Malaysia - GMP, Stability
- Singapore - BSE
- Thailand - HS Max Levels, Claims

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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
• Trade in Goods	• Effective Competition Policy	• Transport	• Strengthening the Role of Micro, Small, and Medium Enterprises	• More strategic and coherent approach towards external economic relations
• Trade in Services	• Consumer Protection	• Information and Communications Technology	• Strengthening the Role of the Private Sector	• Review existing FTAs
• Investment Environment	• Strengthening Intellectual Property Rights Cooperation	• E-commerce	• Public-Private Partnership	• Enhance economic partnerships with non-FTA Dialogue Partners by upgrading and strengthening trade and investment work programmes/plans
• Financial Integration, Financial Inclusion, and Financial Stability	• Productivity-Driven Growth, Innovation, Research and Development, and Technology Commercialisation	• Energy	• Narrowing the Development Gap	• Engage with regional and global partners
• Facilitating Movement of Skilled Labour and Business Visitors	• Taxation Cooperation	• Food, Agriculture, and Forestry	• Contribution of Stakeholders on Regional Integration Efforts	• Continue strongly supporting the multilateral trading system and actively participating in regional fora
• Enhancing Participation in Global Value Chains	• Good Governance	• Tourism		• Continue to promote engagement with global and regional institutions
	• Effective, Efficient, Coherent and Responsive Regulations, and Good Regulatory Practice	• Healthcare		
	• Sustainable Economic Development	• Minerals		
	• Global Megatrends and Emerging Trade-related Issues	• Science and Technology		



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