

# ASEAN TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS REGULATORY AND HARMONIZATION UPDATE

Ornsurang Teerawat  
21.10.2014



**ACCSQ**  
(ASEAN Consultative Committee for Standard and Quality)

**Standards and Conformance**

**WG1**  
(Standards and MRA)

**WG2**  
(Accreditation and Conformity Assessment)

**WG3**  
(Legal Metrology)

**Product Working Groups**  
overseen by Thai FDA

**ACC**  
(ASEAN Cosmetic Committee)

**PPWG**  
(Pharmaceutical Product Working Group)

**MDPWG**  
(Medical Device PWG)

**PFPWG**  
(Prepared Foodstuff PWG)

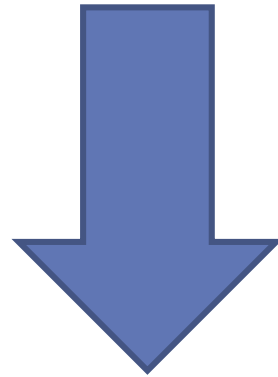
**TMHSPWG**  
(Traditional Medicine and Health Supplements PWG)

# Content

- SEAN Agreement on Traditional Medicines and Health Supplements (TMHS)
- Technical Requirements for Traditional Medicines and Health Supplements (TMHS)
- Procedure towards the Signing of the ASEAN Agreement on TMHS

# ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

ASEAN Agreement on Traditional Medicines and Health Supplements



**ASEAN Agreement  
on Traditional  
Medicines**

**ASEAN Agreement  
on Health  
Supplements**

# ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

Each of Agreements consists of 14 Articles:

ARTICLE 1: Objectives

ARTICLE 2: Definition and Scope of TM/HS\*

ARTICLE 3: General Provisions

ARTICLE 4: Safety, Quality, Efficacy/Claimed benefits and labelling requirements\*

ARTICLE 5: Product Placement

ARTICLE 6: Post Marketing Surveillance

ARTICLE 7: Institutional Arrangements

ARTICLE 8: Special Cases

ARTICLE 9: Implementation

ARTICLE 10: Dispute Settlement

ARTICLE 11: Annexes

ARTICLE 12: Revisions, Modifications and Amendments

ARTICLE 13: Entry into Force

ARTICLE 14: Depository

**Note - \* Both agreements are similar, except Article 2 4 and 11**

# ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

## ARTICLE 1: OBJECTIVES

The objectives of the ASEAN Agreement on TM/HS are:

- a) To enhance cooperation amongst Member States in ensuring the safety, quality and efficacy/claimed benefits of Traditional Medicines marketed in ASEAN region; and,
- b) To facilitate trade of TM/HS through the harmonized technical requirements and guidelines without compromising the safety, quality and efficacy/claimed benefits of these products.

# ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

## ARTICLE 2

### DEFINITION AND SCOPE OF TRADITIONAL MEDICINES

**“Traditional medicines”** mean any medicinal product for human use consisting of active ingredients derived from natural sources (plants, animals and/or minerals) used in the system of traditional practice. It shall not include any sterile preparation, vaccines, any substance derived from human parts, any isolated and characterized chemical substances.

# ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

## ARTICLE 2

### DEFINITION AND SCOPE OF HEALTH SUPPLEMENTS

**“Health Supplements”** mean any product that is used to supplement a diet and to maintain, enhance and improve the healthy function of human body and contains one or more, or a combination of the following:

- a) Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances.
- b) Substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolites.
- c) Synthetic sources of ingredients mentioned in (a) and (b).

It is presented in dosage forms (to be administered) in small unit doses such as capsules, tablets, powder, liquids and it shall not include any sterile preparations (i.e. injectable, eyedrops).



# ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

## **ARTICLE 3 GENERAL PROVISIONS**

Member States shall undertake the necessary measures to ensure that TM/HS which conform to the provisions of this Agreement and its Annexes may be placed on the market.

## **ARTICLE 4 SAFETY, QUALITY, EFFICACY/CLAIMED BENEFITS AND LABELLING REQUIRMENTS**

1. TM/HS placed on the market must not be harmful to human health when consumed or applied.
2. TM/HS shall comply with the conditions set out in the Annexes to the Agreement, as may be applicable.

# ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)

## ARTICLE 14 DEPOSITORY

1. This Agreement shall be signed by all Member States and shall be subject to notification, ratification and/or acceptance by all Member States in accordance with their respective internal requirements necessary for its entry into force.
2. This Agreement shall enter into force on the thirtieth day following the date of deposit of tenth instrument of notification, ratification and/or acceptance with the Secretary-General of ASEAN, which shall be done **no later than 1 December 2020**.
3. ....

# Content

- ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)
- Technical Requirements for traditional medicines and health supplements (TMHS)
- Procedure towards the Signing of the ASEAN Agreement on TMHS

# Technical Requirements for Traditional Medicines and Health Supplements (TMHS)

Technical requirements	Status
<p><b>1. ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Traditional Medicines and Health Supplements</b></p> <p>A list of active substances that all MS are prohibited from being used in or being part of the composition of TMHS products (39 items for TM and 76 items for HS)</p>	<b>Adopted</b>
<p><b>2. ASEAN Guiding Principles for the Use of Additives and Excipients in Traditional Medicines and Health Supplements</b></p> <p>Restricted and prohibited additives and excipients intended for use in TMHS, excluding flavoring agents.</p>	<b>Adopted</b>
<p><b>3. ASEAN Guidelines on Limits of Contaminants for Traditional Medicines and Health Supplements</b></p> <p>Provide specifications on the limits of heavy metals and microbial contaminants and guidance notes on the control of pesticides for TMHS</p> <ul style="list-style-type: none"><li>- Heavy metal: Lead <math>\leq 10</math> ppm, Arsenic <math>\leq 5.0</math>ppm, Mercury <math>\leq 0.5</math> ppm, Cadmium <math>\leq 0.3</math>ppm</li><li>- Microbial limit: use BP as a reference except Indonesia (WHO)</li></ul>	<b>Adopted pending Vietnam</b>

# Technical requirements for Traditional Medicines and Health Supplements (TMHS)

Technical requirements	Status
<p><b>4. ASEAN Guidelines for Minimising the Risk of Transmission of Transmissible Spongiform Encephalopathies in Traditional Medicines and Health Supplements</b></p> <p>Purpose: To minimise the risk of Transmissible Spongiform Encephalopathy (TSE) in TMHS.</p>	<b>Adopted</b>
<p><b>5. ASEAN Guidelines on Stability and Shelf-Life of Traditional Medicines and Health Supplements</b></p> <p>-Provide recommendations for conducting a stability study on TMHS and its shelf-life.</p>	<b>Adopted</b>
<p><b>6. ASEAN Guiding Principles on Safety Substantiation for Traditional Medicines and Health Supplements</b></p> <p>- Provide the safety data substantiation criteria.</p>	<b>Adopted pending Vietnam</b>

# Technical Requirements for Traditional Medicines and Health Supplements (TMHS)

Technical requirements	Status
<p><b>7. ASEAN Guidelines on Claims and Claims Substantiation for Traditional Medicines and Health Supplements</b></p> <p>Provide guidance on making unbiased and truthful claims, supported by adequate evidence in order to protect the consumers from misleading claims.</p> <ul style="list-style-type: none"><li>- Types of TM claims:<ul style="list-style-type: none"><li>• Traditional Health Use Claims</li><li>• Traditional Treatment Claims</li><li>• Scientifically Established Treatment Claims</li></ul></li><li>- Types of HS claims:<ul style="list-style-type: none"><li>• General or Nutritional Claims</li><li>• Functional Claims</li><li>• Disease Risk Reduction Claims</li></ul></li></ul> <p>This guideline also define the requirement for efficacy data submission for TM and HS claims.</p>	<p><b>Adopted</b></p>

# Technical Requirements for Traditional Medicines and Health Supplements (TMHS)

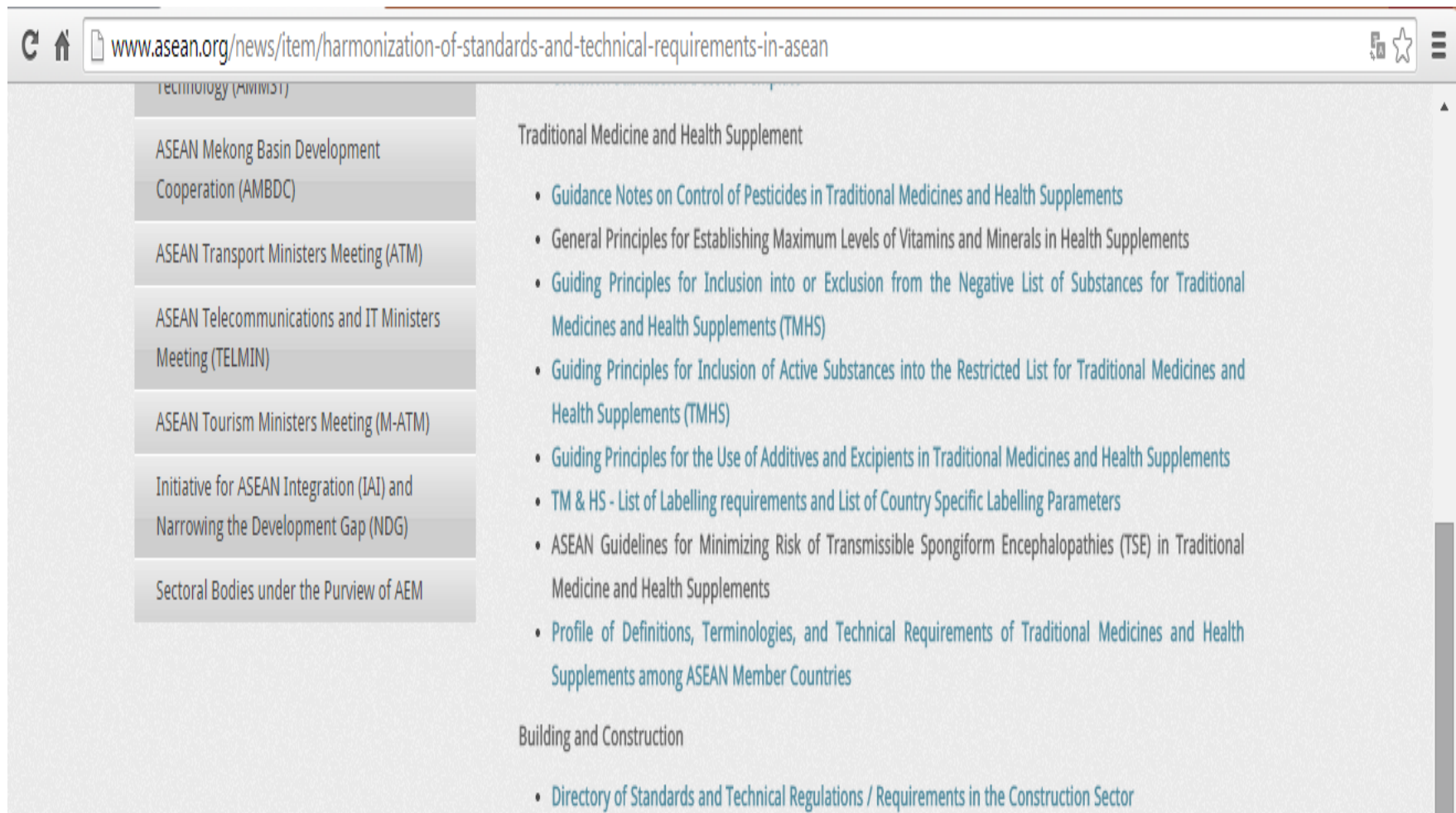
Technical requirements	Status
<p><b>8. ASEAN Guidelines on Good Manufacturing Practice for Traditional Medicines and Health Supplements</b></p> <p>The ASEAN Guideline on GMP for TMHS is applicable to both TM and HS - ASEAN Member States who are PIC/S members will accept the ASEAN Guideline on GMP for TMHS or equivalent guidelines for product placement.</p>	<b>Adopted pending Vietnam</b>
<p><b>9. ASEAN Guidelines on Labelling Requirements for Traditional Medicines and Health Supplements</b></p> <p>- provide the information that shall appear on the label of TMHS product, for example, product name, name and strength of active ingredient etc., and should be English and/or official/national language</p>	<b>Adopted</b>
<p><b>10. ASEAN General Principles for Establishing Maximum Levels of Vitamins and Minerals in Health Supplements</b></p> <p>- provide the maximum daily intake levels of vitamins and minerals in health supplements for ASEAN.</p>	<b>Adopted</b>

# Technical Requirements for Traditional Medicines and Health Supplements (TMHS)

Technical requirements	Status
<p><b>11. List of restricted active ingredients</b></p> <ul style="list-style-type: none"><li>- Contains active substances which are subject to specific restrictions for use in at least one of the ASEAN Member States.</li><li>- Serves as a reference document for regulatory authorities and TMHS industry without legal binding among ASEAN Member States.</li><li>- For example, <i>Actaea racemosa</i>, <i>Berberis</i> sp.</li></ul>	<p><b>Pending information from Member States</b></p>
<p><b>12. Product Dossier Submission</b></p>	<p><b>Further discussed in the next ATSC Meeting</b></p>



# <http://www.asean.org/news/item/harmonization-of-standards-and-technical-requirements-in-asean>



The image shows a screenshot of a web browser displaying the URL [www.asean.org/news/item/harmonization-of-standards-and-technical-requirements-in-asean](http://www.asean.org/news/item/harmonization-of-standards-and-technical-requirements-in-asean). The browser's address bar includes navigation icons (back, forward, home) and utility icons (refresh, star, menu). A sidebar menu on the left lists various ASEAN initiatives and meetings, including:

- Technology (AMMST)
- ASEAN Mekong Basin Development Cooperation (AMBDC)
- ASEAN Transport Ministers Meeting (ATM)
- ASEAN Telecommunications and IT Ministers Meeting (TELMIN)
- ASEAN Tourism Ministers Meeting (M-ATM)
- Initiative for ASEAN Integration (IAI) and Narrowing the Development Gap (NDG)
- Sectoral Bodies under the Purview of AEM

The main content area displays the following sections and links:

### Traditional Medicine and Health Supplement

- [Guidance Notes on Control of Pesticides in Traditional Medicines and Health Supplements](#)
- [General Principles for Establishing Maximum Levels of Vitamins and Minerals in Health Supplements](#)
- [Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Traditional Medicines and Health Supplements \(TMHS\)](#)
- [Guiding Principles for Inclusion of Active Substances into the Restricted List for Traditional Medicines and Health Supplements \(TMHS\)](#)
- [Guiding Principles for the Use of Additives and Excipients in Traditional Medicines and Health Supplements](#)
- [TM & HS - List of Labelling requirements and List of Country Specific Labelling Parameters](#)
- [ASEAN Guidelines for Minimizing Risk of Transmissible Spongiform Encephalopathies \(TSE\) in Traditional Medicine and Health Supplements](#)
- [Profile of Definitions, Terminologies, and Technical Requirements of Traditional Medicines and Health Supplements among ASEAN Member Countries](#)

### Building and Construction

- [Directory of Standards and Technical Regulations / Requirements in the Construction Sector](#)

# Content

- ASEAN Agreement on Traditional Medicines and Health Supplements (TMHS)
- Technical Requirements for traditional medicines and health supplements (TMHS)
- **Procedure towards the Signing of the ASEAN Agreement on TMHS**

# ASEAN Regulatory Framework for TMHS

Activities	2014	31/12/2015	2016	2017	2018	2019	2020	01/01/2021
<ul style="list-style-type: none"> <li>• Finalisation of the Agreement</li> <li>• Endorsement by TMHS PWG</li> <li>• National consultation</li> </ul>								
<ul style="list-style-type: none"> <li>• Legal Scrubbing</li> <li>• Finalisation and endorsement of the Agreement</li> <li>• National approval procedures, as required</li> <li>• Endorsement by ACCSQ and SEOM</li> <li>• Signing by AEM</li> </ul>								
<ul style="list-style-type: none"> <li>• Deposit instruments of ratification/ notification to the ASEAN Secretariat</li> </ul>								
<ul style="list-style-type: none"> <li>• Implementation at regional level</li> </ul>								

# Procedure toward the Signing of the ASEAN Agreement on TMHS

## The Constitution of the Kingdom of Thailand (Interim), B.E. 2557 (2014)

*“A treaty which provides for a change of the territories of Thailand or the external territories that Thailand has sovereign rights or jurisdiction thereon under any treaty or an international law, or requires an enactment of an Act for its implementation or has wide scale effects on economic or social security of the country, shall be approved by the National Legislative Assembly. In this case, the National Legislative Assembly shall complete its deliberation within sixty days as from the date of receipt of such matter.*

*The treaty with wide scale effects on economic or social security of the country under paragraph two means a treaty related to free trade or customs cooperation area, to the use of natural resources, to waive the rights in any natural resources of the country, wholly or partly, or other matters as prescribed by law.”*



**This Agreements shall be approved by Cabinet and the National Legislative Assembly, respectively before implementation.**

## Government sector should do....

- Compare and update rules and regulations to comply with the ASEAN requirements and guidelines, concerning the safety of consumers
- Promote entrepreneurs in the country, particularly SMEs to be ready for the ASEAN Economic Community by disseminating information to have a better understanding and recognizing the importance of adaptation as well as developing the capacity and capability to comply with the regulations.
- Provide necessary measures or ways to promote and help the SMEs in order to improve, develop and enhance the standards of production in accordance with the ASEAN requirements as well as international standards.

# Thank you for your attention

