Association of South East Asian Nations (ASEAN)

ANNEX VII
ASEAN GUIDELINES ON CLAIMS AND CLAIMS SUBSTANTIATION FOR HEALTH SUPPLEMENTS

Disclaimer:

This document is provided for information purpose only and subject to changes, pending the finalisation of the ASEAN Agreement on Regulatory Framework for Health Supplements. Official references to this document can only be made once the said Agreement has been finalised.

Version 2.0

DOCUMENT INFORMATION

This version is adopted at the 22nd ACCSQ TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS SCIENTIFIC COMMITTEE MEETING (ATSC) 3-6 March 2014, Kuala Lumpur, Malaysia and endorsed at the 21st ACCSQ TRADITIONAL MEDICINES AND HEALTH SUPPLEMENTS PRODUCT WORKING GROUP (TMHSPWG) MEETING 27-28 June 2014, Siem Reap, Cambodia.

Version no.	History of adoption and endorsement		Reason for revision
	ATSC adoption date	TMHSPWG Endorsement	
1	22nd ATSC 3-6 March 2014	21st TMHSPWG MEETING 27-28 June 2014	-
2	27th ATSC 1-2 June 2015	23rd TMHSPWG Meeting 4-5 June 2015	Separation of the Guideline for TM and HS

CONTENTS

1. INTRODUCTION

The ASEAN Guidelines on Claims and Claims Substantiation for Health Supplements (HS) is developed by taking into consideration similar guidelines that exist internationally (WHO, CODEX, EU, US, Canada, Australia) and the regulatory situation and stakeholders' interests in the ASEAN region.

The HS claims refer to any message that states, suggests, or implies that a HS ingredient/product has positive contribution and benefit to human health. A balanced approach between consumer protection and encouraging science and innovation is important in implementing the harmonised ASEAN Guidelines on Claims and Claims Substantiation for Health Supplements.

It should also be underlined that this document deals with the guidance of allowable claims and their corresponding levels of literature and scientific substantiation. Certain HS claims need to be substantiated by efficacy data, and these data requirements are defined in the guidelines.

2. OBJECTIVE

This document aims to provide guidance on making unbiased and truthful claims, supported by adequate evidence in order to protect the consumers from misleading claims. This will enable consumers to make informed choices in taking care of their health. Furthermore, this document will facilitate the product placement of HS products and set up requirements for efficacy data submission for certain HS claims.

3. KEY PRINCIPLES OF ASEAN HS CLAIMS AND CLAIMS SUBSTANTIATION

All claims made for HS should:

- Be consistent with the ASEAN definition of HS
- Support the safe, beneficial and appropriate use of the products
- Maintain the level documented usage and/or scientific evidence which is proportionate to the type of claim

- Meet the dosing recommendations stated in the evidence or references for the claimed intended effects, unless otherwise justified
- Not be misleading or false
- Enable consumers to make an informed choice regarding products
- Be for health maintenance and promotion purpose
- Not be medicinal or therapeutic in nature, such as implied for treatment, cure or prevention of diseases
- Be substantiated by good quality evidence that is relevant to the claim

The claimed benefit/efficacy of a product and/or its ingredient(s) shall be based on the totality of the substantiation evidence provided including human, non-clinical and empirical or historical data, as well as other documented evidence, where applicable. Please refer to Table 2.

4. GUIDANCE FOR HS CLAIMS SUBSTANTIATION

HS claims refer to the beneficial effects of consuming HS to promote good health by providing nutrition, enhancing body structure/ function, improving a function, enhancing or preserving health and/or reducing the risk of health related conditions or diseases.

4.1. Types of HS claims

The 3 types of HS claims are stated in Table 1.

- General or Nutritional Claims
- Functional Claims
- Disease Risk Reduction Claims

Functional Claims and Disease Risk Reduction Claims shall be substantiated by the proportional degree of data from efficacy studies and relevant documentation.

Table 1. Scope and examples of the 3 types of HS claims

Type of HS claim	**Scope**	**Examples to illustrate the scope - as determined by the regulatory authority of each Member State**
General or Nutritional	For Nutritional Support and General Health Maintenance. Benefits derived from supplementation beyond a person's daily dietary intake.	• Supplements nutrition • Supports healthy growth and development • Nourishes the body • Relieves general tiredness, weakness • Helps to maintain good health
Functional	Relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health in the context of the total diet on normal functions or biological activities of the body. Maintains or enhances structure or function of the body, excluding disease related claims. Supports health and to relieve/reduce/ lessen/ease minor body discomforts in some physiological processes (e.g. ageing, menopause, pregnancy)*. **as determined by the regulatory authority of each Member State*	• Maintains/Supports healthy joints • Maintains/Supports immunity • Maintains healthy liver function • Maintains/Supports alertness • Maintains/Supports mental performance • Promotes healthy skin • Helps to relieve post-menopausal discomforts • Aids in digestion to relieve indigestion • Bifidobacteria in product A helps to improve slow transit system in 14 days • Supports health in ageing • Supports health in menopause • Supports health in pregnancy
Disease Risk Reduction	Significantly altering or reducing a risk factor of a disease or health related condition*. **as determined by the regulatory authority of each Member State*	• Helps to reduce risk of osteoporosis by strengthening bone • Helps to reduce the risk of dyslipidaemia

4.2. Principles of HS Claims Substantiation

The type of claim must be substantiated by an adequate level of evidence. The major principles of HS claim substantiation are:

Proportional degree of supporting evidence corresponding to the type of HS claims

The Principle of proportional degree of supporting evidence is illustrated in Table 2. When applying the substantiation requirement stated in Table 2, the evidence for Functional Claim is stronger than General or Nutritional Claim. In turn the Disease Risk Reduction Claims will require proportionally stronger scientific support than Functional Claims.

Totality of scientific evidence that demonstrates the beneficial effect

The totality (balance and range) of the evidence to the HS claims are important. Due consideration should be given to all relevant scientific evidence relating to the claimed benefit of the product or ingredient and should not focus only on evidence that supports the effect. In proportion to the type of claims, scientific substantiation should demonstrate a consistent beneficial effect of the ingredient (or product) on specific health aspects or generally recognised biomarkers based on totality of scientific evidence encompassing human studies (observation and intervention), authoritative references, recommendations from international or authoritative bodies, scientific reviews, animal and in-vitro studies.

HS claim substantiation shall be based on finished product, or ingredient(s) with justification as required by the regulatory authority (e.g. rationale of the combination)

4.3. Substantiation of HS Claims

The substantiation of HS claims shall follow Table 2 to reflect the proportional degree of supporting evidence. It is the responsibility of the company to provide the required evidence in order to comply with the criteria to make HS Claims.

For Functional and Disease Risk Reduction Claims, a summary of the scientific evidence including published and unpublished studies should be submitted. In addition, summary of empirical or historical data shall be submitted. Raw data should be submitted when required by the regulatory authority.

Efficacy data to support Disease Risk Reduction Claim shall be generated from studies on the finished product, or ingredient(s), with justification as required by the regulatory authority. Efficacy data should be obtained from human studies; this may be supplemented by data from non-clinical studies.

Human studies

Scientific data could be derived from observational or intervention human studies, that are well designed in accordance with recognized scientific principles, with statistically and clinically significant outcomes, if applicable, addressing the specific HS claim. The acceptable principles for human studies can be referred to internationally accepted guidelines, for example, ICH-GCP Guidelines.

Non-clinical (animal and in vitro) studies

In vitro studies as well as animal studies are intended to generate the non-clinical data. Data from animal study should be derived from animal model which can represent human condition related to claim. The methodology should be an acceptable and valid procedure to measure the parameter. Data from animal studies are important to give the preliminary efficacy data prior to the conduct of human study. When animal and in vitro studies are submitted as substantiation of claims, mechanisms of actions to explain how the ingredient/product confers beneficial effect on health and explanation on the relevance of its findings to human should be included.

Summary of total available scientific data

The total available published and/or unpublished scientific data should be summarized as part of the substantiation documentation. It should contain the following information:

a) Product/Ingredient Studied
b) Intended Use
c) Type of Claim
d) Dosage and Administration
e) Type of Study (example, Human or Animal)
f) Study Design (example, Observation or Experimental)
g) Study population
h) Duration of the Study

i) Study End points

j) Limitation of the Study

k) Study Results

l) Source of Evidence

- i. Author
- ii. Title
- iii. Publication Details (year)
- iv. Type

m) Other information, if any

- i. Ethics Committee approval

For Functional and Disease Risk Reduction Claims, a company who wishes to use the same approved claim for a similar product should provide adequate scientific evidence/data to ensure adequate substantiation.

Table 2. Degree of evidence required to support different types of HS claims

Type of HS claim	Level of evidence	Criteria for Well-documented HS Claims	Evidence to substantiate HS Claims
General or Nutritional	General	- The claim is related to human health in line with scientific or traditional knowledge - Documented in authoritative reference texts - Recognised by reputable or international organisations or regulatory authorities - Claim is not referring to structure and function of body - Adheres to the key principles of ASEAN HS claims - For a HS product making nutritional claim based on vitamin and/or mineral, it is recommended to contain a minimum of 15% Codex NRV (Nutrient Reference Value) per daily dose of the vitamin and/or mineral to qualify it being the source of that vitamin or mineral or as determined by regulatory authorities	**At least 1 of the following evidence (as determined by the regulatory authority of each Member State):** • **Authoritative reference texts e.g. reference textbooks, pharmacopoeia, monographs and scientific journals** • **Scientific opinion from scientific organizations** • **Scientific opinion from regulatory authorities** • **Documented history of use e.g. classical texts, published document from scholar or expert that reports the traditional use of the ingredient concerned**
Functional	Medium	- Functional claim is in line with established knowledge on nutrition and physiology - Documented in authoritative reference texts - Recognised by reputable or international organisations or regulatory authorities - Adheres to the key principles of ASEAN HS claims - For a HS product making functional claim based on vitamin and/or mineral, it is recommended to contain a minimum of 15% Codex NRV (Nutrient Reference Value) per daily dose of the vitamin and/or mineral to qualify it being the source of	**At least 1 compulsory evidence** (as determined by the regulatory authority of each Member State)**:** • Good quality scientific evidence from human studies (only in the event that human experimental study is not ethical, animal studies shall only be acceptable together with

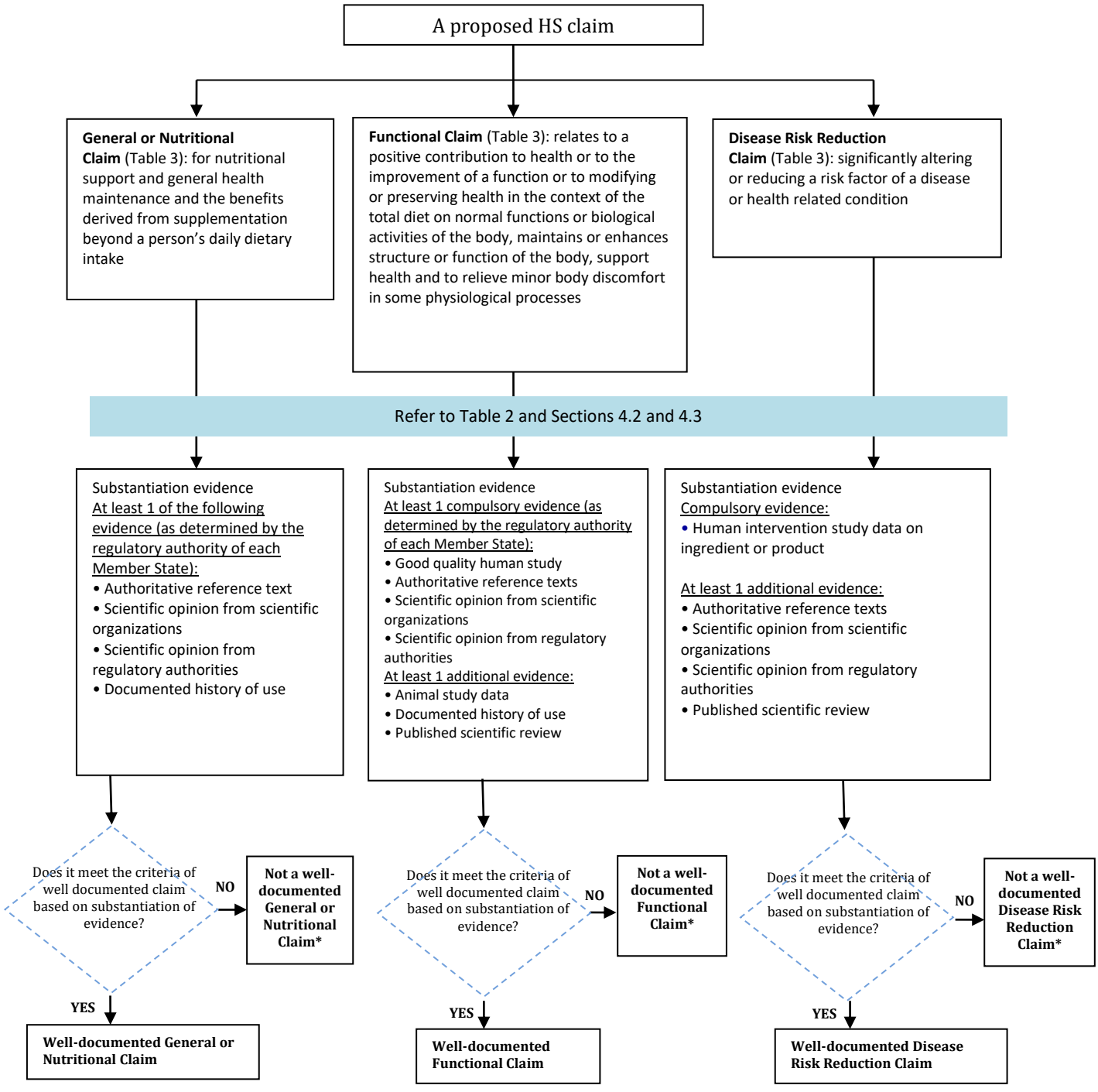
Type of HS claim	Level of evidence	Criteria for Well-documented HS Claims	Evidence to substantiate HS Claims
		that vitamin or mineral or as determined by regulatory authorities	epidemiological studies or other scientific literature and documented traditional use). In case the end point of a human study is not feasible, a surrogate end point can be used. • Authoritative reference texts e.g. reference textbooks, pharmacopoeias, monographs • Scientific opinion from scientific organizations • Scientific opinion from regulatory authorities **At least 1 additional evidence:** • Scientific evidence from animal studies • Documented history of use (e.g. classical texts, published document from scholar or expert that reports the traditional use of the ingredient concerned) • Evidence from published scientific review Relevant company owned scientific data (published and unpublished) can be submitted, if

Type of HS claim	Level of evidence	Criteria for Well-documented HS Claims	Evidence to substantiate HS Claims
			available
Disease Risk Reduction	High	- The relationship between the HS ingredient or product and disease risk reduction is supported by consistent scientific evidence - Documented in authoritative reference texts - Recognised by reputable or international organisations or regulatory authorities - Adheres to the key principles of ASEAN HS claims - For a HS product making disease risk reduction claim based on ingredient, it must contain the amount of the active ingredient that has been shown to be effective in the substantiation data	**Compulsory evidence:** • Scientific evidence from human intervention study on ingredient or product **At least 1 additional evidence:** • Authoritative reference texts e.g., pharmacopoeia, monographs • Scientific opinion from scientific organizations • Scientific opinion from regulatory authorities • Evidence from published scientific reviews or meta-analysis Relevant company owned scientific data (published and unpublished) can be submitted, if available

Note: References that are used to substantiate a HS claim include ASEAN Member States' official pharmacopoeias and monographs.

Decision tree on the evidence required to support HS claims appears as Figure 2. Please note that Figure 1 below should be read in conjunction with the details in Table 2 for full information.

Figure 1: Decision tree on the evidence required to support the different types of HS claims



4.4. Languages and Wordings Used for HS Claims

Appropriate language and wordings must be used to convey the HS claims with a meaning that is proportional to the level of scientific substantiation. Language and words used in HS claims should provide a truthful and non-misleading message on the beneficial effect of the ingredient/product.

4.5. Prohibited HS Claims

HS claims are not allowed to imply treatment, cure or prevention of all diseases or medical conditions. For disease risk reduction claims, diseases prohibited from associating with such claims shall be determined by the regulatory authority of each Member State.