



Association of South East Asian Nations (ASEAN)

ANNEX IX ASEAN GUIDELINES ON LABELLING REQUIREMENTS 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.



DOCUMENT INFORMATION

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INTRODUCTION

This guideline applies to health supplements to ensure the safe and effective use of health supplements among consumers and facilitate registration process among ASEAN member states. It also promotes proper storage and logistic condition.

DEFINITIONS

“Health Supplements” means 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, metabolite
- 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, liquid and it shall not include any sterile preparations (i.e. injectables, eye drops).

“Active ingredient” means a substance produces the intended activity of a health supplement.

“Batch or Lot number” means a designation (in numbers, or letters, or combination of both) that identifies the batch and that permits the complete history of the batch including all stages of production, control and distribution, to be traced and reviewed.

“Container” means an article that contains and protects the health supplement. This includes primary packaging components and/or secondary packaging components, if latter are intended to provide additional protection to the product. The packaging components shall be a blister pack, strip pack, bottle, sachet, tube, or other similar articles, but does not include an article intended for ingestion.



“Container Labelling / Labelling” means all information that appears on the container, including that on the outer packaging such as carton.

“Country’s registration / Listing / Notification number” means the combination of numbers, symbols and letters reflecting the identification of a health supplement assigned by the National Control / Regulatory Authority.

“Dosage form” means the usual product type of health supplement (e.g. tablet, capsule, solution, powder, etc.) that contains active ingredient(s) generally, but not necessarily, in association with excipients.

“Expiry date” means a date fixed for each individual batch before which the batch still meets the required standard specifications for quality.

“Manufacturing date / Date of Manufacture” means a date fixed for the individual batch, indicating the starting date of the manufacture.

“Manufacturer” means a company that carries out at least one step of production as well as the final release of the finished product.

“Marketing authorisation holder/MAH” means the company or corporate or legal entity in the field of health supplement in whose name the marketing authorisation has been granted. This party is responsible for all aspects of the product, including quality and compliance with the conditions of marketing authorisation. The authorised holder must be subjected to legislation in the country that issued the marketing authorisation, which normally means being physically located in that country.

“Package insert” means any printed information supplied with the container or primary pack.

“Small label” means a label with very limited space to display minimal information requirements in the small container as described in the General Labelling Requirements for health supplement. The dimension of small label shall be determined by each Member State.

“Strip / Blister pack label” means a label affixed to or printed on the strip or blister pack. The strip / blister pack needs to be repacked in another container or accompanied with a catch cover whose label can display information described in General labelling



requirements for health supplement so that consumers can obtain such information at the point of purchase.

“Intended use or indication” means a statement of the purpose or purposes for which health supplement is intended to be used.

GUIDING PRINCIPLES

1. Health supplements shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any aspect.
2. Health supplements shall not be described or presented on any label or in any labelling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product.
3. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed there on with clarity and conspicuousness and without obscuring design.
4. The label information should be English and/or official/national language(s) subject to the regulation of each Member State and be written clearly and easy to understand. Languages other than English may be included on labels with a required declaration to confirm that the meaning in the other languages is the same as that given in the English and/or official language(s).

Languages used for labelling in each Member State are as follows:

- In Brunei Darussalam, the official language is Bahasa Melayu or Malay language. Label information can appear in Malay language and/or English language. However in the event there is contradiction, the interpretation provided in the Malay language will prevail. Nevertheless the English language is still recognised in Brunei Darussalam as an authentic text.
- In Cambodia, the official language is Khmer. Label information should be in Khmer. However other language such as English and French may be used in addition to Khmer.



- In Indonesia, the official and national language is Indonesian language, therefore the language in the label must be written in Indonesian language. However other language may be used in addition to Indonesian language.
- In Lao PDR, the official language is Lao. Label information should be in Lao. However other language in smaller fonts, such as English, may be used.
- In Malaysia, the official language is Bahasa Malaysia however the label information can be in Bahasa Malaysia and/or English. Other languages, if any, may be used in addition to these two languages such as Mandarin, Tamil, Arabic.
- In Myanmar, the official language is Myanmar, therefore the language in the label will be Myanmar but other languages may be used such as English or Mandarin.
- In the Philippines, the official languages are Filipino and English. Label information should be in English and / or Filipino. Other languages, if any, may be used in addition to these two languages.
- In Singapore, the official languages are Malay, Chinese, Tamil and English. Label Information should be in English. Other languages, if any, may be used in addition to English."
- In Thailand, the official and national language is Thai, therefore the language in the label is Thai however other language may be used such as English.
- In Viet Nam, the official language is Vietnamese. Label information should be in Vietnamese. However, other language may be used in a font size not larger than Vietnamese.

GENERAL LABELLING REQUIREMENTS FOR HEALTH SUPPLEMENTS

The following information shall appear on the label of health supplements.

1. Product Name

The product name and the brand name, if applicable should not be misleading or deceptive to the consumer. The product and brand names should be deemed appropriate by the respective Member States.



2. Dosage Form

3. Name and Strength of Active ingredient

The name and quantity of plants or animals from which the active ingredient is derived should be declared in scientific name followed by plant part constituting the crude drug, and type of preparation where applicable. The use of the common / local name of the active ingredient is optional. For mineral, common / chemical name should be used.

For example:

- Each capsule contains: Curcuma longa (rhizome) 350 mg.
- Each capsule contains: Compound herbal extract 20 mg.
- Prepared from leaves of Plant A, Root of Plant B and leaves of Plant C

4. Batch or lot number

Each container shall be printed or permanently marked. The batch or lot number shall be preceded by title such as "Batch number", "BN" etc.

5. Manufacturing and expiry date, or expiry date only

The manufacturing date and expiry date, or expiry date only should be declared as month and year and preceded by title such as "Manufacturing date", "MFG" "Expiry date", "EXP" etc.

6. Directions of use

Directions of use must clearly state the route of administration as well as the dose for each target population for which the product is intended.

7. Indication or Intended use

The statement of the purpose or intention of use for health supplements should be declared according to the "ASEAN Guidelines on Claims and Claims Substantiation for Health Supplements".

8. Storage condition

The statement declares a condition to which the health supplements should be stored properly until the expiry date. Refer to "ASEAN Guidelines on Stability Study and Shelf-Life of Health Supplements".

9. Country's registration / listing / notification number (if applicable)



The combination of numbers, symbols and letters assigned to the health supplements which is approved by the National Regulatory Authority (NRA) shall be declared, if applicable.

10. Name and address of manufacturer

The complete name and address of the manufacturer of the product shall be declared.

11. Name and address of marketing authorisation holder/importer

The complete name and address of the marketing authorisation holder/importer of the product shall be declared.

12. Warning (if any)

The statement declares a warning for consumers' awareness before using health supplements. The warning statement assigned by the National Regulatory Authority (NRA) should be declared. The term "Warning" can be used interchangeably, but not limited to terms such as "Side Effects", "Contra-indications" and "Precautions" as appropriate.

13. Pack size

The net contents shall be declared in the metric system. The net contents shall be declared in the following manner:

- For liquid form, by volume;
- For solid form such as tablet, soft capsule, hard capsule, powder, etc. by weight or amount;
- For semi-solid or viscous form, either by weight or volume.

14. Special statements

- alcohol content, if any
- for external use, as applicable

SMALL LABEL

The small label should declare at least the following:

1. Product name and brand name, if applicable



2. Country's registration / listing / notification number (country specific)
3. Batch or lot number
4. Manufacturing and expiry date, or expiry date only
5. Other information according to general labelling requirements should be declared on package insert and / or another container or accompanied with a catch cover.

STRIP / BLISTER PACK LABEL

The label on strip / blister pack should declare at least the following:

1. Product name and brand name, if applicable
2. Country's registration / listing / notification number (country specific)
3. Batch or lot number
4. Manufacturing and expiry date, or expiry date only
5. Other information according to general labelling requirements should be declared on package insert and / or another container or accompanied with a catch cover.

COUNTRY SPECIFIC REQUIREMENTS FOR HEALTH SUPPLEMENTS

Country specific requirements are allowed if they are deemed necessary for the reasons of identification, safety, quality, culture and religion. However, minimization of country specific requirement should be encouraged. Such country specific requirements with reasons should however be made known to the other member states and be updated into the compilation of country specific requirement for health supplements from member states in a timely manner.

The compilation of country specific requirement for health supplements from member states appears in Appendix 1.



REFERENCES

1. *CODEX Alimentarius International Food Standards. General Standard for the Labelling of Prepackaged Foods. Labelling of Prepackage Food (CODEX STAN 1-1985) 2008:1-7.*
2. Therapeutic Goods Administration (TGA). Registration of Complementary Medicines. Australian Regulatory Guidelines for Complementary Medicines (ARGCM) 2005.
3. *Therapeutic Goods Administration (TGA). General requirements for labels for medicines Therapeutic Goods Act 1989: Therapeutic Goods Order No.69 2001.*
4. *EUROPEAN COMMISSION. Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use. Belgium: 2006.*
5. *ASEAN Guideline on Good Manufacturing Practice for Health Supplements.*



APPENDIX 1 COUNTRY SPECIFIC REQUIREMENTS FOR HEALTH SUPPLEMENTS

Country	Country Specific Requirements
Brunei Darussalam	Sources of ingredients from animal origin.
Cambodia	"Health supplements" / "Food supplements" / "Dietary supplements"
Indonesia	<p>"Health supplements" / "Food supplements" / "Dietary supplements"</p> <p>Statement on additive added (Preservative, colorant, flavour, sweetener)</p> <p>Note:</p> <ul style="list-style-type: none">- Act of the Consumer Protection, No.8 of 1999.- Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.23.3644 of 2004, on Principle of Food Supplement Control.- Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.41.1381 of 2005, on Regulation Guidelines of Food Supplement Control.- Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no.HK.00.05.52.4321 of 2004, on Regulation Guidelines of Food Supplement Control. <p>Source of ingredient derived from animal origin including gelatine.</p> <p>Note:</p> <ul style="list-style-type: none">- Act of the Consumer Protection, No.8 of 1999.- Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.23.3644 of 2004, on Principle of Food Supplement Control.- Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.41.1381 of 2005, on Regulation Guidelines of Food Supplement Control.- Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.52.4321 of 2004, on Regulation Guidelines of Food Supplement Control.



Country	Country Specific Requirements
	<p>Recommended daily allowance (RDA) for vitamins/minerals used as health supplements.</p> <p><i>Note:</i></p> <p>- Decree of The Head of National Agency of Drug and Food Control The Republic of Indonesia no. HK.00.05.52.6291 of 2007, on Nutrition Reference Values.</p>
Lao PDR	-
Malaysia	<p>Statement on additive added (Preservative, colorant, flavour, sweetener)</p> <p><i>Note: Name and content of preservative(s), where present</i></p>
	Hologram
	<p>Source of ingredient derived from animal origin including gelatine.</p> <p><i>Note : For product containing animal origin(s) (active, excipient and/or capsule shell), the source(s) need to be declared</i></p>
	The words “ Keep out of reach of children’ or words bearing similar meaning in both Bahasa Malaysia & English
	Use of the HALAL logo will be considered for health supplement for both the local and export market, provided that such products have been certified and approved as HALAL by the local authority.
Myanmar	Health supplements or alike
Philippines	“Food supplements” / “Dietary supplements”
	<p>Recommended daily allowance (RDA) for vitamins/minerals used as food/dietary supplements.</p> <p><i>Note: Revised standard terms as 2002 Recommended Energy and Nutrients Intakes (RENI) per day (adopted as per Bureau Circular No.16 s.2005)</i></p>
	<p>The caption “NO APPROVED THERAPEUTIC CLAIMS” shall be printed in the principal display panel of all labelling materials, font size 14, font type Arial, all capital and bold letters.</p> <p><i>Note: As per Bureau Circular No.2 s. 1999</i></p>



Country	Country Specific Requirements
	Allergen information, as applicable and Nutrition Information/Facts
	Expiry/Expiration Date – Day Month Year <i>Note: As per Administrative Order 2014-0030</i>
Singapore	-
Thailand	“Dietary supplements” <i>Note: Notification No.293 (2005 Re: Dietary Supplement)</i>
	Statement on additive added (Preservative, colorant, flavour, sweetener) <i>Note: Notification No.293 (2005 Re: Dietary Supplement)</i>
	“Not recommended to use in children or pregnancy.” <i>Note: Food and Drug Administration Notification entitled “Explanation of Ministry of Public Health Notifications No.293 (2005) entitled “Dietary Supplements” and No.294 (2005) entitled “Royal Jelly and Royal Jelly Products”</i>
	“Various food of 5 groups of nutrients should be taken regularly in appropriate proportion.” or similarly meaning statements. <i>Note: Notification No.309 (2007 Re: Dietary Supplement (No.2))</i>
	“No effect on prevention or treatment of diseases.” <i>Note: Notification No.309 (2007 Re: Dietary Supplement (No.2))</i>
Viet Nam	“Health supplements” / “Food supplements” / “Dietary supplements”
	Statement on additive added (Preservative, colorant, flavour, sweetener)