



Asia Innovation-Ready Food Regulatory Systems Initiative

Second Working Meeting

Advancing Collaborative Assessments, Regulatory Guidance and Innovation-Ready Food Regulatory Systems

Convened by GFORSS, in collaboration with



Non-Nutrients Health Claims in SEA – overview of current situation

E-Siong Tee

International Life Sciences Institute SEA Region

Nutrition Society of Malaysia

1. Regulatory status of health claims for non-nutrients (other function claims) in Southeast Asia What claims are already approved in the region
2. Regulatory framework for application for new other function claims
 - ❖ How can we approach in submitting a health claim
3. Sharing some resources by International Life Sciences Institute (ILSI SEA Region)
 - ❖ Publications on functional foods/bioactive components

Harmonisation of divergent regulations in SEA



- Efforts by International Life Sciences Institute (ILSI) SEA Region to **promote harmonize nutrition labelling and claims regulations** in the for the past 20 years
 - ❖ Series of **12 seminars and workshops** from 2001
 - ❖ Attended by **regulatory officials from ASEAN member states academia, industry experts**
 - ❖ **Discussed harmonisation of nutrition labelling regulations and health claims**
 - ❖ **13th seminar and workshop on 23-24 September 2025, in Kuala Lumpur**



Regulatory status of **other function claims*** for non-nutritional substances in 6 SEA countries

Country	Other function claims	
	<i>Regulation or guideline</i>	<i>Positive list</i>
Indonesia	Yes, Regulation Number 1/2022**	Yes, claims for 5 groups of non-nutritional substances, eg fibre, isomaltulose, phytosterols
Malaysia	Yes, Regulation 18F, 2020. Food Regulations Malaysia 1985	Yes, 43 other function claims for 22 “other food components” (non-nutrients), eg beta-glucan, GOS, FOS, soy protein, physterols
Philippines	No, Follow Codex Guideline	Positive list being developed
Singapore	Yes, A Guide to Nutrition Labelling for Food Products, Health Promotion Board, 2024	Yes, 17 other function claims for 12 “other food components” (non-nutrients), chromium, collagen, DHA & ARA
Thailand	Yes, Notification of Min of Public Health #447 B.E. 2566 (2023); Public Manual 2020	Yes, 6 categories of nutrients/other components and dietary conditions, eg beta-glucan, phytosterols, choline, DHA and 8 statements permitted
Vietnam	No, Follow Codex Guideline	no positive list

**The other function claims in this table are according to the definition of Codex Alimentarius Guidelines (CAC-GL 23-1997)*

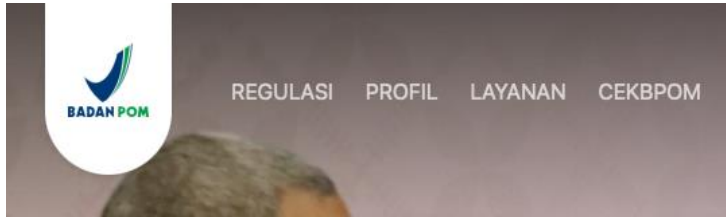
*** In Indonesia, the term ‘other function claim’ is not used*

Regulatory **framework for application** for new nutrition and health claims

Country	Documented system			No documented system
	Established expert review committee	Application form published	Scientific evidence required	
Indonesia	✓	✓	✓	
Malaysia	✓	✓	✓	
Philippines	✓	✓	✓	
Singapore	✓	✓	✓	
Thailand	✓	✓	✓	
Vietnam				✓

- Four countries with specific regulation and positive list of permitted bioactive non nutritional component –
- Industry may apply for use of new health claims and reviewed on a case-by-case basis
- Different approaches adopted to consider applications, but some general similarities
 - ❖ each claim must be accompanied by scientific data to substantiate the application
 - ❖ data from randomised, placebo-controlled, double-blind human trials preferred
 - ❖ some similar requirements in the application forms of the countries
- Regulatory framework established to review applications
 - ❖ applications will be reviewed by a panel of experts from various agencies and expertise
 - ❖ different approaches in the 4 countries, composition of committees

Indonesia



REGULATION OF THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL OF THE

REPUBLIC OF INDONESIA

NUMBER 1 YEAR 2022

CONCERNING

MONITORING OF CLAIMS ON LABELS AND ADVERTISEMENTS OF PROCESSED FOODS

- **Non-nutrient** means any chemical compounds or **bioactive/functional components** found in food which do not function as **Nutrients** but **may affect health**.
- **Nutrition/Non-Nutrition Claim** means any statement which states, indicates, or implies that a food has particular nutritional/non-nutritional properties including the energy value and the content of protein, fat and carbohydrates, and vitamins and minerals.
- **Health Claim** means any representation that states, suggests, or implies that a **relationship exists** between **a food or a constituent of that food and health**.
- **Nutrient/Non-nutrient Function Claim** means a claim that describes the **physiological role** of the Nutrient/Non-nutrient for growth, development and normal functions of the body

Applications for new claims

- Claims and Claim requirements other than those stated in this Authority Regulation **can only be applicable after obtaining a written approval** from the Chairperson of the Authority, *c.q.* Director of Processed Food Standardization.
- In order to obtain a **written approval** as referred to in Article 18, Article 22 section (3), and Article 23, Business Actors must **submit an application for assessment** to the Chairperson of the Authority *c.q.* Director of Processed Food Standardization.
- The application for assessment as referred to in section (1) is **submitted online** through the official website of public service of the Indonesian Food and Drug Authority.
- The application as referred to in section (1) must be supported by **complete data** according to the objective as **set forth in Annex XI** as an integral part of this Authority Regulation.
- The **assessment of application** as referred to in Article 24 section (1) is carried out in accordance with the procedures of Claim assessment as **set forth in Annex XII** as an integral part of this Authority Regulation.

REGULATION OF THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL OF THE REPUBLIC OF
INDONESIA NUMBER 1 OF 2022

CONCERNING MONITORING OF CLAIMS ON LABELS AND ADVERTISEMENTS OF PROCESSED FOODS

ASSESSMENT OF COMPLETENESS OF APPLICATION DATA

A. NEW CLAIMS OTHER THAN CLAIMS RELATED TO MICROORGANISMS

Information to be provided include:

- Administrative data
- Data of nutrients/no-nutritional substance
 - Name of nutrient/non-nutritional substance
 - Specifications
 - History of use
 - Production process
- Claim submission data
 - Claim applied
 - Amount of nutrient/non nutritional substance to be added
- Data of processed food
- Scientific evidence or references
 - References

ANNEX XII

REGULATION OF THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL OF THE REPUBLIC OF INDONESIA NUMBER 1 OF 2022 CONCERNING MONITORING OF CLAIMS ON LABELS AND ADVERTISEMENTS OF PROCESSED FOODS

CLAIM REVIEW PROCEDURE

Claims must first go through an assessment by relevant and impartial experts and be based on scientific evidence that can be accounted for so that they meet the following criteria:

1. support national nutrition and/or health policies;
2. not related to the treatment and prevention of diseases;
3. not encouraging wrong consumption patterns;
4. based on a specific total diet for health claims (reduced of disease risk claims); and
5. true and not misleading.

REGULATION OF THE NATIONAL AGENCY FOR DRUG AND FOOD CONTROL OF THE REPUBLIC OF
INDONESIA NUMBER 1 OF 2022

CONCERNING MONITORING OF CLAIMS ON LABELS AND ADVERTISEMENTS OF PROCESSED FOODS

CLAIM REVIEW PROCEDURE

Assessment principles

1. Research required for the process of submitting a new claim.
 - Research on the product ready for consumption
 - Detailed information of the non-nutrient including chemical and physical properties, complete safety assessment data, human tolerance studies,
2. Biomarkers and End points
3. Thorough evaluation of the existing data
 - Research that has been published in peer-reviewed journals is preferred.
 - Research is carried out by independent researchers or institutions or other institutions that have no conflict of interest.
 - the use of the product demonstrated statistically and clinically significant effects according to claims and recommended intake amounts.
4. Monitoring and Evaluation



Malaysia Food Regulations 1985

Note: food components must first be approved for use as “added nutrients” before applications for other function claims can be considered

Regulation 26. Added Nutrient

- (1) In these Regulations, “added nutrient” includes any mineral, vitamin, amino acid, fatty acid, nucleotide or other food components which, when added singly or in combination to food, improves the nutritional value of the food
- (2) The added nutrients specified in Table I to the Twelfth Schedule or with prior written approval of the Director shall be the permitted added nutrient
 - vitamins and minerals
 - amino acids, fatty acids
 - nucleotides
 - 25 other food components – non nutritional substances

Companies may apply to FSQP to add nutrients or non-nutrients to this table

**APPLICATION FOR ADDITION TO PERMITTED NUTRIENT LIST
[TABLE (I) OF TWELFTH SCHEDULE]**

Prescribed format contains 18 items, including ...

- Name the nutrient/other food component to be added to Table
- State the chemical structure and formula of the nutrient/other food component and describe it in precise chemical terms and state all physical properties.
- Summarize the method of manufacture
- Provide detailed information on the physiological role(s)
- Name the food(s) to which this nutrient /other food component is to be added.
- State the beneficial effect of adding the nutrient /other food component to the food and provide sound scientific evidence on the benefit.
- Show information regarding the stability and bioavailability of the nutrient /other food component in the food(s) in which it is to be added
- State the analytical method to determine the amount of the nutrient /other food component in the raw, processed and/or finished food.
- Submit all data on safety evaluation derived from both chronic and acute studies conducted on the nutrient /other food component

Malaysia Food Regulations also has provisions to make ‘other function claims’

Regulation 18F. Other function Claim

- (1) In this Regulation, “other function claim” means a claim that describes specific beneficial effect of other food component in the food that gives positive contribution to health or improvement of a function of the body.
- (2) An other function claim shall not imply or include any statement to the effect that the nutrient would afford a cure or treatment for a disease or protection from a disease.
- (3) No label which describes any food shall include any claims relating to the function of other food component in the body unless the food for which the function claim is made complies with the minimum amount of the other food component and other conditions specified in Table IV to the Fifth A Schedule.
- (4) No label on a package containing any food shall bear other function claim except those claims permitted in these Regulations or with prior written approval of the Director.

Definition of other function claim is similar to that of Codex Alimentarius Guideline of Nutrition and Health Claims (CAC/GL 12-1997)

Companies may apply to FSQP new other function claims

APPLICATION FOR NUTRITION CLAIMS (Reg 18C, 18D, 18E, 18F)

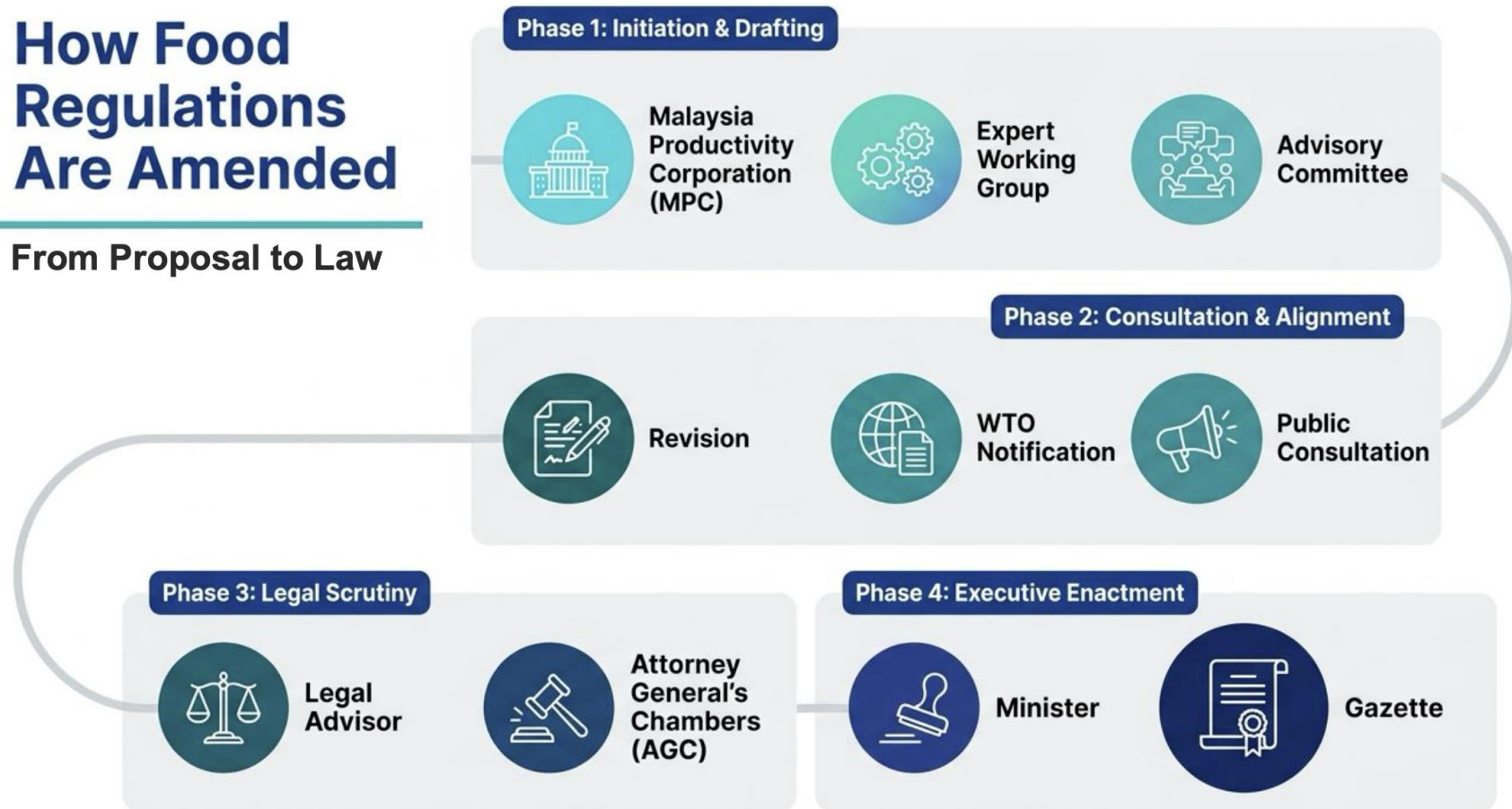
Prescribed format contains 18 items, including ...

- State the nutrient concerned and the proposed nutrition claim (nutrient content claim, comparative claim, nutrient function claim or other function claim). If the said nutrient is to be added to food and it is not listed in Table (I) of Twelfth Schedule as a permitted added nutrient, a submission for its inclusion to the list has to be made to Ministry of Health Malaysia using the format entitled *Application for Addition to Permitted Added Nutrient List [Table (I) of Twelfth Schedule]*.
- Provide detailed information on the physiological role(s)
- Name the food(s) to which this nutrient /other food component is to be added.
- State the beneficial effect of adding the nutrient /other food component to the food and provide sound scientific evidence on the benefit.
- Show information regarding the stability and bioavailability of the nutrient /other food component in the food(s) in which it is to be added
- State the analytical method to determine the amount of the nutrient /other food component in the raw, processed and/or finished food.
- Submit all data on safety evaluation derived from both chronic and acute studies conducted on the nutrient /other food component

Flow chart of amendment of food regulations under Food Act 1983

How Food Regulations Are Amended

From Proposal to Law



Slide courtesy of Ms Nurul Hidayati, Food Safety & Quality Programme, Ministry of Health Malaysia, 2026 (with permission)



Notification of Ministry of Public Health
(No. 447) B.E. 2566 (2023)

Issued by virtue of the Food Act B.E. 2522
Re: Health Claims made on Food Labelling

Other function claim means a claim of specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

“Food constituent” means a composition of food, including nutrients and other substances both naturally occurring and adding to food.

“Other substance” means a substance other than a nutrient that has a nutritional or physiological effect.

- Food with health claims shall
 - be safe and comply with particular notifications. In case of novel food, it shall be evaluated on safety assessment prior to claim substantiation.
 - have food constituent, nutrient or other substance for which the claim is made is in a form and a significant quantity that provides a beneficial nutritional or physiological effects, as established by generally accepted scientific evidence.
- Health claims shall be understood the beneficial effects as expressed in the claims by general consumers. It shall refer to the food ready for consumption in accordance with the instruction indicated on the label. The quantity of consumption shall be in the appropriate proportion.

- Health claims shall be based on and substantiated by current relevant generally accepted scientific evidences. The scientific evidences shall be sufficient to substantiate the physiological effect claimed. The scientific evidences provided shall be well-designed human intervention studies in the target group and can be measured by appropriate biomarkers which consist of the following information:
 - The quantity of the food or food constituent and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet.
 - In case of other function claims, information on the composition of the food or food constituent relevant to the accepted diet-health relationship; and the effect of the food or food constituent to health
- The quantity of the food or food constituent that the claim is made shall be measured by a validated method.

- Food with other function claims and reduction of disease risk claims shall contain the following nutrients per reference amount and per serving, or per 100 g or 100 mL for foods without reference amount established:

Total fat	less than 13 g
Saturated fat	less than 4 g
Cholesterol	less than 60 mg
Sodium	less than 300 mg
Total sugar	less than 13 g

- Health claims statements other than those specified in the annex 1, 2 and 3 attached to this notification shall be assessed by a nutrition and health claim assessment center recognized by the Food and Drug Administration, Thailand. The assessment report together with relevant information described in the annex 4 of this notification shall be submitted to and approved by the Food and Drug Administration.

Note:

Annex 1 = Nutrient function claim statements

Annex 2 = Other function claim statement

Annex 3 = Reduction of disease risk claim statements

- The Notification provide detailed information on labelling requirements including
 - the quantity of food constituent, nutrient or other substance that is the subject of the claim.
 - a quantity of the food and pattern of consumption required to obtain the claimed beneficial effect
- Application form for submission of health claim for assessment is provided

Annex 4. Evidences submitted together with an application for consideration of health claims assessment results

Part 1: General information

- Incl product name, outcome variables, wording of the claim, etc

Part 2: Characterization of the food or food constituent

- information regarding the other substance, characteristics, analytical method, manufacture, stability, etc

Part 3: Information on the effect of the food or food constituent(s) on health according to the type of claim

Other function claims:

- 1) The specific body function that is the subject of the claimed effect.
- 2) The rationale why the specific body function is a beneficial physiological effect for which the claim is intended.
- 3) How the specific body function can be assessed in vivo in humans.

Specify the outcome variable(s) and the methods of measurement proposed to assess the claimed effect in human studies.

Application form for submission of health claim assessment

Company/Partnership/Shop.....

Address.....

.....

Tel.....Fax.....

E-mail.....

Date.....Month.....B.E.....

Re: Request to submit health claim assessment

To: Secretary General of Food and Drug Administration

Attachment: 1. Two copies of health claim assessment report and supporting evidenced documents

2. One set of recording device contained data as in attachment 1

Since I am..... on behalf of
(Company/Partnership/Shop).....

intend to submit the health claim assessment result of food or its compositions from the efficacy and suitability of health claim assessment unit recognized by the FDA that be summarized as follows:

Steps to submission of a health claim for assessment

- Check if the intended claims is already listed in Annex 1, 2 or 3 of the Notification 447
- If not, **prepare a dossier** following the requirement of the Notification
- A **safety assessment body** recognized by Thai FDA conducts the safety and claim assessment
- Obtain the **health claim assessment report**
- **Submit** the assessment report **to the FDA**

The safety assessment bodies recognized by the FDA, as outlined in the official guidelines.

1. Thailand Center for Nutrition and Health Claim Assessment, Foundation for Nutrition Development (CNACT).
2. Academic Service Center, Chulalongkorn University

Singapore



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Note: matters related to nutrition labelling and claims in the Singapore Food Regulations are now being controlled by Singapore Health Promotion Board

A GUIDE TO NUTRITION LABELLING FOR FOOD PRODUCTS (SINGAPORE)

A publication of the
Health Promotion Board (HPB)



Revised August 2024

6.3 Other Function Claim

Other function claims refer to claims about the specific beneficial effects of consuming foods or their food constituents as part of the total diet on the body's normal functions or biological activities by positively contributing to health, improving the function, modifying or preserving health.

Example: “Substance A (naming the effect of substance A on improving or modifying a physiological function or biological activity associated with health). Food Y contains x grams of substance A.”

- Industry may **apply for use of new health claims** and reviewed on a case-by-case basis

APPLICATION FOR USE OF HEALTH CLAIMS FOR FOOD INTENDED FOR SALE IN SINGAPORE

The guidance information, application form and checklist incorporated in this document are meant for applications for use of health claims on food products. "Food" means any substance, liquid, product or preparation which is intended for human consumption through ingestion and includes —

GUIDANCE INFORMATION

The application form consists of the following seven sections:

Part A: Applicant information

Part B: Summary of proposed claim

Part C: Summary of studies submitted

Part D: Table of content of supporting documents submitted

Annex 1: Synopsis of individual studies

Annex 2: Summary of application

Annex 3: Checklist

APPLICATION FORM

Part A: Applicant Information

Part B: Summary of Proposed Claim

- Other substance for which the claim is made
- Target consumer
- Propose wording of the claim
- Conditions of use
- National and international regulatory status

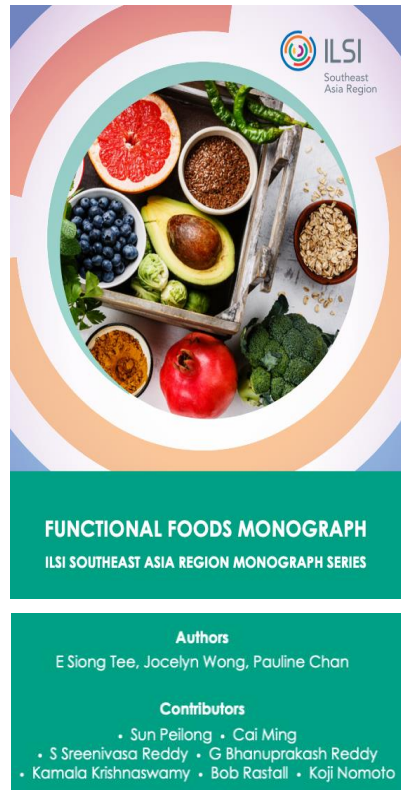
Part C: Summary of studies submitted

- All published or unpublished human and non-human studies that are relevant for substantiation of the proposed claims should be submitted for consideration.
Both data in favour and data not in favour should be included
- Focus on human intervention studies, eg RCT
- Provide synopsis for each study cited

Part D: Table of contents of the supporting documents

3. some resources by International Life Sciences Institute (ILSI SEA Region)

ILSI Monograph on Functional foods (2017, 2018, 2019, 2021)



Originally Published: December 2017
Revised: August 2018, December 2019, October 2021

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Table of Contents

Introduction	4
Addressing Functional Foods in Asia - ILSI SEA Region's Initiatives	5
Chapter 1: Essential Characteristics and Attributes of Functional Foods	7
Chapter 2: Current Regulatory Status of Functional Foods and Health Claims in Southeast Asia	10
Chapter 3: Scientific Substantiation of Health Claims - Regulatory Framework and Review Process	17
Chapter 4: Case Studies on Functional Foods in Southeast Asia	25
- Case Study 1. Mushroom: Nature and Bioactivities of Lentinula Edodes	
- Case Study 2. Turmeric: Health Benefits (<i>Curcumin, Longa, Linn</i>)	
- Case Study 3. Prebiotics: Inulin-type Fructans	
- Case Study 4: Probiotics: From Current Concept to Development of Future Prospects	

- **Regulatory status** on the use and the health claims for functional ingredients / bioactives permitted in SEA is **unclear and not documented**
- A **review** was thus conducted to document the regulatory status (**Tee & Chan, 2022**)

Mal J Nutr 28(3): 461-505, 2022

REVIEW

Regulatory status of bioactive non-nutritional food components in Southeast Asian countries

E-Siong Tee* & Pauline Chan

International Life Science Institute (ILSI) Southeast Asia Region, Singapore

<https://doi.org/10.31246/mjn-2022-review-28-3>



- **Indonesia updated Reg 1/2021 with Reg 1/2022**

ILSI guidelines for scientific substantiation and regulatory framework for health claims

Appendix 1: Guidelines for the Scientific Substantiation of Nutrition and Health Claims for Foods / Functional Foods

1. Types of studies required for substantiation of claims

- Studies should preferably be conducted on the whole functional foods in the form to be consumed rather than on extracted components.
- Foods containing added functional food ingredient(s) may not need individual studies to be conducted if they can show bioequivalency compared to the primary study conducted.
- Nutrient function claims* may be permitted based on authoritative statements from recognized health authorities and accepted texts.
- Scientific intervention

Appendix 3: Regulatory Framework for Nutrition Labeling and Claims for Food - Harmonization in the Southeast Asia Region

1. Establish National Expert Committee on Nutrition and Health Claims

- Establish terms of reference
- Seek approval from appropriate authorities
- Select members based on discipline and experience – aim for multiagency, multidisciplinary

2. Make provisions for nutrition/health claims in existing food regulations

Review of Nutrition Labelling, Nutrition & Health claims in 10 Asian countries



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2022

TABLE OF CONTENTS

INTRODUCTION	4
STATUS OF NUTRITION LABELING, NUTRITION AND HEALTH CLAIMS REGULATION - CODEX ALIMENTARIUS AND SELECTED ASIAN COUNTRIES AND REGIONS	5
Chapter 1: Codex Alimentarius	6
Chapter 2: China	21
Chapter 3: Hong Kong, China	42
Chapter 4: Japan	62
Chapter 5: Korea	88
Chapter 6: Southeast Asia Region	105
6.1 Indonesia	106
6.2 Malaysia	133
6.3 Philippines	159
6.4 Singapore	168
6.5 Thailand	193
Chapter 7: Taiwan	215
DISCUSSION AND CONCLUSION	239



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摘要提交截止

2027年4月1日



早鸟注册开放

2026年7月1日



早鸟注册截止

2027年6月30日



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