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REVIEW

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

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ABSTRACT

A review conducted on the regulatory status of bioactive non-nutritional food components in foods and beverages in eight Southeast Asian countries indicates these components have been recognised for their health benefits. Indonesia and Malaysia have promulgated specific regulations allowing the addition of these bioactive components in foods and beverages, provided a list of the permitted components that may be used, and clear process for the industry to apply for new components. Both countries also have separate regulations that govern the making of function claims which refer to the beneficial physiological or health effects brought about by such bioactive components. The other six countries do not have a specific regulation governing the use of these bioactive components. However, these countries also permit the making of similar function claims, provided they are scientifically substantiated, preferably human clinical trials. Each country has slightly different requirements and process in place for reviewing applications for claims. All countries, except Myanmar, also allow the sale and marketing of foods containing probiotics, another functional food component. Indonesia, Malaysia, Philippines and Thailand have promulgated specific probiotic regulations and, except for Indonesia, have published permitted list of probiotics. All seven countries have provisions for the industry to apply for the use of new probiotics. Malaysia, Philippines, Singapore and Thailand permit the use of a pre-approved generic function claims related to probiotics. The sharing of experiences in regulatory approaches would be beneficial to the advancement of scientific and regulatory development of bioactive non-nutritional food components in the region and would benefit all stakeholders.

Keywords: bioactive food components, food regulations, functional components, non-nutritional components

INTRODUCTION

Nutrients, as defined by Codex Alimentarius, are substances normally consumed as a constituent of food which provide energy and which are needed for growth, development and maintenance of life. A deficit of nutrients may cause characteristic biochemical or physiological changes to occur (FAO/WHO, 2017). The traditional major groups of nutrients in foods come to mind, namely carbohydrates, fats, proteins, vitamins, minerals and water.

Foods also contain non-nutritional food components or constituents that are biologically active compounds. They include a variety of components of plant and animal origin and have been

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known by various names as well as a number of live lactic acid bacteria that have been recognised as probiotics. All these bioactive non-nutritional food components have been shown through many epidemiological and clinical studies to be able to serve physiological roles beyond meeting basic nutritional requirements and may possess health-enhancing properties. They have been generally recognised as bioactive or functional components (Tee, Wong & Chan, 2021).

Recognising the potential beneficial health effects, regulatory authorities in some countries in the region have established regulatory framework to allow the addition of bioactive non-nutritional functional food components to foods and beverages. Permission is often given on a case-by-case basis, upon submission of applications supported by scientific data. Some countries also permit these components to make health claims, specifically "other function claims", as defined by Codex Alimentarius guideline (FAO/WHO, 2013), if they meet the required regulatory criteria.

However, the regulatory status on the use of these bioactive components or constituents and the health claims permitted to be made in relation to these components in Southeast Asian (SEA) countries is unclear and not documented. A review was thus conducted to document the regulatory status of the addition of bioactive non-nutritional food components to foods and beverages (hereafter in this publication referred to as foods). Such information may serve as:

- useful information for food companies in their innovation programmes to add bioactive non-nutritional food components to improve the nutritional profile of their products;
- reference for regulators for the introduction of a regulation to permit the addition of bioactive non-nutritional food components and the associated other function claims
- basis for discussion for harmonisation of the use of bioactive non-nutritional food components or the regulatory review framework governing these components among countries in the region.

This publication documents findings obtained from the review.

METHODOLOGY

A survey template was prepared by the authors to obtain information regarding regulatory control of bioactive non-nutritional food components in SEA countries. The key information in the template include the following two broad topics:

1. Regulatory status of use of bioactive non-nutritional food components, including information on whether these components are permitted to be added to foods, availability of specific regulation, if a positive list of permitted such food components is published and requirements and review process for application for use of such bioactive food components;
2. Regulatory status of permitted health claims related to bioactive non-nutritional food components, and if permitted, the application requirements and review process for such health claims.

The official regulations or documents related to the use of bioactive non-nutritional food components were obtained from regulatory authorities and their respective websites. Pertinent information were extracted from these documents. Where necessary, officials and experts from regulatory authorities

were consulted on specific aspects of the survey and requested to assist in providing and verifying the information in the template. The entire review including verification of information with regulatory experts was carried out from mid 2020 till end 2021. During preparation of the manuscript in 2022, effort was still made to check for updates in the regulations and guidelines.

Information on the use of bioactive non-nutritional food components in the Codex Alimentarius system, specifically in relation to health claims, is also obtained for inclusion in this publication. It is well recognised that guidelines and standards from the Codex system serve as references to countries in the development of national regulations.

RESULTS

The required information were only obtained from eight of the ten countries in SEA, namely Brunei Darussalam, Indonesia, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam. No response was obtained from Cambodia and Laos regulatory authorities and no relevant documents were obtainable from the official websites of these organisations.

Results of the survey are presented in accordance to the two broad topics mentioned above, that is in relation to the use of bioactive non-nutritional food components in foods and associated health claims. Before presenting findings from the eight SEA countries, the status in Codex Alimentarius is first summarised. Within each of the topics, the status in each country is separately presented.

Regulatory framework for the addition of bioactive non-nutritional components to foods and beverages

Table 1 summarises how Codex framework and authorities in eight SEA countries regulate the use of bioactive non-nutritional components in foods and beverages. Codex framework and all countries have made provisions for the use of these food components in foods. However, the regulatory approaches in Codex and each of these countries vary considerably, details of which are summarised in the following paragraphs.

Codex Alimentarius

There is no specific document within the Codex system that provides guideline on the use of bioactive non-nutritional food components, such as within the context of this review. However, the Codex framework does recognise the positive roles that bioactive non-nutritional components in foods may play in human health. This is evidenced from the provisions made for health claims to be made on "food constituents" in the Codex Guidelines for Use of Nutrition and Health Claims CAC/GL 23-1997 (FAO/WHO, 2013). In this Guidelines, health claim is defined as *any representation that states, suggests, or implies that a relationship exists between a food or a constituent of that food and health.* Health claims include the following: (1) nutrient function claim; (2) other function claim, and (3) reduction of disease risk claim. The three claims refer to different relationship between a food or its constituents and various physiological functions or health effects, as defined below:

(1) *Nutrient function claims describe the physiological role of the nutrient in growth, development and normal functions of the body.*

(2) *Other function claims describe 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.*

Table 1. Summary of regulatory framework for addition of bioactive non-nutritional food components in eight SEA countries

	Specific regulation or guideline	*Terminology used*	*Positive list of permitted bioactive components*	*Application for use of new bioactive components*
Codex Alimentarius	No specific Codex guide on the use of bioactive components. However, Codex guideline on claims has made provisions for health claims to be made on "food constituents" which is to be differentiated from role of nutrients in nutrient function claim	Main term is "food constituent"	No positive list	Not applicable
Brunei Darussalam	No specific regulation permitting use of specific bioactive components or probiotics	Various terms used, including novel ingredients, food ingredients, lactic acid producing bacteria	No positive list of permitted bioactive components and probiotics	No specific framework for applications which will be assessed on a case-by-case basis
Indonesia	Regulation 30 of 2021 on Requirements for the Addition of Nutrients and Non-nutritional Substances to Processed Foods; Regulation 1/2022 on Monitoring of Claims on Processed Food Label and Advertising permits use of probiotics in processed foods	The specific term used in regulation is "non-nutritional substances" and include compounds or bioactive/ functional components found in food that do not function as nutritional substances but affect health. The term probiotics is in accordance with FAO/WHO 2001 consultation report definition	Positive list of 16 non-nutritional substances in Regulation 30/2021. No positive list of permitted probiotics	Applications for use of new non-nutritional substances and probiotics can be made to the authorities accompanied by safety and scientific data. Regulatory framework established to review applications.

Table 1. Summary of regulatory framework for addition of bioactive non-nutritional food components in eight SEA countries (cont'd)

	Specific regulation or guideline	*Terminology used*	*Positive list of permitted bioactive components*	*Application for use of new bioactive components*
Malaysia	Regulation 26 Added Nutrients permits use of other food components and Regulation 26A regulation provides for use of probiotics in foods and beverages	The specific term used in regulation is "other food components", listed as a group of non-nutritional components in the list of permitted added nutrients. The use of the term Probiotics is in line with FAO/WHO 2001 consultation report definition	Listed in Table I of the Twelfth Schedule of Regulation 26 lists a total of 25 other food components, 11 of which are various forms of dietary fibre. Table in Regulation 26A lists 32 permitted strains of probiotics	Applications for new other food components and probiotics can be made using a prescribed application forms. Regulatory framework established to review applications, require scientific data to demonstrate safety and beneficial effects
Myanmar	No specific regulation permitting use of specific bioactive components or probiotics	Various terms used, including ingredients of known food sources such as plant/botanical, animal and microbial including their metabolites, derivatives or enzymes	No positive list of permitted bioactive components and probiotics	No specific framework for applications which will be assessed on a case-by-case basis; data on safety and specific health benefits to be provided
Philippines	No specific regulation for the use of bioactive non-nutritional components. BFAD Circular No. 16s 2004 provides for use of probiotics in foods	Various terms used, including "any substances" and "dietary ingredients". Bioactive substances like flavonoids, carotenoids, antioxidants, phytochemicals, lycopene, fatty acids, peptides are collectively termed as "any substance". The use of the term Probiotics in BFAD Circular No. 16s 2004 is in line with FAO/WHO 2001 consultation report definition	No positive list of permitted bioactive components. BFAD circular No. 16s 2004 published a list of 5 genera/species of microorganisms to be used as probiotics	Applications for new bioactive components may be made through product registration under Administrative Order 2014-0029 through an online process; no prescribed form. Applications for new probiotics can be made using electronic registration system under FDA Circular 2016-014

Table 1. Summary of regulatory framework for addition of bioactive non-nutritional food components in eight SEA countries (cont'd)

	Specific regulation or guideline	*Terminology used*	*Positive list of permitted bioactive components*	*Application for use of new bioactive components*
Singapore	No specific regulation for the use of bioactive non-nutritional components or probiotics.	Various terms used, including food ingredients, novel foods. The use of the term Probiotics is in line with FAO/WHO 2001 consultation report definition	No positive list of permitted bioactive components and probiotics	In most cases, the use of bioactive food components is tied up with other function claims - see next section on health claims. Applications for new probiotics must be accompanied by safety and scientific data
Thailand	No specific regulation for the use of bioactive non-nutritional components. Use of probiotics in foods is permitted under two Notifications of the Ministry of Public Health: No. 339, B.E. 2554 (2011) and No. 346, B.E 2555(2012)	Various terms used, including food ingredients, novel ingredient. The use of the term Probiotics is in line with FAO/WHO 2001 consultation report definition	No positive list of permitted bioactive components. MoPH notification No. 339 has published a list of 23 species of microorganisms to be used as probiotics in foods	Applications for use of bioactive non-nutritional food components is linked to applications for other function claims (see next section on health claims). Applications for new probiotics are via an online system, accompanied by data on safety functional role
Vietnam	No specific regulation for the use of bioactive non-nutritional components or probiotics in foods. However, ingredients with biological activities may be added to specific supplemented foods under MOH Vietnam Circular 2014.	Various terms used, including "healthful components for the body" and biologically active substances. Probiotics is one of the permitted "healthful components"	No positive list of permitted "healthful components for the body" and probiotics	No specific framework for consideration of applications for the use of any food components/ constituents that they intend to add to supplemented foods. Application to register a new bacteria as a probiotic can be made under supplemented food, supported by safety data

(3) *Reduction of disease risk claims refer to claims relating the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition.*

There is a clear distinction between claims that may be made on nutrients versus food constituents. Nutrient function claim refers to relationship between conventionally recognised nutrients (e.g. vitamins, minerals, protein) with their physiological functions. On the other hand, other function claim and reduction of disease risk claim make reference to the effect of "consumption of foods or their constituents" and health.

In the annex of this guideline which provides recommendations on the scientific substantiation of health claims, the process for substantiation include identifying the "proposed relationship between the food or food constituent and the health effect". A few examples of such food constitutents given in the annex are plant sterols, fibres and lactic acid bacteria. It is clear that the food constituents in these Codex health claims refer to non-nutritional food components that are bioactive and may bring about positive health effects.

With regard to the use of probiotics in foods and beverages, there is currently no specific Codex text on this. Back in 2001, there were two expert consultations organised by Food and Agriculture and Organization (FAO) and World Health Organization (WHO), the parent organisations of Codex Alimentarius (FAO/WHO, 2001; FAO/WHO, 2002). In the 2001 consultation, a definition of probiotics was proposed and among the various recommendations, it was felt that the regulatory status of probiotics as a component in food has to be established on an international level.

In this regard, there is a currently a proposal to develop a harmonised guideline on probiotics within the Codex system. It was last discussed in the 41st session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in 2019 and is expected to be re-tabled for discussion at the 43rd session of CCNFSDU in March 2023 (FAO/WHO, 2019).

Brunei Darussalam

The Food Safety and Quality Control Division (FSQCD) of the Ministry of Health has been the food safety regulatory authority in Brunei Darussalam. In a recent development, the Brunei Darussalam Food Authority (BDFA) was established on 1 January 2021 to strengthen and develop a robust food safety and quality system in the country (official website: https://www.moh.gov.bn/SitePages/Food%20Safety%20and%20Quality%20Control%20Division.aspx).

There is no specific regulation permitting the use of bioactive non-nutritional food components in foods/beverages under the Public Health (Food) Regulations (R1, chapter 182) (MOH Brunei, 2001). However, if there is an interest to use a specific ingredient, the industry may make enquiries to the BDFA, which will assess each application on a case-by-case basis.

In addition to the above, there are regulations permitting the use of yet another category of functional food component, namely lactic acid producing bacteria in foods. Foods containing these bacteria are milk drink or cultured milk drink (Regulation 139), sour cream (Regulation 150), and yoghurt (Regulation 162).

Novel ingredients or any ingredients not covered in the current legislation are reviewed administratively on a case-by-case basis. Importers may enquire about the suitability of an ingredient

to the BDFA. The assessment duration varies depending on the ingredient in question. In most cases, the ingredient is advised to follow the requirements under Codex Alimentarius standards.

Indonesia

The food control authority in Indonesia is the National Agency of Drug and Food Control or Indonesian Food and Drug Authority (Indonesian FDA) (official website: https://www.pom.go.id/new/home/en).

Regulation 30 of 2021 by the Indonesian authorities recently updated the specific regulation that spells out the Requirements for the Addition of Nutrients and Non-nutritional Substances to Processed Foods (FDA Indonesia, 2021). Nutrients are defined in the said regulations as substances or compounds contained in food consisting of carbohydrates, dietary fibre, protein, fat, vitamins, minerals, water, and other components that are beneficial for human growth, development and health. At the same time, the regulation has stated that non-nutritional substances are compounds or bioactive/functional components found in food that do not function as nutritional substances but affect health.

Appendix 1 of the said regulation has provided a positive list of 16 non-nutritional substances that may be added to processed foods. This appendix also lists 55 compounds under the section of nutrients that may be added to processed foods. Upon reviewing this list, several of them could also be considered as non-nutritional substances. These include several carbohydrate derivatives and dietary fibres as well as several miscellaneous substances. Table 2 of this review therefore lists the 16 non-nutritional substances as well as 11 of these "nutrients" in Appendix 1 of the said regulation.

As indicated in Table 2, the list has indicated the food categories to which the non-nutritional substance may be added and the conditions or requirements that must be met for such addition.

Companies may apply to the Indonesian FDA for the use of other non-nutritional substances that are not in the current positive list. Appendix II of the said Regulation has provided an application form that is to be used for such applications. Important data to be provided re the non-nutritional substances include the name of the substance, amount to be added to the food, estimated total daily intake, specifications of the substance, production process, history of use in food and its regulatory status in other countries. Information on the category and name of the food to which the substance is to be added and the purpose of such addition are also required to be provided. Documentation to support the safety of the non-nutritional substance must be provided with the application.

It is to be noted that this Regulation refers to permission for the addition of these non-nutritional substances to foods and does not give permission for making health claims in relation to these food components. Hence, the industry may add these approved non-nutritional substances to processed foods without making any health claim. The Regulation governing health claims for non-nutritional substances is discussion in the next section.

In addition to the non-nutritional substances or food components referred to above, Indonesia Food Regulations also permit the use of yet another category of functional component to foods, namely probiotics and make approved health claims. This is permitted in Regulation 1 of 2022 on Monitoring of Claims on Labels and Advertisements of Processed Foods (FDA Indonesia, 2022). No positive list of probiotics approved for use is published. Industry may apply to the Indonesian FDA for use of microorganisms as probiotics in foods. More details on the provisions for use of probiotics under thie Regulation is given

Table 2. Non-nutritional substances† that may be added to processed foods in Indonesia and the required conditions

No.	*Non-nutritional substance*	*Food category*	*Conditions/Requirements*
1.	Lactic acid	All types of food	Case by case review
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
2.	Phytostanol, both in the ester and free form	Margarine, margarine spread, dairy products and their processed products, breakfast cereals, mayonnaise and salad dressings, and milk-flavoured drinks	Maximum of 3 g/day
3.	Phytosterol, both in the ester and free form	Margarine, margarine spread, dairy products and their processed products, breakfast cereals, mayonnaise and salad dressings, and milk-flavoured drinks	Maximum of 3 g/day
4.	Glucosamine	All types of food	Maximum of 1500 mg/day
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
5.	β-hydroxy-β-methylbutyrate (HMB)	All types of food	Case by case review
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
6.	Isoflavone	All types of food	Case by case review
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations

Table 2. Non-nutritional substances† that may be added to processed foods in Indonesia and the required conditions (cont'd)

No.	*Non-nutritional substance*	*Food category*	*Conditions/Requirements*
7.	Caffeine	All types of food	The requirements refer to the Regulation Number 34 of 2019 concerning Food Categories
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
8.	Catechin	All types of food	Case by case review
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
9.	Collagen	All types of food	Sufficient to obtain the desired characteristics
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
10.	Colostrum	Milk and products	Sufficient to obtain the desired characteristics
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
11.	Chondroitin	All types of food	Maximum 1200 mg/day
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
12.	Lutein from *Tagetes erecta*	All types of food	Sufficient to obtain the desired characteristics
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations

Table 2. Non-nutritional substances† that may be added to processed foods in Indonesia and the required conditions (cont'd)

No.	*Non-nutritional substance*	*Food category*	*Conditions/Requirements*
13.	L-Theanine	All types of food	Sufficient to obtain the desired characteristics
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
14.	Ubiquinone/Coenzyme Q10	All types of food	Case by case review
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
15.	Zeaxanthin-rich extract	All types of food	Sufficient to obtain the desired characteristics
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
16.	Lycopene	All types of food	Sufficient to obtain the desired characteristics
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
17	Isomaltulose	All types of food	In accordance with the provisions of NRV for total carbohydrate
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations

Table 2. Non-nutritional substances† that may be added to processed foods in Indonesia and the required conditions (cont'd)

No.	*Non-nutritional substance*	*Food category*	*Conditions/Requirements*
18	Isomalto-oligosaccharide - IMO	All types of food	Maximum of 30 g/day
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
19	Sucromalt	All types of food	In accordance with the provisions of NRV for total carbohydrate
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
20	Beta-glucan	All types of food	In accordance with the provisions of NRV for dietary fibre
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
21	Fructooligosaccharide – FOS with degree of polymerization 3-10	All types of food	In accordance with the provisions of NRV for dietary fibre
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
22	Galactooligosaccharide – GOS	All types of food	In accordance with the provisions of NRV for dietary fibre
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations

Table 2. Non-nutritional substances† that may be added to processed foods in Indonesia and the required conditions (cont'd)

No.	*Non-nutritional substance*	*Food category*	*Conditions/Requirements*
23	Inulin	All types of food	In accordance with the provisions of NRV for dietary fibre
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
24	Resistant maltodextrin/ Resistant starch Type 4/ Distarch Phosphate	All types of food	In accordance with the provisions of NRV for dietary fibre
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
25	Pectin	All types of food	In accordance with the provisions of NRV for dietary fibre
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
26	Polydextrose	All types of food	In accordance with the provisions of NRV for dietary fibre
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations
27	Psyllium	All types of food	In accordance with the provisions of NRV for dietary fibre
		Processed food for Special Nutritional Needs in accordance with the provisions of the legislation	Requirements refer to Regulation Number 1 of 2018 concerning Supervision of Processed Food for Special Nutritional Purposes and its amendment regulations

NRV, Nutrient reference value

Source: Appendix I of the Regulation 30 of 2021 concerning Requirements for the Addition of Nutrients and Non-Nutritional Substances to Processed Foods (FDA Indonesia, 2021)

†This table includes 16 non-nutritional substances in Appendix 1 of the said regulation (numbers 1-16), as well as 11 "nutrients" that may be included in this list (numbers 17-27).

in the second broad topic of this review, i.e. on health claims.

Malaysia

The regulatory authority in Malaysia for food safety is Food Safety and Quality Division, Ministry of Health Malaysia (official website: http://fsq.moh.gov.my/).

There is a specific regulation in the Malaysia Food Regulations 1985 (MOH Malaysia, 2017a) which governs the addition of bioactive non-nutritional food components to foods and beverages. This provision is contained in Regulation 26, titled Added Nutrient, which provides for the addition of a variety of nutrients to foods, including "other food components", the term used in this Regulation for bioactive non-nutritional food components. In this Regulation, meaning of the term "added nutrient" has been broadened and is defined as: 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.

The Regulation further stipulates that only nutrients contained in a positive list in Table I of Twelfth Schedule are permitted to be added to foods (MOH Malaysia, 2017a). This Table lists the following "nutrients" that may be added to foods: 1. Vitamins and minerals, 2. Amino acids, 3. Fatty acids 4. Nucleotides, and 5. Other food components. The last named category, "other food components" have been included as a separate category from the "classical" nutrients of vitamins, minerals, fatty acids and amino acids.

The "other food components" in Table I of the Twelfth Schedule are reproduced in Table 3 of this review. This positive list includes a total of 25 bioactive non-nutritional food components, 11 of which are various forms of dietary fibre. All the food components in this list may be added to foods and beverages, and have arisen from applications from the food industry.

Industry may apply to add "other food components" to the positive list summarised above. Applicants are required to complete a specific form prescribed by FSQD (Application for Addition to Permitted Added Nutrient List) and provide information on the limit of probable intake of the nutrient, the chemical structure, the physiological role of the nutrient, expected beneficial effects, stability and bioavailability, analytical method, data on safety evaluation and approval by other country. The form can be downloaded from this link: http://fsq.moh.gov.my/v6/xs/page.php?id=72.

The scientific information that must be submitted to substantiate the application must be all available literature related to the application including both positive and negative findings on the application. Data from human intervention trials are preferred. Epidemiological and experimental studies and review papers related to the component may be included as supportive evidences. Studies should include those conducted by other organisations or institutions and result of these studies should be published in peer reviewed journals. To facilitate review by expert committee members, summaries of the studies should be presented in table form.

An expert committee has been established to review all applications. The committee consist of relevant practitioners and academicians, particularly those in the field of food, nutrition and health, from related government agencies, academia and professional organisations. The review process for applications is as summarised in the flow chart in Figure 1.

This Regulation refers to permission for the addition of these non-nutritional components to foods and does not give permission for making health claims

Table 3. List of permitted "other food components" that may be added to foods in Malaysia

D-ribose
Calcium 3-hydroxy-3-methyl butyrate monohydrate (CaHMB)/ hydroxy methylbutyrate (HMB) (only permitted in formula dietary food)
Epigallocatechin gallate (EGCG)
Isomaltulose (except in infant formula)
Lactotripeptide [which consists of L-valine-L-proline-L-proline (VPP) and L-isoleucine-L-proline-L-proline (IPP) with proportion of VPP:IPP between 0.56 to 1.77 (addition is only permitted for fruit juice, vegetable juice and milk product except for infant formula, follow-up formula and formulated milk powder for children)]
Mixture containing 50 percent (weight per weight) galactooligosaccharide (GOS) and 50 per cent (weight per weight) polydextrose (PDX)
Sialic acid (from milk)
Plant sterols or plant stanols or phytosterols or phytostanols (comprising mainly of sitosterol, campesterol, stigmasterol and other related plant stanol)
Plant sterol esters (comprising mainly of campesterol ester, stigmasterol ester and beta-sitosterol ester)
Soy protein
Sucromalt (only permitted in formula dietary food)
Beta glucan from yeast
Bovine lactoferrin
Slowly Digestable Starch (SDS)
Dietary fibre
Acacia gum/gum arabic (only from Acacia senegal and Acacia seyal)
Galactooligosaccharide (GOS)
High amylose maize resistant starch (HAMRS) (not permitted in infant formula and follow-up formula)
Inulin
Beta glucan from oat soluble fibre
Beta glucan from barley
Oligofructose/fructooligosaccharide
Oligofructose-inulin mixture containing shorter chain inulin (oligofructose DP 3-9) and longer chain inulin (inulin DP ≥ 10) in a 50:50 ratio ± 10% each
Oligosaccharide mixture containing 90 per cent (weight per weight) of oligogalactosyl-lactose [galactooligosaccharides (GOS)] and 10 per cent (weight per weight) oligofructosyl saccharose [long chain fructooligosaccharide (lcFOS)]
Polydextrose
Resistant dextrin/resistant maltodextrin (not permitted in infant formula and follow-up formula)

Source: Table I of the Twelfth Schedule, Malaysia Food Regulations 1985 (MOH Malaysia, 2020)

in relation to these food components. Hence, the industry may add these approved components to foods and beverages without making any health claim. The regulation governing health claims for bioactive non-nutritional food components is discussed in the next section.

In addition to the food components referred to above, Malaysia Food Regulations also permit the addition of yet another category of functional component to foods, namely probiotics. This is permitted under Regulation 26A which spells out details such as definition of probiotics, conditions required namely that the probiotic cultures shall remain viable and the probiotic count shall not be less than 10^6cfu/ml or cfu/g during the shelf life of the food containing these, and labelling requirements. The regulation also includes a positive list of 32 permitted strains of probiotics that may be used. Industry may apply for use of new probiotic strains using a prescribed form which spells out in detail the required information to be submitted for consideration by FSQD (MOH Malaysia, 2017b; Tee, Hardin & Au, 2021).

Myanmar

Governing authority on food safety in Myanmar would mainly be Department of Food and Drug Administration (FDA), Ministry of Health and Sports (official website: https://www.mohs.gov.mm).

There is no specific regulation regarding the use of bioactive non-nutritional food components in Myanmar. No positive list has been established for these food components that have been approved for use. FDA can inform industry and consumers if there are enquiries if an ingredient of interest is permitted to be used in foods or beverages.

Companies may apply for the use of bioactive non-nutritional food components and be considered by the FDA on a case-by-case basis. Bioactive components that may be considered are ingredients of known food sources such as plant/botanical, animal and microbial including their metabolites, derivatives or enzymes. Scientific evidence on its health benefits and safety must be submitted for consideration. For very new (novel) ingredient/bioactive substance or extract from uncommon food source, FDA evaluates the scientific evidence relevant to its specific health benefits as a preliminary assessment (document review only).

There is however no specific framework established for reviewing applications for use of new bioactive non-nutritional food components, and no independent scientific or expert committee has been established yet for the critical review.

There does not appear to be a specific regulation on probiotics in Myanmar, though products containing these microorganisms are available on the market (Koirala & Anal, 2021).

Philippines

The regulatory authority in the Philippines on food safety is the Food and Drug Administration (official website: https://www.fda.gov.ph/).

There is no specific regulation for addition of bioactive non-nutritional food components to foods and beverages. However, bioactive food ingredients may be permitted to be added to foods and dietary supplements. In the definition of food and food/dietary supplement based on Republic Act 9711 (Republic of the Philippines, 2009), “any substances” and “dietary ingredients” may be added:

“Food means any processed substance, which is intended for human consumption and includes drinks for human beings, beverages, chewing gum and “any substances”, which have been used as an ingredient in the manufacture, preparation or treatment of food.”

“Food/dietary supplement’ means a processed food product intended

Figure 1. Flow chart of amendment of food regulations under Food Act 1983

to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamin, mineral, herb, or other botanical, amino acid, and dietary substance to increase the total daily intake".

Bioactive substances like flavonoids, carotenoids, antioxidants, phytochemicals, lycopene, fatty acids, peptides are collectively termed as "any substance".

There is no positive list of bioactive non-nutritional food components permitted for food use. FDA can inform stakeholders through replies to their inquiries via letters, emails, calls or face-

to-face discussion (for walk-in clients) and through results of their registration application.

Industry may apply for the use of bioactive non-nutritional food components as provided for in Administrative Order No. 2014-0029 Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and Other Food Products, and For Other Purposes (DOH Philippines, 2014). Bioactive non-nutritional food components are approved by product registration provided that safety is established. The applicant may file an online application which will be assessed by Center for Food Regulation and Research based on the submitted safety data, if any, and other documentary requirements based on this A.O. 2014-0029. There is no specific prescribed form for submitting applications. No details of the requirements for application or type of scientific information required have been provided.

Besides the above mentioned bioactive non-nutritional food components, Philippines also permit the addition of probiotics to foods. The Bureau of Food and Drug (BFAD) Circular No. 16s 2004 has provided a definition of probiotics, specific labelling requirements, and published a list of 5 genera/species of microorganisms to be used as probiotics in the Philippines (BFAD, 2004). Companies may apply for the use of probiotics not in the current approved list using the electronic registration system under FDA Circular 2016-014 (FDA Philippines, 2016). Scientific data must be submitted to demonstrate that the new bacterial strain must provide evidence of safety and effectiveness as a probiotic.

Singapore

The Singapore Food Agency (SFA) is the authority to oversee food safety and food security from farm-to-fork in Singapore (official website: www.sfa.gov.sg).

Bioactive non-nutritional food components are permitted to be added to foods and beverages. However, there is no specific regulation for this purpose. In most cases, the use of bioactive food components is tied up with other function claims, which are permitted by SFA. The regulation governing health claims for such bioactive food components is discussed in the next section. SFA also permits bioactive food components which do not have pre-approved function claims to be used in foods. SFA does not publish a positive list of permitted bioactive food components.

On the other hand, with the increased interest on the production of novel foods/ingredients which do not have a history of being consumed by humans as food, SFA has released a document on the food safety information that would be required for novel food safety assessment which was last updated in September 2022 (SFA, 2022). The information requested include potential food safety risks such as toxicity, allergenicity, safety of its production method, and dietary exposure arising from consumption. Companies that wish to submit the application must also provide detailed information on the materials used in their manufacturing processes and how these manufacturing processes are controlled to prevent food safety risks. These safety assessments will be reviewed and updated periodically to facilitate the safety assessments by the industry and ensure food safety.

In terms of probiotics, unlike in Indonesia, Malaysia, Philippines and Thailand, there is no specific regulation regarding the use of probiotics in foods in Singapore. There is also no published list of permitted strains of probiotics that may be used. Nevertheless, Singapore Food Regulations permits strains of *bifidobacteria* and *lactobacillus* that have a proven long history of safe use to be used as probiotics in suitable categories of food products, including cultured milk drink and yoghurt (SFA, 2021).

For the use of new microorganisms for use as probiotics in foods in Singapore, an application may be submitted to SFA. All needed documents must be submitted, including data on identification, characterisation and safety for use by the intended target groups (Tee *et al.*, 2021).

Thailand

Thailand Food and Drug Administration (Thai FDA), Ministry of Public Health is the regulatory authority for food safety in Thailand (official website: www.fda.moph.go.th).

There is no specific regulation, definition or description of bioactive non-nutritional food components in the food regulations in Thailand. Nevertheless, these components are permitted to be added to foods and beverages with pre-marketing approval.

The uses of bioactive non-nutritional food components are tied up with other function claims, which are permitted by Thai FDA. Industry may apply for the use of a food component and the associated other function claim on a case-by-case basis. This is summarised in the section on regulatory framework on health claims related to bioactive non-nutritional food components.

Applications for use of bioactive non-nutritional food components is linked to applications for other function claims. If the food component is a novel ingredient, safety assessment of the component is needed. Refer to section below on regulatory framework for health claims.

Besides the above provisions, Thai FDA also permits the use of probiotics in foods, according to the following notifications of Ministry of Public Health (MoPH):

a. Notification of the Ministry of Public Health (No. 339) B.E. 2554 (2011) Re: Use of Probiotic Microorganisms in Foods (MoPH Thailand, 2011).
b. Notification of the Ministry of Public Health (No. 346) B.E 2555(2012) Re: Use of Probiotic Microorganisms in Foods (No.2) (MoPH Thailand, 2012).

The MoPH notification No. 339 provides details of the probiotics, including definition, number of viable microorganisms required in the product, labelling requirements and has provided a list of 23 species of microorganisms that are permitted for use in foods. Manufacturers or importers in Thailand may apply for the use of probiotic microorganisms other than those specified in the positive list. Applications can be submitted using a form online and provide the needed information, including scientific substantiation on the safety and functional role or health benefits (MoPH Thailand, 2011).

Vietnam

The authority responsible for management of food safety issues of domestic and imported foods in Vietnam is the Vietnam Food Administration (VFA), of the Ministry of Health (official website: www.vfa.gov.vn).

There is no specific regulation for the use of bioactive non-nutritional food components in Vietnam. Nevertheless, ingredients with biological activities may be added to specific functional foods. This is provided for in the Ministry of Health Vietnam circular on regulating functional foods (MOH Vietnam, 2014). In this Circular, functional foods include supplemented foods, health protection foods (health supplement, food supplement, dietary supplement), medical foods and foods used for special dietary uses.

In Article 2 of this MOH 2014 circular, supplemented foods have been defined as conventional foods supplemented with micronutrients and other healthful components for the body such as vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, prebiotics and other biologically active substances.

Table 4. Summary of regulatory framework for health claims related to bioactive non-nutritional food components in eight SEA countries

	Permitted health claims†	*Regulation or guideline*	*Positive list of permitted health claims*	*Application for new health claims*
Codex Alimentarius	Other function claim, reduction of disease risk claim	Codex Guidelines for Use of Nutrition and Health Claims CAC/GL 23-1997	Not provided	Not applicable
Brunei Darussalam	Other function claim, reduction of disease risk claim	No specific regulation; Codex Guidelines are applicable	No positive list of health claims and those related to probiotics	Yes; no specific framework for applications, applications will be reviewed on a case-by case basis
Indonesia	Function claims for nutrients and non-nutritional substances, reduction of disease risk claim	Regulation 1/2022, Republic of Indonesia	List provided in regulation; 10 function claims for 5 groups of non-nutritional substances. Only one generic function claim permitted for probiotics	Applications can be made using a prescribed application form. Regulatory framework established to review applications, procedure for assessment of applications summarised in regulation. Require scientific data to substantiate intended claim.
Malaysia	Other function claim permitted. Reduction of disease reduction claim not permitted	Regulation 18F (amendment 2020) of Malaysia Food Regulations 1985	List provided in regulation for 22 non-nutritional components for 43 other function claims. Only one generic function claim permitted for probiotics	Applications for other function claims can be made using a prescribed application form. Regulatory framework established to review applications, require scientific data to substantiate intended claim
Myanmar	Other function claim, reduction of disease risk claim	No specific regulation	No positive list of health claims and those related to probiotics	No specific framework for review, require scientific substantiation

Table 4. Summary of regulatory framework for health claims related to bioactive non-nutritional food components in eight SEA countries (cont'd)

	Permitted health claims[†]	*Regulation or guideline*	*Positive list of permitted health claims*	*Application for new health claims*
Philippines	Other function claim, reduction of disease risk claim	Bureau Circular No. 2007-002, Republic of Philippines	No list of other function claims provided, but four pre-approved claims related to probiotics available	Applications for health claims may be made under Administrative Order 2014-0029; no prescribed form. Companies may apply for use of health claims on probiotics
Singapore	Other function claim, reduction of disease risk claim	Guide to Food Labelling and Advertisements, 2021, Singapore Food Agency	A list of 17 other function claims for 12 bioactive non-nutritional food components provided. List includes four function claims related to probiotics	Applications for health claims can be made using a prescribed application form. Regulatory framework established to review applications, require scientific data to substantiate intended claim
Thailand	Other function claim, reduction of disease risk claim	Provided under Food Act B.E. 2522. Regulation on health claims is being drafted. Permitted health claims and associated conditions are given in the Public Manual on Requesting for assessment of health claim by Thai FDA 2020	No list of other function claims provided. One generic pre-approved claim related to probiotics available	The Public Manual provides details of regulatory framework, requirements for application and review of process; require scientific substantiation. Industry may apply for health claims on probiotics, with scientific substantiation
Vietnam	Other function claim, reduction of disease risk claim	No specific regulation; MOH Circular on Regulating Management of Functional Foods makes provision for health claims for functional foods	No positive list of health claims and those related to probiotics	Industry may apply for health claims with scientific substantiation. No review framework established

[†]Nutrition function claims are not included as they relate to physiological role of nutrients whereas this review focuses on other function claim and reduction of disease risk claim which refer to the potential health effects of non-nutritional functional food components

Currently, there is no published list of "healthful components for the body" that are permitted to be used in supplemented foods. There is no specific framework, but companies may apply to the MOH Vietnam for the use of any food components/constituents that they intend to add to their supplemented food products.

In Vietnam, there is no specific regulation or legal definition of probiotics. However, as indicated above, the MOH Circular allows the addition of "healthful components for the body" to supplemented foods, and probiotics are included as one of these substances. The sale of probiotics in foods is regulated through several government agencies, including the Vietnam Food Administration (VFA) and inspectors of the Ministry of Health, Department of Health and Food Safety Management Agencies, Vietnam Directorate of Market Surveillance (Ministry of Industry and Trade) and its agencies at the provincial levels (Tee *et al.*, 2021).

Manufacturers may apply to the VFA to register a bacteria strain for use under supplemented food. Permission for the use of the bacteria strain is given based on the strength of scientific evidence of the product or ingredient. More details on the management of probiotics under functional foods, which includes supplemented foods and dietary supplements is provided in Circular No. 43/2014/TT-BYT (MOH Vietnam, 2014).

Status of regulatory framework for health claims related to bioactive non-nutritional food components

Table 4 summarises the status of health claims permitted to be made in relation to bioactive non-nutritional food components in Codex framework and the eight SEA countries in this review. As can be seen from the Table, all the countries in the review permit the use of other function claim and reduction of disease risk claim and the definitions of these are line line to those of Codex guideline. However, the regulatory framework in each country varies considerably, details of which are summarised in the following paragraphs.

Codex Alimentarius

As summarised in the first section of the results of the review, Codex Guidelines for Use of Nutrition and Health Claims CAC/GL 23-1997 has made provisions for making of health claims (FAO/WHO, 2013). In the context of this review, the relevant health claims are other function claim and reduction of disease risk claim, linking the role of "consumption of foods or their constituents" and health. As previously explained, the food constituents in these Codex health claims refer to non-nutritional food components that are bioactive and may bring about positive health effects.

Brunei Darussalam

The Public Health (Food) Regulation (R1, chapter 182) of Brunei Darussalam has not provided specific regulations on health claims (MOH Brunei, 2001). The Regulation has stipulated that under such circumstances, Codex Alimentarius standards shall apply, including the Codex guidelines on claims CAC/GL 1-1979 (FAO/WHO, 2009), and the Codex guidelines for use of Nutrition and Health Claims CAC/GL 23-1997 (FAO/WHO, 2013).

There is no positive list of permitted health claims. The industry may enquire to the BDFA, through letters, emails or other channels, whether a particular health claim is permitted. Claims that are intended to be included on the packaging or to be displayed during sale should first be submitted to the BDFA and shall be reviewed on a case-by-case basis.

There is also no specific framework for application for use of health claims for bioactive non-nutritional food components. Nevertheless, companies

may apply to the BDFA for consideration on a case-by-case basis by experts appointed by the Authority.

Indonesia

In Indonesia, claims on labels of processed foods are provided for in Regulation 1 of 2022 on Monitoring of Claims on Labels and Advertisements of Processed Foods (FDA Indonesia, 2022). The permitted claims on food labels as stipulated in Article 2 of the Regulation are: claims on nutrients and non-nutritional substances, health claims, isotonic claim, vegan claim and claims related to microorganisms. Non-nutritional substances in these regulations refer to compounds or bioactive/functional components contained in food that do not function as nutrients but affect health. This is the same as defined in Regulation 30 of 2021 on Requirements for the Addition of Nutrients and Non-nutritional Substances to Processed Foods (FDA Indonesia, 2021).

Health claims in Regulation 1 of 2022 are *"any form of description stating, suggesting or implying that there is a relationship between food or food ingredients and health"*. Three types of health claims are permitted in these regulations: (a) function claim for nutrients and non-nutritional substances, (b) reduction of disease risk claim and (c) glycaemic claim. Function claims for nutrients and non-nutritional substances are *"claims that describe the physiological role of nutrients/non-nutritional substances for normal growth, development and function of the body"*. The reduction of disease risk claim is a *"claim that links food consumption or food components in the total diet with a reduced risk of developing a disease or certain health conditions"*.

This definition of health claim is similar to that of Codex Guidelines for Use of Nutrition and Health Claims CAC/GL 23-1997 (FAO/WHO, 2013). However, it should be pointed out that the classification of health claims in these regulations are not the same as those in the Codex Guidelines, as outlined above. It is noted that the term "other function claim" is not used and the term function claim is used for both nutrients and non-nutritional substances.

Annex VII of Regulation 1 of 2022 has provided a list of the permitted function claims for nutrients and non-nutrients (FDA Indonesia, 2022). The permitted function claims for non-nutrients are extracted and presented in Table 5 of this review. These include ten function claims for five non-nutritional substances, namely several types of dietary fibre (which includes psyllium, beta glucan from oats and/or barley, inulin from chicory and pectin from fruits; resistant maltodextrin/resistant dextrin, insoluble dietary fibre and slowly digestible starch), isomaltulose, sucromalt, xylitol and phytosterols/phytostanols and their esters. There are various conditions to be met to be eligble to make these claims.

This Regulation also permits making of reduction of disease risk claim. However, there is no published positive list of permitted claims. It is interesting to note that under the list of nutrient function claims in Appendix VII, one of the permitted claims for folic acid is:

Supplemental intake of folic acid improves maternal folate status; low maternal folate status is a risk factor for development of neural tube defect in the developing fetus.

As indicated above, permitted claims under Article 2 of Regulation 1/2022 include claims related to microorganisms, with the following conditions:

a. processed foods using live microorganisms must meet the requirements of safety, quality, and benefits;
b. types of microorganisms that can be used on processed food is determined by the Head of the Agency;

Table 5. List of permitted function claims for non-nutritional substances in Indonesia

Non-nutritional substance	*Claim statement*
Dietary fibre†	1. Soluble dietary fibre (psyllium, beta glucan from oats and/or barley, inulin from chicory and pectin from fruits) can help protect/maintain the function of the digestive tract Conditions: a. Processed food must include fibre as a constituent; and b. Processed food contains at least 3 g per serving of soluble dietary fibre
	2. Soluble dietary fibre (resistant maltodextrin/resistant dextrin) can help protect/maintain the function of the digestive tract Conditions: a. Processed food must include fibre as a constituent; and b. Processed food contains at least 5 g per serving of soluble dietary fibre
	3. Soluble dietary fibre (psyllium, beta glucan from oats and/or barley, inulin from chicory and pectin from fruits) can help lower blood cholesterol levels when accompanied with a diet low in saturated fat and cholesterol Conditions: a. Processed food must include fibre as a constituent; b. Processed food contains at least 3 g per serving of soluble dietary fibre c. Maximum total fat is 3 g per serving; or if the serving is less than 50 g, maximum total fat content is 3 g per 50 g; d. Maximum saturated fat is 1 g per serving and maximum calories from saturated fat is 15%; if the amount per serving is less than 100 g, maximum saturated fat content is at 1 g per 100 g and maximum calories from saturated fat 10%; and e. Maximum cholesterol at is 20 mg per serving; or if the serving is less than 50 g, maximum cholesterol content is 20 mg per 50 g Warning: The claim must be accompanied by the statements: a. Food consumption should be accompanied by the consumption of food low in fat, low in saturated fat and/or low cholesterol b. Consumption of these products must be accompanied by a healthy lifestyle
	4. Soluble dietary fibre (psyllium, beta glucan from oats and/or barley, inulin from chicory and pectin from fruits) and resistant maltodextrin/resistant dextrin can contribute to lowering the rise of blood sugar after a meal if accompanied with a balanced diet Conditions: a. Processed food must include fibre as a constituent; and b. Processed food contains at least 3 g per serving of soluble dietary fibre c. If the source of soluble dietary fibre used is in the form of resistant maltodextrin/resistant dextrin, then the amount of soluble dietary fibre should be at least 5 g per serving

Table 5. List of permitted function claims for non-nutritional substances in Indonesia (cont'd)

Non-nutritional substance	*Claim statement*
	5. Insoluble dietary fibre facilitates bowel movements (laxative), when accompanied by drinking enough water. Conditions: a. Processed food must include fibre as a constituent; and b. Processed food contains at least 3 g per serving of insoluble dietary fibre
	6. Contains slowly digestible starch (SDS) .....% of total starch. Conditions: a. At least 55% of energy is from available carbohydrates; b. At least 55% of available carbohydrates is total starch; and c. At least 40% of total starch is slowly digestible starch (SDS).
Isomaltulose	Isomaltulose is a sugar substitute sweetener that does not cause a rapid rise in blood glucose after consuming this product Condition: The processed food must meet the requirements for low sugar claim
Sucromalt	Sucromalt is a sugar substitute sweetener that does not cause a rapid rise in blood glucose after consumption of this product Conditions: a. The processed food must meet the requirements for low sugar claim b. The composition of sucromalt consists of fructose (35-45% dry weight), leucrose (7-15% dry weight), mono- and disaccharides (at most 3% dry weight) and oligasaccharides (40-60% dry weight).
Xylitol	Helps maintain naturally white teeth Conditions: a. The processed food contains at least 15% xylitol; b. The processed food must also contain at least 0.5% calcium carbonate; and c. Inclusion of the claim must be accompanied by inclusion of advice to consumers to keep brushing their teeth regularly
Phytosterol/ phytostanol, both in the ester and free form	Phytosterol/phytostanol/physterol ester/phytostanol ester helps lower cholesterol in patients with hyperlipidemia / hypercholesterolemia, when accompanied by a diet low in saturated fat and cholesterol Conditions: a. The processed food must contains 1.5 – 3 g of phytosterols/ phytostanol per day; and b. The claim may only be declared on margarine, spreadable margarine, dairy products and their processed products, breakfast cereals, mayonnaise, salad dressings and milk-flavoured drinks

Source: Annex VII of Regulation 1/2022 of the Indonesian FDA (2022)
[†]Must meet the requirement for claim as "source"

c. claims related to microorganisms can only be used after obtaining written approval from the Head the Agency. There is no published list of permitted health claims on microorganisms.

In relation to making health claims, Regulation 1/2022 has pointed that the following must be taken into consideration:

a. type, quantity, and function of nutrients or non-nutritional substances;
b. a reasonable amount of food consumed per day;
c. balanced food consumption pattern;
d. public health condition;
e. the appropriateness of the food to serve as a carrier for the nutrient or non-nutritional substance; and
f. appropriateness of the food to include claims.

In addition, Article 5 of the said Regulation summarises the requirements for making claims on labels of processed foods. Besides meeting the basic requirements for the relevant food category, processed foods must meet the following nutritional criteria before a claim (including other function claim) can be placed on the label:

One serving of the processed food must not exceed the following nutritional parameters:

- 18 g total fat;
- 6 g of saturated fat;
- 60 mg cholesterol; and
- 300 mg sodium.

This regulation has also clearly specified that manufacturers are prohibited from the following:

a. include claims for processed foods intended for infants, except otherwise provided for;
b. include claims for reducing disease risk for processed foods intended for children aged 1 (one) to 3 (three) years, except otherwise provided for;
c. include claims declaring free of nutritional/non-nutritional substances in processed foods which naturally do not contain nutritional/non-nutritional substances, except otherwise provided for;
d. contains a statement that the consumption of the processed food can meet all the nutritional needs;
e. list claims that leverage concerns of consumers;
f. include claims that cause consumers to consume the processed food in an inappropriate manner; and/or
g. include a claim that illustrates that the processed food can prevent, treat or cure disease.

Industry may apply for additional health claims not currently in the positive list via an online system of the Indonesian FDA. Chapter III of the said Regulation 1/2022 deals with review of applications for new claims (FDA Indonesia, 2022). The information that are required to be submitted for the intended claim is provided in Annex XI of the said regulations which has six sections. Part A stipulates the requirements for claims which are not related to microorganisms (i.e. claims related to nutritional and non-nutritional substances and health claims, isotonic claim and vegan claim). Information required include those related to the intended claim and regarding the foods bearing the claim, as well as scientific substiation documents.

Parts B-F of this Annex XI provide the requirements for claims related to microorganisms. Parts B and C lists the data requirements for starter cultures with identified and unidentified microorganisms in fermentation foods; part D presents data requirements for microorganisms for use as

food ingredients (without claim as probiotic). Part E lists in detail the data requirements for use of probiotics in processed foods. These include full details of the microorganism, functional characteristics, safety data and beneficial effects. Details on the intended food for addition of the probiotic are also required, including amount of the microorganism to be added.

For microorganisms which have been approved for use in foods and beverages, industry may apply for functional health claims or reduction of disease risk claims. Details of the requirements are provide in Part F of Annex XI. The requirements for the data to be submitted to substantiate the intended claim are indicated in this part.

Regulation 1/2022 also details out the procedure for review of applications for claims in Annex XII. Detailed information on the food must be provided including physical and chemical properties of the food, metabolism, toxicological data from animals as well as tolerance studies on humans. For reduction of disease risk claim, evidence must preferably be provided through randomised controlled trials. A list of items to be noted when conducting human trials are provided in the Annex, including subjects of the study, dietary data and statistical methods. The appropriate biomarkers and end point are also explained. Applications shall be evaluated by an independent panel of experts. The scientific findings submitted should demonstate that consumption of an amount of the food as recommended shall bring about a statistically and clinically significant claimed effect.

Annex XIII outlines the procedure for review of the safety and beneficial effects of microorganisms in foods, either in fermentation process or added to food with or without the inclusion of probiotic claims and/or health claims. Of particular relevance to this publication are the sections related to the review of probiotics either with or without health claims. The permitted claim on the label of approved products are:

- claim of "Probiotics" which can be accompanied by a generic claim, *"Helps maintain a healthy digestive tract"*.
- health claims (function claims and disease risk reduction claims) can be listed according to the findings of beneficial effects obtained.

All the types of claims pemitted under this Regulation must be proven by the results of the analysis of accredited laboratories or government laboratories. In the case of imported processed foods, analysis results can be issued by:

a. laboratory from the country of origin that has been accredited by the competent authority in the country of origin; or
b. laboratory from the country of origin that has mutual recognition agreements with authorised institutions and/or accredited laboratories in Indonesia.

Malaysia

Health claims permitted in the Malaysia Food Regulations 1985 are nutrient function claim and other function claim. Disease risk reduction claim is not permitted in Malaysia. Relevant to this review is other function claim in Regulation 18F (MOH Malaysia, 2020), defined as:

> *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.*

The said Regulation has provided a positive list of permitted other function claims as given in Table IV to the Fifth A Schedule (see Table 6). As listed in the Table, there are 22 bioactive non-nutritional food components in

this positive list for 43 other function claims. Each other function claim in the Table also lists the minimum amount of the bioactive food component and other conditions that must be met. The Regulation also emphasises that 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.

The industry may apply for new other function claims not in the positive list. Applicants must be made in a specific form prescribed by FSQD (Application for Nutrition Function Claim) (available from MOH website: http://fsq.moh.gov.my/v6/xs/page.php?id=72). A prerequisite is that the bioactive non-nutritional food components must first be approved for use as a permitted added nutrient in Table I of the Twelfth Schedule. The items required in the application form are similar to that for applying for addition of bioactive food components to the positive list. Besides the basic information required, the application must provide scientific data to substantiate the other function claim and state the minimum amount required for the claimed effect as specified in Table III to the Fifth A Schedule. More details of the data required and the application review process by the expert committee are as summarised in the section on applying for use of new bioactive non-nutritional food components.

As discussed in the previous section, Regulation 26A of Malaysia Food Regulations 1985 permits the addition of probiotic cultures to foods (MOH Malaysia, 2017b). With regard to permitted health claim for probiotic-containing foods, only a pre-approved generic function claim is permitted under this regulation, namely: *"Probiotic cultures help in improving intestinal or gut function"* or any other words of similar meaning. Malaysia does not allow disease risk reduction health claims to be made on foods, including probiotic-containing foods, although 'other function claims' may be considered, if supported by scientific substantiation.

Myanmar

There is no specific regulatory framework for reviewing applications for health claims related to bioactive non-nutritional food components. Applications may be submitted to FDA, accompanied by scientific substantiation, and will be reviewed and permitted on a case-by-case basis. FDA does not publish a positive list of permitted health claims. FDA can inform industry and consumers if there are enquiries if a particular health claim is permitted. It is however emphasised that the permitted claim should not state or imply that it can prevent, treat or cure any disease. There are no provisions for health claims related to probiotics.

Philippines

Health claims are permitted by the FDA in the Philippines, via Bureau Circular No. 2007-002, Guidelines in the Use of Nutrition and Health Claims in Food (FDA Philippines, 2007). This circular announces the adoption of the Codex Alimentarius Commission Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) (FAO/WHO, 2013) in the evaluation of the use of nutrition and health claims in food labelling and in the advertisement of food products. As summarised above, these Codex guidelines provide for making of other function claims for beneficial effects related to bioactive non-nutritional food components.

FDA of the Philippines does not publish a positive list of permitted health claims, including those related to bioactive non-nutritional food components. Stakeholders can be informed of permitted health claims through replies to their inquiries via letters, emails, calls or face-to-face

Table 6. List of permitted other function claims and required conditions in Malaysia

Component	*Claims*	*Minimum amount required*	*Conditions*
Beta glucan	Beta glucan from (state the source) helps reduce cholesterol.	0.75 g per serving	(i) Source of beta glucan shall be from oat and barley. (ii) The food to be added with beta glucan shall also contain total dietary fibre for not less than amount required to claim as "source": – 3 g per 100 g (solids) – 1.5 g per 100 ml (liquids) (iii) There shall be written on the label the following statement: "Amount recommended for cholesterol lowering effect is 3 g per day".
Beta glucan from barley soluble fibre	(i) Beta glucan from barley soluble fibre helps lower the rise of blood glucose provided it is not consumed together with other food. (ii) Beta glucan from barley soluble fibre contributes to the reduction of the rise in blood glucose provided it is not consumed together with other food.	6.5 g per 100g	(i) This claim is only permitted in cereal and cereal based product. (ii) This claim is only permitted for product where the macronutrient profile (carbohydrate, protein and fat) complies with Recommended Nutrient Intake (RNI) Malaysia. (iii) There shall be written on the label the following statement: "Before deciding to use this product, seek the advice of a health professional".
Beta glucan from oat soluble fibre	Beta glucan from oat soluble fibre helps to lower the rise of blood glucose provided it is not consumed together with other food.	6.5 g per 100 g	(i) This claim is only permitted in cereal and cereal based product. (ii) This claim is only permitted for product where the macronutrient profile (carbohydrates, proteins and fats) complies with the Recommended Nutrient Intake (RNI) Malaysia. (iii) There shall be written on the label of cereal and cereal based product the following statement: "Before deciding to use this product seek the advice of a health professional".
Beta glucan from yeast	Beta glucan from yeast may help to support immune system associated with colds.	0.05 g per serving	(i) Beta glucan from yeast shall be more than 75% on a dry weight basis. (ii) There shall be written on the label the following statement: "Amount recommended for claim effect is 0.2 g per day".

Table 6. List of permitted other function claims and required conditions in Malaysia (cont'd)

Component	*Claims*	*Minimum amount required*	*Conditions*
Beta palmitin	(i) Beta palmitin contributes to increase calcium absorption. (ii) Beta palmitin contributes to increase fat absorption.	(i) >18 percent C16:0 content based on total fatty acids (ii) > 40 per cent C16:0 in sn-2 position based on total C16:0 content	Nil
Bifidobacterium lactis	(i) *Bifidobacterium lactis* helps to improve a beneficial intestinal microflora. (ii) *Bifidobacterium lactis* helps to reduce the incidence of diarrhea.	1 x 10^6 minimum viable cells per gram	These claims are only permitted in infant formula, follow-up formula, formulated milk powder for children and cereal based food for infant and children.
Calcium 3-hydroxy-3-methyl butyrate monohydrate (CaHMB)	(i) CaHMB helps to regain strength. (ii) CaHMB supports tissue building.	1.5 g per serving	This claim is only permitted in formula dietary foods.
Galacto-oligosaccharide (GOS) and polydextrose (PDX) mixture	GOS and PDX mixture is a prebiotic. GOS and PDX mixture is a bifidogenic.	0.4g per100ml (0.2g per100ml GOS and 0.2 g per 100ml PDX)	(i) Mixture containing 50 per cent (weight over weight) GOS and 50 percent (weight over weight) PDX. (ii) These claims are only permitted in infant formula and follow-up formula.
Oligofructose-inulin mixture	Oligofructose-inulin mixture helps to increase calcium absorption and increase bone mineral density when taken with calcium rich food.	2 g per serving	(i) Oligofructose-inulin mixture containing shorter chain inulin-(oligofructose DP 3-9) and longer chain inulin (inulin DP ≥10) in a 50:50 ratio ± 10% each. (ii) Total fructant content in the mixture shall be more than 90 per cent on dry weight basis.

Table 6. List of permitted other function claims and required conditions in Malaysia (cont'd)

Component	*Claims*	*Minimum amount required*	*Conditions*
Oligosaccharide mixture containing galacto-oligosaccharide (GOS) and long chain fructo-oligosaccharide (lcFOS)	Oligosaccharide mixture containing GOS and lcFOS helps to improve the gut or intestinal immune system of infant.	The component (oligosaccharide mixture) shall be 0.8 g per 100 ml.	(i) Oligosaccharide mixture containing 90 per cent (weight per weight) GOS and 10 per cent (weight per weight) lcFOS. (ii) This claim is only permitted in infant formula and follow up formula.
	(i) Oligosaccharide mixture containing GOS and lcFOS is a prebiotic. (ii) Oligosaccharide mixture containing GOS and lcFOS is a bifidogenic. (iii) Oligosaccharide mixture containing GOS and lcFOS helps to increase intestinal bifidobacteria. (iv) Oligosaccharide mixture containing GOS and lcFOS helps to maintain a good intestinal environment.	0.4 g per 100 ml	(i) Oligosaccharide mixture containing 90 per cent (weight per weight) GOS and 10 per cent (weight per weight) lcFOS. (ii) These claims are only permitted in infant formula, follow up formula and formulated milk powder for children. (iii) The component (oligosaccharide mixture) shall not exceed 0.8 g per 100 ml.
Resistant dextrin or resistant maltodextrin	Resistant dextrin or resistant maltodextrin is a soluble dietary fibre that helps to regulate or promote regular bowel movement.	2.5 g per serving	Addition and claim for resistant dextrin or resistant maltodextrin are not permitted in infant formula.
	(i) Resistant dextrin or resistant maltodextrin is a prebiotic. (ii) Resistant dextrin or resistant maltodextrin is a bifidogenic. (iii) Resistant dextrin or resistant maltodextrin helps increase intestinal bifidobacteria. (iv) Resistant dextrin or resistant maltodextrin helps maintain a good intestinal environment.	4 g per serving	The minimum amount that must be present in the food to give the claim effect is proposed to be 8 g per day.

Table 6. List of permitted other function claims and required conditions in Malaysia (cont'd)

Component	*Claims*	*Minimum amount required*	*Conditions*
Docosahexaenoic acid (DHA) and Arachidonic acid (ARA)	DHA and ARA helps to contribute in the visual development of infant.	A combination of 17 mg per 100 kcal DHA and 34 mg per 100 kcal of ARA	This claim is only permitted in infant formula product.
D-ribose	D-ribose helps to promote energy recovery during or after physical activities.	3 g per serving	i) This claim is only permitted in formula dietary foods. ii) There shall be written on the label the following statement: "Do not exceed 2 servings per day".
Inulin	(i) Inulin is a prebiotic. (ii) Inulin is a bifidogenic. (iii) Inulin helps to increase intestinal bifidobacteria and maintain a good intestinal environment.	1.25 g per serving	This minimum level is specified for food other than infant formula.
		0.4 g per 100 ml on a ready to drink basis	(i) This minimum level is specified for infant formula only. (ii) The component (inulin and oligofructose/ fructooligosaccride (FOS)) shall not exceed 0.6 g per 100 ml.
Isomaltulose	(i) Isomaltulose is a slowly hydrolysed to glucose and fructose compared to sucrose. (ii) Isomaltulose provides longer lasting energy compared to sucrose. (iii) Isomaltulose is a slowly released source of energy compared to sucrose.	15 g per serving	Addition and claim for isomaltulose are not permitted in infant formula.

Table 6. List of permitted other function claims and required conditions in Malaysia (cont'd)

Component	*Claims*	*Minimum amount required*	*Conditions*
High amylose maize resistant starch (HAMRS)	HAMRS helps to improve or promote intestinal function or environment.	2.5 g per serving	Nil
Lutein	Lutein as a predominant macular pigment in the retina that is able to filter blue light and helps to protect the eyes.	2.5 µg per 100ml (3.7 µg per 100 kcal)	This minimum level is specified for infant formula only.
		20 µg per 100ml (30 µg per 100 kcal)	This minimum level is specified for follow up formula only.
		20 µg per 100ml (20 µg per 100 kcal)	This minimum level is specified for formulated milk powder for children only.
Oligofructose/ fructo-oligosaccharide (FOS)	(i) FOS is a prebiotic. (ii) FOS is a bifidogenic. (iii) FOS helps to increase intestinal bifidobacteria and maintain a good intestinal environment.	1.25 g per serving	This minimum level is specified for food other than infant formula.
		0.4 g per 100 ml on a ready to drink basis	(i) This minimum level is specified for infant formula only. (ii) The component of inulin and FOS shall not exceed 0.6 g per 100 ml.
Polydextrose	(i) Polydextrose is a bifidogenic. (ii) Polydextrose helps increase intestinal bifidobacteria. (iii) Polydextrose helps maintain a good intestinal microflora.	1.25 g per serving	Nil
Soy protein	Soy protein helps to reduce cholesterol.	5 g per serving	There shall be written on the label the following statement: "Amount recommended to give the lowering effect on the blood cholesterol is 25 g per day".

Table 6. List of permitted other function claims and required conditions in Malaysia (cont'd)

Component	*Claims*	*Minimum amount required*	*Conditions*
Plant sterol or plant stanol or plant sterol ester	Plant sterol or plant stanol or plant sterol ester helps reduce cholesterol.	0.4 g per serving in a "free basis" form.	(i) Types of plant sterol or plant stanol permitted: "plant sterol or plant stanol, phytosterols or phytostanol, sitosterol, campesterol, stigmasterol or other related plant stanol". (ii) Types of plant sterol esters permitted: "campesterol ester, stigmasterol ester and beta-sitosterol ester" (iii) Amount of plant sterol or plant stanol or plant sterol ester in a "free basis" form to be added in food shall not exceed 3 g per day. (iv) Statement of the total amount of plant sterol or plant stanol or plant sterol ester contained in the product shall be expressed in metric units per 100 g or per 100 ml or per package if the package contains only a single portion and per serving as quantified on the label. (v) Only the terms "plant sterol" or "plant stanol" or "plant sterol ester" shall be used in stating the presence of such components. (vi) There shall be written on the label the following statements: a) "Not recommended for pregnant and lactating women, and young children under the age of five years"; b) "Persons on cholesterol-lowering medication shall seek medical advice before consuming this product"; c) "This product is consumed as part of a balanced and varied diet and shall include regular consumption of fruits and vegetables to help maintain the carotenoid level"; and d) "With added plant sterols or plant stanol or plant sterol ester" in not less than 10 point lettering".

Table 6. List of permitted other function claims and required conditions in Malaysia (cont'd)

Component	*Claims*	*Minimum amount required*	*Conditions*
Slowly digestible starch (SDS)	A food containing slowly digestible starch (SDS), consumed as part of the normal first meal of the day, releases carbohydrates gradually and provides energy throughout the morning	At least 40% of the available starch must be present as slowly digestible starch (SDS)	Claim only permitted for SDS from starch naturally occurring in starchy foods where available carbohydrates provide at least 55 % of the total energy and where at least 55 % of the available carbohydrates is available starch.

For all the above claims, words/sentences of similar meaning can also be used
Source: Table IV of the Fifth A Schedule, Malaysia Food Regulations 1985 (MOH Malaysia, 2020)

discussion (for walk-in clients) and through results of their registration application.

However, industry may apply to the FDA for the use of any intended health claims related to bioactive non-nutritional food components. This is provided for under Administrative Order No. 2014-0029 Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and Other Food Products, and For Other Purposes (DOH Philippines, 2014). There is no specific prescribed form for submitting applications. No details of the requirements for application or type of scientific information required have been provided.

With regard to health claims for probiotics, the BFAD Circular in the Philippines has allowed the use of four pre-approved claims related to probiotics and can be reflected on the product labels, used for advertisement and product promotion (BFAD, 2004). These claims include enhancement of intestinal ecology, improvement of lactose malabsorption, improvement of digestion and aid to the enhancement of natural resistance to intestinal infections. Companies are permitted to apply for the use of these specified health claims on probiotics by going through the same review process as the procedure for evaluation of probiotics for food use.

Singapore

Health claims are permitted in Singapore, including nutrient function claims, other function claims and reduction of disease risk claims. A list of the three types of approved health claims is included in "A Guide to Food Labelling and Advertisements" (SFA, 2021). The definitions of these claims are as given in Codex Alimentarius Guidelines for Use of Nutrition and Health Claims (FAO/WHO, 2013). Other function claims describe the health effect of bioactive non-nutritional food constituents, e.g.

"Probiotics helps in digestion" or *"Inulin helps in calcium absorption"*. A total of 17 other function claims for 12 bioactive food components are in the list of accepted claims (SFA, 2021) (Table 7).

Industry may apply to the SFA for the use of new health claims, including other function claims using a prescribed application form. An outline of the application procedure is given in the Guide mentioned above (SFA, 2021). Besides the identity of the food constituent and its characteristics, reports of human intervention studies (at least 5 but not more than 10, and preferably published in the past 10 years) must be submitted to substantiate the proposed claim. Guidance information (including details or scientific data required), application form and checklist for application are provided in the document. Form for Application For Use Of Health Claims For Food Intended For Sale In Singapore is available from the SFA e-services website: https://www.sfa.gov.sg/e-services?type=food-manufacturing&page=1.

All applications will be reviewed by an expert committee which comprises reputable scientific experts with relevant professional training and experience from various government bodies, tertiary institutions and industry associations.

In the list of permitted other function claims mentioned above (Table 7), four function claims relating to the role of probiotics in helping to maintain a healthy digestive system through suppressing the growth of harmful bacteria may be used for probiotic-containing foods. The exact species of the probiotic present in the product must be specified on the label. The viable count of the probiotic present in the product that is able to bring about the claimed effect must also be indicated (SFA, 2021).

Thailand

Health claims are provided for under Food Act B.E. 2522, specifically sections 6(10), 40 and 41 (MoPH Thailand, 1979). A regulation on health claims is being drafted by the Thai FDA. In the meantime, details of the permitted health claims and the associated conditions of use are given in the Public Manual on Requesting for assessment of health claim by Thai FDA (FDA Thailand, 2020). Three types of health claims are permitted and their definition are as in the Codex guidelines on Nutrition and Health Claims (CAC/GL 23-1997), namely nutrient function claim, other function claim and reduction of disease risk claim. (FAO/WHO, 2013).

Other function claims are defined as *"presentations of properties or benefits that describe 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"*.

The Public Manual outlines various criteria and conditions to be met for the health claims. Other function claims will not be permitted for foods that contain:

- Total fat more than 13 g, or
- Saturated fat more than 4 g, or
- Cholesterol more than 600 mg, or
- Sodium more than 360 mg

in amount of one recommended serving size and one serving size declared on labels, or if no recommended serving size specified, nutrient content in 100 g or 100 ml is calculated.

The Public Manual gives a great deal of emphasis on the importance of submitting the required scientific evidences to substantiate the applied claim. Health claims shall be based on relevant and available scientific evidence which is sufficient to prove relation between such claim and health. It consists of 2 parts of data including information on:

Table 7. List of acceptable other function claims in Singapore

Nutrients / Food constituents	*Claims*	*Criteria*
Chromium	Chromium contributes to normal macronutrient metabolism	• ≥ 6mcg in per 100g or 100ml of food • The amount of chromium must be declared under the nutrition information panel
Collagen	Collagen is a protein in connective tissues found in skin, bones and muscles	• The addition of collagen has to be disclosed under the statement of ingredients
Docosahexaenoic acid (DHA) and Arachidonic acid (ARA) – claim only for food for children up to 3 years of age	DHA and ARA are important building blocks for development of the brain and eyes for children up to 3 years of age.	• Food must be labelled clearly for this age group • The amounts of DHA and ARA must be declared under the nutrition information panel
Nucleotides - claim only for food for children up to 6 years of age	Nucleotides are essential to normal cell function and replication, which are important for the overall growth and development of children up to 6 years of age	• Food must be labelled clearly for this age group • The amounts of nucleotides must be declared under the nutrition information panel
Taurine - claim only for food for children up to 6 years of age	Taurine helps to support overall mental and physical development for children up to 6 years of age	• Food must be labelled clearly for this age group • The amount of taurine must be declared under the nutrition information panel
Inulin	1. Inulin helps in calcium absorption	• ≥ 133.33mg of calcium in per reference quantity of the food as specified Table 8 in section “Nutrition claims” • The amount of calcium must be declared under the nutrition information panel • The amount of inulin present in each serving or other equivalents of the product must be declared on the product label • Food manufacturer/importer to ensure that the amount and combinations of shorter and longer chain inulin present in the product can bring about the claimed effect.
	2. Inulin helps support growth or beneficial bacteria/good intestinal flora in gut	• Food manufacturer/importer to ensure that the amount of inulin present in the product can bring about the claimed effect.
	3. Inulin helps increase intestinal bifidobacteria and helps maintain a good intestinal environment	

Table 7. List of acceptable other function claims in Singapore (cont'd)

Nutrients / Food constituents	*Claims*	*Criteria*
Oligofructose (Fructo-oligosaccharides)	Oligofructose stimulates the bifidobacteria, resulting in a significant increase of the beneficial bifidobacteria in the intestinal tract. At the same time, the presence of less desirable bacteria is significantly reduced	• Food manufacturer/importer to ensure that the amount of the oligofructose present in the product can bring about the claimed effect.
Prebiotics	Prebiotic promotes the growth of good *Bifidus* bacteria to help maintain a healthy digestive system	• The exact identity of the prebiotic and must be declared on the product label • Food manufacturer/importer to ensure that the amount of prebiotic present in the product can bring about the claimed effect.
Prebiotic blend of Galacto-oligosaccharides and long chain Fructo-oligosaccharide	Prebiotic blend (galacto- oligosaccharides and long chain fructo- oligosaccharides) support the child's natural defenses for children up to 6 years of age	• The combination of Galacto- oligosaccharides and long chain Fructo-oligosaccharide present in the product must be in ratio of 9:1
Probiotics	1. Probiotics to help maintain a healthy digestive system 2. Probiotics helps in digestion 3. Probiotics helps to maintain a desirable balance of beneficial bacterial in the digestive system 4. Probiotics helps to suppress/fight against harmful bacteria in the digestive system, thereby helping to maintain a healthy digestive system	• The exact specie of the probiotic present in the product must be declared on the product label • Food manufacturer/importer • to ensure that the viable count of the probiotic present in the product can bring about the claimed effect.

Table 7. List of acceptable other function claims in Singapore (cont'd)

Nutrients / Food constituents	*Claims*	*Criteria*
Plant sterols/stanols	Plant sterols/stanols have been shown to lower/ reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease	• Phytosterols, phytosterol esters, phytostanols or phytostanol esters may only be added to — (i) any edible vegetable fat or oil containing not more than 20 g of saturated fat per 100 g of total fat; (ii) any margarine or fat spread containing not more than 27 g of saturated fat per 100 g of total fat; or (iii) any other food containing not more than 3 g of total fat per 100 g or 1.5 g of total fat per 100 ml. • The following mandatory information must be declared on the product label: (i) The product is a special purpose food intended for people who want to lower their blood cholesterol level; (ii) The product may not be nutritionally appropriate for pregnant and breast- feeding women and children under the age of 5 years; (iii) The product should be used as part of a balanced and varied diet; (iv) Consumption in a day of a total of more than 3g of phytosterols and/or phytostanols does not provide any additional benefit in lowering blood cholesterol levels; (v) Consumption in a day of a total of at least 2g of phytosterols and/or phytostanols has been shown to lower blood cholesterol levels; and (vi) A statement suggesting the amount of the food (in g or ml) to be consumed each time (referred to as a serving), and a statement of the total amount of phytosterols and phytostanols that each serving contains.

Table 7. List of acceptable other function claims in Singapore (cont'd)

Nutrients / Food constituents	*Claims*	*Criteria*
Barley or Oat beta-glucan	Barley beta-glucans / Oat beta-glucans have been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease.	• The cholesterol, saturated fatty acids and trans fatty acids present in the food must be within the following levels: (i) in the case of solid food — a. not more than 20 mg of cholesterol per 100 g; b. not more than 1.5 g of saturated fatty acids and c. trans fatty acids per 100 g; and d. not more than 10% of kilocalories from e. saturated fatty acids and trans fatty acids; or (ii) in the case of liquid food — a. not more than 10 mg of cholesterol per 100 ml; b. not more than 0.75 g of saturated fatty acids and c. trans fatty acids per 100 ml; and d. not more than 10% of kilocalories from saturated fatty acids and trans fatty acids. • The following mandatory information must be declared on the product label: (i) a statement or statements to the like effect that consumption of at least 3 g of barley beta-glucans or oat beta-glucans (as the case may be) in a day has been shown to lower blood cholesterol levels; and (ii) the amounts of barley beta-glucan or oat beta-glucans (as the case may be), cholesterol, saturated fatty acids and trans fatty acids, present in the food under the nutrition information panel.

a. the physiological role of the nutrient or on an acceptable relationship between diet and health;
b. the composition of the product relevant to the physiological role of the nutrient or the acceptable relationship between diet and health unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food.

Applications for other function claims shall submit scientific evidence documents for consideration in the form of full copy of well-designed human intervention study published in reliable journal and either of the following document:

a. Systematic review or meta-analysis published in reliable journal or;
b. Recognised and reliable technical opinions from international recognised agencies, organisations, or scientific expert committee.

Supporting documents that may be submitted with the application include peer-reviewed published articles, animal study *in vivo, ex vivo*, or *in vitro*, observational evidence of epidemiological study which provide results consistent with the number of well-designed study, evidence-based reference texts, or other recognised and reliable texts (if any).

Details of the steps required to be taken by a corporate company when submitting an application for other function claim (or other health claims) is provided in detail in the afore-mentioned Public Manual. The review process undertaken by FDA is also outlined. Currently the Centre for Nutrition Assessment and Health Claims for Food Products of Thailand (CNACT) is designated by the Thai FDA for the review procedure. An ad hoc review/ expert committee involving a minimum of 3 experts from relevant subject areas relevant to the product/constituent is appointed to carry out the review. After completion of the assessment, a report is submitted to the Thai FDA for final approval. Once approved, the food component/constituent name and function can be displayed on food label. Advertisement can also be made after approval.

In relation to health claims for probiotics, a generic pre-approved health claim: *"Beneficial microorganism to the body"* or words of similar meaning may be used with prior approval by the Thai FDA (MoPH Thailand, 2011). Industry or importers may apply for probiotics health claims using a prescribed form. The regulation has provided clear guidelines for the criteria, procedure and conditions when submitting a health claim on probiotics. Scientific substantiation of the intended claim should be obtained from well-designed human intervention studies from at least two different institutes (MoPH Thailand, 2011).

Vietnam

There is no specific regulatory framework for making of health claims for biologically active ingredients in supplemented foods. The MOH Circular on Regulating Management of Functional Foods (MOH Vietnam, 2014) makes provision for the making of nutrition and health claims for functional foods. Article 8 outlines the health claims related to supplemented foods. The Circular emphasises that health claims can only be made when there is sufficient scientific evidence.

For probiotic-containing foods, there are no pre-approved health claims. However, companies may apply for health claims for these foods. The application for health claims follows the same procedure and requirements for application of a probiotic strain to be

registered for use under supplemented food or health supplement (Tee *et al.*, 2021).

DISCUSSION

From a review of the documents in Codex Alimentarius and the existing regulations in the eight SEA countries, it is clear that there is a great deal of importance being given to the role that bioactive food components may play in human health. These are not the traditionally recognised macro- and micro-nutrients.

There are significant differences in the regulatory control of the use of these bioactive food components in the eight countries in this review. Indonesia and Malaysia have promulgated specific regulations in relation to the addition of these bioactive non-nutritional food components in foods and beverages. Both countries have provided a positive list of the permitted bioactive food components that may be used, and also provided clear process for the industry to apply for additional such food components. Both countries have separate regulations that govern the making of function claims for non-nutrients, which refer to the beneficial physiological or health effects brought about by bioactive non-nutritional food components.

The other six countries in the review do not have specific regulations governing the use of bioactive non-nutritional food components. However, all these countries permit the making of other function claims, provided they are substantiated by scientific studies. This indicates the recognition given to the positive physiological roles that such non-nutritional components may have in the body.

All the eight countries in the review permit the making of function claims for non-nutritional substances. All these countries have regulations for this purpose or adopt Codex Alimentarius guideline on claims. Indonesia, Malaysia and Singapore have published positive list of permitted function claims for non-nutritional substances. Indonesia does not use the term “other function claim” for health benefits imparted by non-nutritional substances although the concept is the same.

All countries also permit industry to apply for additional function claims, though each country has slightly different requirements and process in place. One common requirement in all the countries is that applications must be accompanied by scientific evidence, preferably from human clinical trials.

In addition to the bioactive non-nutritional food components which as are the main focus of this review, all countries, except Myanmar allow the sale and marketing of probiotics in foods, another important functional food component. Indonesia, Malaysia, Philippines and Thailand have promulgated specific probiotic regulations and, except for Indonesia, have published positive list of probiotic strains that may be added to foods and beverages. All seven countries have provisions for the industry to apply for the use of probiotic strains, supported by the relevant documents on safety and beneficial effects. Malaysia, Philippines, Singapore and Thailand permit the use of a small number of pre-approved generic function claims related to probiotics.

CONCLUSION

Numerous epidemiological and clinical studies have demonstrated that bioactive non-nutritional food components or constituents are able to serve physiological roles beyond meeting basic nutritional requirements and may possess health-enhancing properties. This review has shown that all eight countries recognise the potential health

effects of these bioactive or functional components, and have made provisions in the regulatory framework for these non-nutritional substances. Two countries, Indonesia and Malaysia, have promulgated specific regulations to enable the addition of these components to foods with specific conditions. The other six countries, Brunei Darussalam, Myanmar, Philippines, Singapore, Thailand and Vietnam allow these food components to be used via applications for making other function claims, if they can be substantiated by scientific data. Codex Alimentarius guideline on claims has also a specific claim, other function claim, recognising the potential health benefits of such food components.

This review has indicated that there are significant differences in the approach to permitting the use of bioactive non-nutritional food components, the process for reviewing applications, as well as the associated other function claims. It does indicate that there are opportunities for sharing of experiences of the established systems, and discussion to potentially harmonise these processes among regulatory agencies in the region. Such a networking platform would be beneficial to the advancement of scientific and regulatory development of bioactive non-nutritional food components in the region and would benefit all stakeholders.

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Authors' contributions

Both authors contributed to the conceptualisation of paper, obtained regulations/documents for analysis, analysed and extracted relevant information, drafted manuscript, finalised manuscript for publication.

Conflict of interest

Authors declare that they have no conflicts of interest.

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