

The Development of Functional Food in Indonesia: Based on Regulation Compared to Other Countries

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Abstract: The trend of the prevalence of degenerative diseases is increasing nowadays including in Indonesia. As the level of education and the level of income of the Indonesian people grow, consumers' desire for food products is increasingly complex. In choosing food products, people today do not only choose foods that have a satisfying effect but are looking for products with other advantages, one of which is functional value for health. In developing functional food products in the food industry, many aspects must be considered and influenced for development. One of these aspects is the regulation governing the functional food. With the existence of clarity of regulation in the registration of functional food or food with claims to be an opportunity for the food industry in Indonesia to produce healthy food. However, many regulations governing food have caused the growth of the food industry in Indonesia to begin to decline. This paper examines the development of functional food based on regulation in Indonesia and compared to other countries such as Canada, India, Thailand, and Malaysia. Regulations regarding functional food issued by Indonesia are not much different from countries that have issued similar regulations. The food industry that will sell food products with health or other functional claims must provide scientific evidence and clinical trials to humans. However, this is burdensome for the food industry because clinical trials on food that are applied are almost the same as clinical trials on medicinal products.

1 INTRODUCTION

At this time, Indonesia faces a prolonged problem related to food that has an impact on nutrition and health. Consumption patterns and unhealthy lifestyles have caused malnutrition and health problems. This is indicated by the results of basic health research in 2018 (National Institute of Health Research and Development, 2019) which states that the trend of non-communicable diseases in Indonesia is increasing such as diabetes mellitus, hypertension and obesity compared to the results of health basic research in 2013 (Figure 1). In the end, the Indonesian people began to realize this condition, which led to a shift in consumption patterns that began to realize the importance of healthy living. Along with the increasing public awareness of food, the demand for healthy food is also increasingly shifting. Food that is now starting to be in great demand by consumers is functional food that is food that not only has good nutritional composition and attractive appearance and taste, but also has certain physiological functions for the body, for example to lower blood pressure, reduce

cholesterol levels, reduce levels blood sugar, increase the absorption of calcium, and others.

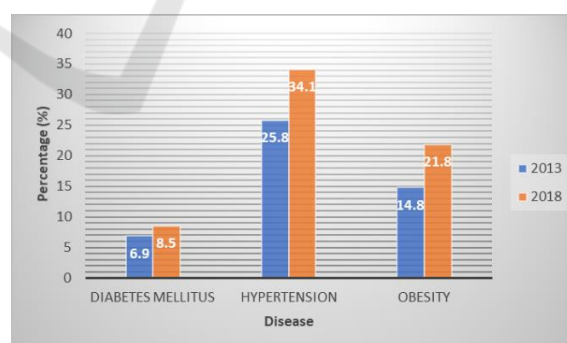


Figure 1: Trend of non-communicable diseases. *Source: National Institute of Health Research and Development, 2019.*

In Asia, where functional foods have been regarded as an integral part of the culture for many years, there is a firm belief that foods and medicine come from the same source and serve the same purpose. However, functional foods actually have a

quite long history. In China, Japan and other Asian countries, many types of foods have traditionally been associated with specific health benefits (Weststrate *et.al*, 2002). In Japan, research on functional foods started in the early 1980s. In 1991, a specific regulatory framework concerning Food for Specific Health Use (called FOSHU) was introduced, which made it possible to make limited health claims after receiving approval from the Ministry of Health. The key to success for food manufacturers is to develop products that are accepted by consumers and are consistent with the consumer's understanding and appreciation of functional foods within the existing culture. However, scientists and regulators have only recently begun to agree that the functionality of functional foods should be found in whole foods rather than in their individual components (Verschuren, 2002). After the introduction of the FOSHU regulation, the number of functional food products increased, especially from 1997 to 2007, according to consumer demand, the net sales of the FOSHU products were the highest in 2007 at 6.2 billion dollars (110 JPY/USD) (Iwatani and Yamamoto, 2019). In Canada there is also no universally accepted definition of functional foods, but 60% of the people select foods they believe are functional. Canada also has undertaken initiatives to establish nutrient and health claims regulations. These claims describe the relationship between a food component and a disease or health-related condition. The approval of claims has been based on an extensive review of existing scientific literature in the form of an authoritative statement of a scientific body (Verschuren, 2002).

Functional food manufacturers follow specific processes to assure the creation of products with true values. Many regulatory authorities around the world craft strict and detailed regulations and standards to ensure the efficiency and safety of the foods. The regulatory bodies also may study if the products provide true value for consumers. Regulations vary from country to country, which makes exporting functional foods a challenging task, especially if the regulations are not clear, or if the products have not been customized to suit the regulation of the importing country (Farid *et.al*, 2019).

Indonesia itself has huge opportunities for the development of the functional food industry. Currently, there has been a great deal of attention given to the functionality of foods that are endemic in Indonesia. Indonesia's traditional food wealth is very diverse and is believed to have certain health benefits, tempeh, honey, turmeric, ginger, aromatic ginger (*kencur*), *Curcuma zanthorrhiza* (Javanese turmeric),

Javanese tamarind juice and so forth. Several types of Indonesian local foodstuffs whose prospects have been assessed for functional foodstuff include uwi (*Dioscorea alata*) (Hapsari, 2014), microalgae (Nur, 2014), and sweet potatoes (Ginting *et al*, 2011). Javanese tradition in the development of herbal medicine, is a traditional wealth that has the potential to develop functional foods typical of Indonesia.

To support the development of functional food industry in Indonesia, there are several policies that have been issued by government. However, these regulations have not had a significant impact on the development of functional food products or food with claims in Indonesia. Functional food in Indonesia is more dominated by processed food sourced from fibre, milk and flour. In addition, the growth of the food and beverage industry in Indonesia in 2018 has decreased which is only about 7.91% compared to 2017 where the growth of 9.23% (Ministry of Industry, 2019). Therefore, this paper explains the development of functional food in Indonesia based on the functional food registration process in accordance with policies issued by Indonesia compared to other countries such as Canada, India, Thailand and Malaysia.

2 METHOD

This paper is based on the results of a comparative study with scientific review of the relevant literature and regulations or policies issued by authorized officials in their respective countries (Canada, India, Thailand and Malaysia) related to functional food regulation. The selection of the countries to be studied is based on the similarities of those countries in the regulation of functional food.

The comparative study reveals the information about the specific regulation, year of implementation, the regulatory agencies, the definition of functional food, claims, and requirements and systems for clinical trials in each country.

3 THE DEVELOPMENT OF FUNCTIONAL FOOD REGULATION IN INDONESIA

Regulation on functional food in Indonesia began since Head of *Badan Pengawas Obat dan Makanan* (the national authority on Food and Drugs in Indonesia) has issued basic provisions on functional food supervision No.HK.00.05.52.0685. However,

the food fortification program that was launched in 1996 to improve the nutritional status of the community in line with functional foods which classified as dietary foods. The most popular constituents of functional foods, promoted by food industries for young children, are the very long essential polyunsaturated fatty acids, such as omega-3 (eicosapentaenoic acid and docosahexaenoic acid) and omega-6 fatty acids as well as calcium (Zawistowski, 2014). Functional foods in Indonesia can be marketed using the same regulatory system that is applied for conventional foods, as long as this category of foods contains.

This regulation defined a functional food as processed food that contains one or more functional components which, based on scientific studies, have certain physiological functions, are proven to be harmless and beneficial to health. On the food label, permitted claims are nutrition content claims and nutrition function claims, while health claims are prohibited.

In 2011, BPOM revised the regulation about Basic provisions on functional food supervision in 2005 with Regulation of the head of BPOM regarding claims in labels, and processed food advertising supervision. In this regulation, functional food definition is still being used. It regulates about processed food with claim. There are three claims that approved by the government to registered functional food. Three claims consist of nutrition claim, health

claim and glycaemic index claims. There are 2 additional claims that did not exist in the previous regulation, which is health claims and glycaemic index claims. In nutrition claim consist of nutrition claim and nutrient function claims. Then, in health claims consist of nutrition function claims, other function claims, and disease risk reduction claim.

Based on regulation, functional food must meet the following requirements:

- a. contains types of food components in the amount according to the limits specified as set out in Table 1 about other functional claims and Table 2 about claims for disease risk reduction;
- b. has sensory characteristics such as appearance, colour, or texture consistency and taste acceptable to consumers; and
- c. served and consumed as food or drinks.

Function claim and disease risk reduction claim must be based on the results of human studies that meet applicable scientific principles (experimental randomized controlled trials (RCT) or observational studies if experimental studies are not possible). In vitro and animal research can be submitted to support the application.

In this regulation, a list of diseases that can be prevented through the content of functional food components has been established in it as listed in Table 2.

Table 1: Types of Food Component for Other Functional Claim.

Types of Food Component	Claims	Requirements
Soluble dietary fibre (Psyllium, beta glucan from oats, inulin from chicory and pectin from fruits)	help reduce blood cholesterol levels if accompanied by a diet low in saturated fat and low in cholesterol.	<ol style="list-style-type: none"> a. Must include the constituent components and their sources; b. Containing fibre at least 3 g per serving c. total fat as much as 3 g per serving, or if the serving is less than 50 g then the total fat content is as much as 3 g per 50 g; d. saturated fat as much as 1 g per serving and calories derived from saturated fat as much as 15%, if the amount of serving is less than 100 grams, then the saturated fat content is as much as 1 gram per 100 grams and calories derived from saturated fat 10% maximum; e. cholesterol as much as 20 mg per serving, or if the serving is less than 50 g, the cholesterol content is as much as 20 mg per 50 g.
Soluble food fibre (Psyllium, beta glucan from oats, inulin from chicory and pectin from fruits)	Maintain the functioning of the digestive tract.	<ol style="list-style-type: none"> a. Must include the constituent components and their sources; b. Containing fibre at least 3 g per serving
Insoluble food fibre	Facilitate bowel movements (laxatives) and accompanied by drinking enough water	<ol style="list-style-type: none"> a. Must include the constituent components and their sources; b. Containing fibre at least 3 g per serving c. Soluble fibre (beta glucan) oats of at least 3 grams or more per day. d. Soluble fibre from psyllium seed husk of at least 7 grams per day.

Table 1: Types of Food Component for Other Functional Claim. (Cont.)

Types of Food Component	Claims	Requirements
Phytosterols and Phyto stanols	Reduce the absorption of cholesterol from food in the intestine if accompanied by a diet low in fat, low in saturated fat, and low in cholesterol.	<ul style="list-style-type: none"> Esterifying a mixture of phytosterols from edible oil with food grade fatty acids. A mixture of phytosterols must contain at least 80% beta-sitosterol, camp sterol and stigmasterol (combined weight). Esterifying a derivative of a Phyto stanols mixture from edible oil or a by-product of the process of making craft paper pulp with food grade fatty acids. The phyto stanols mixture must contain at least 80% cytostanol and campestanol (combined weight). at least 0.65 grams phytosterols per serving for spread and salad dressing or; at least 1.7 grams phytostanols per serving for spreads, salad dressing, snack bars, pickled milk; Only apply for types of food that do not require high heating in its preparation; Must meet following requirements: <ol style="list-style-type: none"> total fat as much as 3 g per serving, or if the serving is less than 50 g then the total fat content is as much as 3 g per 50 g; saturated fat as much as 1 g per serving and calories derived from saturated fat as much as 15%, if the amount of serving is less than 100 grams, then the saturated fat content is as much as 1 gram per 100 grams and calories derived from saturated fat 10% maximum; cholesterol as much as 20 mg per serving, or if the serving is less than 50 g, the cholesterol content is as much as 20 mg per 50 g. For food products that contain vegetable oil, replacement of the word "phytosterols" and " phyto stanols " to "sterol esters and vegetable oil stanols esters" allowed the origin of the vegetable oil is the only source of sterol ester / stanols in the food product. Fat content may exceed 3 g per 50 g by adding the statement: "see nutrition information for fat content value", but still contains 0.65 g or 1.7 g phyto stanols phytosterols per 50 grams of food especially for product spreads and salad dressings. Meet minimum nutrient requirements, except for salad dressing.

Source: Appendix IV in Regulation of Head BPOM, 2011.

Table 2: Types of Food Component for Disease Risk Reduction Claims.

Types of Food Component	Claims for Disease Risk Reduction	Requirement
Folic acid	<ul style="list-style-type: none"> Reduce the risk of failure of neural tube defects in the fetus, with a balanced nutritional diet. Reduce the risk of failure of neural tube defects in the fetus with accompanied by a balanced nutritional diet. 	<ul style="list-style-type: none"> Consumption of these foods a day can meet 100% RDA of folic acid. The food must not contain vitamin A in the form of retinol or pro vitamin A and vitamin D more than 100% AKG a day. The label should include a recommendation regarding product preparation, which is: "The product should be dissolved in boiled water which has a maximum temperature of 40° C, because at high temperatures folic acid will be damaged".
Calcium	Can help slow the occurrence of osteoporosis in the future if accompanied by regular physical exercise and balanced nutritional consumption.	<ul style="list-style-type: none"> Must contain at least 75% of the RDA per day according to age group. Phosphorus levels should not exceed calcium levels. Calcium should not be associated with height increase (bone length).

Table 2: Types of Food Component for Disease Risk Reduction Claims. (Cont.)

Types of Food Component	Claims for Disease Risk Reduction	Requirement
Sugar Alcohol/ Polyol	Can help reduce the risk of dental caries, when associated with lifestyle habits.	<ul style="list-style-type: none"> Does not contain mono- and di-saccharides. Possible using the following shortened claim: "This food can help reduce the risk of dental caries". Must not mention the degree of reduction in the risk of dental caries due to consumption of food containing polyols. Shall not be mentioned that the consumption of food containing polyols are the only way to reduce the risk of dental caries.
Dietary fiber soluble (psyllium, beta glucan from oats, inulin from chicory and pectin from fruit, inulin from chicory and pectin from fruit)	<ul style="list-style-type: none"> Can help reduce the risk of coronary heart disease, a disease associated with multi factors. Can help control blood sugar in patients with diabetes mellitus type II. 	<ul style="list-style-type: none"> Meet the following requirements: <ul style="list-style-type: none"> a. As much as 3 g total fat per serving, or if the serving is less than 50 g, the total fat content is as much as 3 g per 50 g; b. As much as 1 g saturated fat per serving and calories derived from saturated fat as much as 15%, if the amount of serving is less than 100 grams, then the saturated fat content is as much as 1 gram per 100 grams and calories derived from saturated fat 10% maximum; c. as much as 20 mg cholesterol per serving, or if the serving is less than 50 g, the cholesterol content is as much as 20 mg per 50 g. At least 0.6 g soluble food fibre per serving; Prohibited to include statements related to colon cancer. At least 3 g soluble fibre (beta glucan) oats or more per day. At least 7 g soluble fibre from psyllium seed husk per day.
Phytosterols and phytostanols	Can help reduce the risk of coronary heart disease.	<ul style="list-style-type: none"> Food contains phytosterols of at least 0.65 grams per serving for spread and salad dressing or; Food contains phytostanols of at least 1.7 grams of phytostanols per serving for spreads, salad dressing, snack bars, pickled milk; Only apply for types of food that do not require high heating in its preparation; Must meet following requirements: <ul style="list-style-type: none"> d. total fat as much as 3 g per serving, or if the serving is less than 50 g then the total fat content is as much as 3 g per 50 g; e. saturated fat as much as 1 g per serving and calories derived from saturated fat as much as 15%, if the amount of serving is less than 100 grams, then the saturated fat content is as much as 1 gram per 100 grams and calories derived from saturated fat 10% maximum; f. cholesterol as much as 20 mg per serving, or if the serving is less than 50 g, the cholesterol content is as much as 20 mg per 50 g. For food products that contain vegetable oil, replacement of the word "phytosterols" and " phytostanols " to "sterol esters and vegetable oil stanols esters" allowed the origin of the vegetable oil is the only source of sterol ester / stanols in the food product. Fat content may exceed 3 g per 50 g by adding the statement: "see nutrition information for fat content value", but still contains 0.65 g or 1.7 g phyto stanols phytosterols per 50 grams of food especially for product spreads and salad dressings. Meet minimum nutrient requirements, except for salad dressing.

Table 2: Types of Food Component for Disease Risk Reduction Claims. (Cont.)

Types of Food Component	Claims for Disease Risk Reduction	Requirement
Peptides and Certain Proteins (Soybeans)	Can help reduce the risk of coronary heart disease.	<ul style="list-style-type: none"> Contains at least 6.25 g of soy protein per serving; Must meet the requirements: <ol style="list-style-type: none"> as much as 120 mg sodium; as much as 3 g total fat per serving, or if the serving is less than 50 g then the total fat content is as much as 3 g per 50 g; as much as 1 g saturated fat per serving and calories derived from saturated fat as much as 15%, if the amount of serving is less than 100 grams, then the saturated fat content is as much as 1 gram per 100 grams and calories derived from saturated fat 10% maximum; as much as 20 mg cholesterol per serving, or if the serving is less than 50 g, the cholesterol content is as much as 20 mg per 50 g. Must specify the amount of soy protein per serving.
Soy Isoflavones (daidzein, daidzin, genistein, genistin)	Can help reduce cholesterol levels in the blood, so that it can help reduce the risk of atherosclerosis and coronary heart disease".	<ul style="list-style-type: none"> Must contain soy protein or peptide (as a non-isoflavone component) and not be a pure isoflavone; Must contain at least 5 mg isoflavones per serving; Meet the following requirements: <ol style="list-style-type: none"> as much as 3 g total fat per serving, or if the serving is less than 50 g then the total fat content is as much as 3 g per 50 g; as much as 1 g saturated fat per serving and calories derived from saturated fat as much as 15%, if the amount of serving is less than 100 grams, then the saturated fat content is as much as 1 gram per 100 grams and calories derived from saturated fat 10% maximum; as much as 20 mg cholesterol per serving, or if the serving is less than 50 g, the cholesterol content is as much as 20 mg per 50 g.

Source: Appendix IV in Regulation of Head BPOM, 2011.

After the issuance of revised regulation in 2011, trend of product registration on food with claim in Indonesia was declined until 2015. In 2016, trend of product registration was increase again as shown in Figure 2. This indicates that the regulations issued by the government cannot all be understood by the applicants for registration of food products with claims. This is caused by a change in the type of claim that is permitted and the procedure for obtaining approval of the claim.

In 2016, the National Agency of Drug & Food Control (BPOM), revised the regulation. There are some changes in the regulation of which is the elimination of the definitions of functional foods and its criteria. The regulation states that the definition of functional food is replaced by food with claims. However, this regulation increases the number of claims in processed food.

Claim in processed food that approved by National Agency of Drug and Food Control are nutrition claim, health claim and other claims. Nutritional claim consists of nutrient content claim, and comparative nutrient claim. Health claims consist of nutritional function claims, other functional claims,

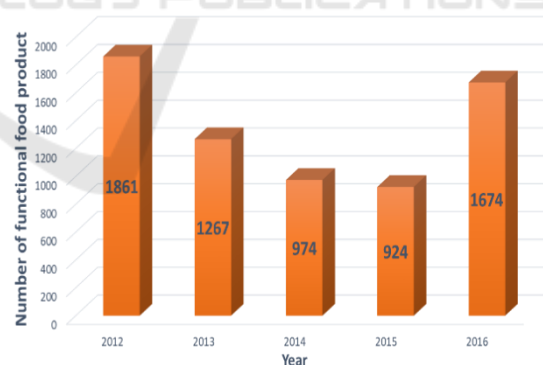


Figure 2: Trend of Product Registration on Food with Claim in Indonesia. Source: The National Agency of Drug & Food Control (NADFC/BPOM), 2019.

and disease risk reduction claim. Other claims consist of isotonic claim, no sugar addition claim, lactose claim, and gluten claim.

Another revision that is in the new regulations is the removal of the list of diseases (that shown in Table 2) that can be prevented through disease risk reduction claim and replaced with legislation that any

disease risk reduction claim submission by writing to the Head of the National Agency of Drug & Food Control (BPOM) to do the assessment.

4 REGULATION COMPARISON TO OTHER COUNTRIES

In this section, we explore the regulation around the world who have similarities regulation in Indonesia. Functional food is regulated by the rules to protect people from consumption of wrong claimed food.

4.1 Canada

In Canada, there are no regulations dealing specifically with nutraceuticals or functional foods. All foods and drugs fall under the provisions of the Food and Drugs Act and Regulations. Food is under the governance of the Food Directorate branch of Health Canada and all health claims applications are assessed using the Food and Drug Regulations under the Canada Food and Drug Act. In 1953, The Canadian Food and Drugs Act and Regulations was passed into law. In this regulation, definition of food is any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever. In the summer of 1996, the Food Directorate of the Health Protection Branch of Health Canada began deliberations, resulting in a policy options paper and in which the proposed definition for a nutraceutical was a product that has been isolated or purified from foods and is generally sold in medicinal forms not usually associated with food (Fitzpatrick, 2004). This institution helps people make informed decisions about food choices provided they are truthful and not misleading. They assess whether health claims are truthful and not misleading by reviewing mandatory and voluntary pre-market submissions. Depending on the novelty of the substance that is the subject of the health claim, the food product may also be subject to safety assessment if it is considered a novel food.

Health Canada in 2001 created the Natural Health Product Directorate (NHPD) to resolve the inconsistencies in the system. The directorate introduced a drafted regulation that addressed issues relating to product licensing, site licensing, good manufacturing practices, labelling and packaging, clinical trials, and adverse reaction reporting. The NHP regulation in Canada came into effect in 2004. Previously, the status quo practice was that natural

health products were not defined by the Canada Food and Drug Act (nutraceuticals were only defined) (Malla, *et.al*, 2013). Since 2004, Health Canada has authorized more than 61,000 NHPs for sale in Canada (as of February 27, 2013) as well as 1250 manufacturing sites for these products (Harrison & Nestmann, 2014).

NHPs are typically sold as capsules, tablets, or liquid preparations, like pharmaceutical products. When these ingredients are incorporated into food products, they are generally not classified as NHPs. But in 1998, Health Canada clearly distinguishes between functional food and nutraceuticals. Nutraceuticals are isolated or purified nutrients sold in medicinal form (e.g. pill form, or more broadly, in doses); nutraceuticals must have a health effect. A functional food is similar in appearance to, or may be, a conventional food; is consumed as part of a usual diet and is demonstrated to have physiological benefits and/or reduce the risk of chronic disease beyond basic nutritional functions (Health Canada 1998). Functional foods are regulated not by the NHP guidelines but rather by the Food Directorate of Health Canada. Finally, a nutraceutical is a product isolated or purified from foods that is generally sold in medicinal form, not usually associated with food; is demonstrated to have a physiological benefit or provide protection against chronic disease (Walji & Boon, 2008).

Canada lacks a comprehensive statutory framework to deal with functional food claims, and there is currently confusion between the classification of natural health products (NHPs) and functional foods. NHPs and foods are both regulated under the Canadian Food and Drugs Act (Act), in accordance with the applicable provisions of the Food and Drug Regulations or the Natural Health Product Regulations (NHP Regulations). A product may be classified as both a food and an NHP, in which case, the product is subject to the NHP Regulations, but is exempt from the provisions of the Act and the Food and Drug Regulations as they specifically relate to food. A guidance document, "Classification of Products at the Food-Natural Health Product Interface" was released in 2009 to assist in determining whether products that share characteristics of both foods and natural health products would be classified as food or NHPs food products that are not NHPs must comply with all the quality and safety requirements of the Food and Drug Regulations. Functional food claims can be broadly grouped into three main categories: nutritional claims, general health claims and risk-reduction claims. The labelling restrictions and requirements

for functional foods depend primarily on the type of functional claim that is being asserted. (McMahon & Reguly, 2010).

There are two types of food health claims, namely disease risk reduction claims and function claims. A disease risk reduction claim is a statement that links a food or constituent of a food to reducing the risk of developing a diet-related disease or condition. A function claim is a statement about the specific beneficial effects that the consumption of a food or food constituent has on normal functions or biological activities of the body. (Health Canada, 2019). Health claims and nutrient content claims are permitted under the Food and Drug Regulations (FDR) Act. A health claim is any claim that relates the consumption of a food or ingredient and health. Disease risk reduction claims relate the consumption of food (or a food component) and the risk of developing a diet-related disease. There are nine disease risk reduction claims currently permitted in Canada (Malla *et.al*, 2013).

1. Low sodium and high potassium and reduced risk of high blood pressure,
2. Adequate Vitamin D and calcium intake and reduced risk of osteoporosis,
3. A diet low in saturated and trans fatty acids and reduced risk of heart disease,
4. Consumption of fruit and vegetables and reduced risk of some kinds of cancer,
5. Maximal fermentable carbohydrates in gum and reduced risk of dental caries or cavities,
6. Phytosterols and lowering of cholesterol,
7. Oat fibre and reduced risk of heart disease,
8. Barley products and blood cholesterol lowering,
9. Unsaturated fat and blood cholesterol lowering.

Disease risk reduction claims must not be misleading. As such, they must be based on adequate scientific evidence and it should be reasonable and feasible for an individual to consume an effective amount of the food in the context of a healthy diet. Except for a few exempt foods ("local," "test market," or "specialty" foods), claims must appear in both English and French. When the disease risk reduction claim is made, the food must also declare a Nutrition Facts table, including the amount of nutrient, mineral, or vitamin that has the disease risk reducing effect (Malla, *et.al*, 2013).

4.2 Thailand

In Thailand, food regulatory system is under the authority of the Food and Drug Administration (FDA), which is a sub department of the Ministry of

Public Health (MOPH). This bureau controls food business in Thailand. And regulation for food is under the Food Act B.E. 2522 (Ratanakorn, 2016). In Thailand, Food innovation has the potential to grow the Thai food industry. As increase in the population of elderly people and lifestyle-related diseases eventually caused the necessity for positioning the foods not only for function as nutrition, but also for sensory/satisfaction and health, there was increasing interested in the functional food. From literatures and documents found that Thai functional foods are categorized as group of foods for special dietary uses and fortified food with health claims. Rules and regulations governing the labelling of functional food products is an important to commercialization of functional foods in Thailand too. Thailand's health food market is 160,000 million Baht or 4.58 billion U.S. dollars in 2014. The market growth is about 6.1 percent per year and is growing at 6.0 percent per year until 2016. From that market, the top place at Thailand's health food market was functional food. (Supachaturat, 2017).

Based on Thai Food and Drug Administration, functional food refers to food with special dietary uses and has a similar appearance with conventional food. It is consumed as part of a normal diet, and exhibit physiological benefits such as the possibility of reducing the risk of chronic diseases (Nor *et.al.*, 2016). In Thailand, nutritional labelling is mandatory only for the following categories of foods: (1) foods with nutrition claim, comparative or nutrient function claim, (2) foods with claims of specific benefits or functions to the body or specific ingredients, (3) foods for specific target groups, for instance, school children and the elderly, (4) other foods prescribed by the Food and Drug Administration Office. In order to make these claims, the nutrient must be present in food in certain quantities. Health claims are not permitted under current food regulations; however, the health authorities are examining the draft Codex document on health claims and developing claims that can be used in support of functional foods (Zawistowski, 2014). For other claims, the FDA must approve such claims by reviewing all supporting evidence, including the safety data (Ratanakorn, 2016).

In 2015, the Bureau of Food, The Food and Drug Administration of Thailand has published regulation about Public Manual Requesting for assessment of health claim. This regulation revised that health claims are permitted for food label. The claimed benefit should arise from the consumption of a reasonable quantity of the food or food constituents in the context of a healthy diet and shall not depend

on benefit from consumption together with other food although it is normal practice or having intention to consume together such as breakfast cereal is consumed with milk. Health claims for nutrient claim shall be based on scientific evidences to substantiate the types of health claims as follows with systematic review of Literature and Meta-analysis that published in reliable journals or Recognized and reliable technical opinions from international recognized agencies, organizations, or expert committee or, and full copy of well-designed human intervention study or other reasonable human intervention study which number of samples and sufficient preliminary study for consideration that published in reliable journals as Full Text. For diseases risk reduction, shall be has requirement same as nutrient claims, with adding supporting documents include peer-reviewed published articles, animal study in vivo, ex vivo, or in vitro, observational evidence of epidemiological study which given its result consistent with the number of well-designed study, evidence-based reference texts, or other recognized and reliable texts (if any). Adequacy of scientific evidence document depends on quality of evidence that supported claims on efficacy of food or constituents especially shall be consistent with recommended use, objective of health claims, dosage form, recommended intake duration of intake and risk information (FDA, MPOH, 2016).

4.3 Malaysia

In Malaysia, the definition of functional foods and nutraceuticals is still inconclusive. The term “functional foods” is not used in the regulatory system and there is no official definition of the term. Food products are regulated under the Malaysian Food Regulations 1985. A new regulation on nutrition labelling and claims for foods was gazetted on March 31, 2003 (Tee *et.al*, 2004). Nutraceuticals and functional foods in Malaysia are distributed under the food supplement category and not covered by the Food and Drug Act. In trying to control the quality and safety of these products to the consumers, the Malaysian government under the jurisdiction of Ministry of Health has assigned three bodies to participate in the implementation of laws concerning nutraceuticals and functional foods. The three institutions consist of the National Pharmaceutical Bureau, the Department of Food Quality, and Malaysian National Codex Committee (Arshad, 2003).

So, there are no specific regulations for health foods or functional foods. Currently, there are only

regulations on nutrition labelling and claims. However, the government has appointed the Drug Control Authority (DCA) and the National Pharmaceutical Control Bureau to formulate a separate regulation for dietary supplements (Lau, 2014). The Food Safety and Quality Division (FSQD), Ministry of Health Malaysia has established a regulatory framework to review applications for health claims by food industry. An Expert Working Group on Nutrition, Health Claims and Advertisement meets regularly to evaluate applications. Information required for applications are clearly spell out (Tee, *et.al*, 2018).

In December 2010, Guide to Nutrition Labelling and Claims for food industry has published by Expert Committee on Nutrition, Health Claims and Advertisement (Siong, T.E. et al, 2010). According to Guide Book, there are several nutrition claims that could be permitted in Malaysia as followed:

- Nutrient content claim
- Nutrient comparative claim
- Nutrient function claim and other function claim
- Claim for enrichment, fortification, or other words of similar meaning

In Malaysia, the market for functional food is enormous and still growing. The product considered competitive products, whereby various products under this category are often developed and introduced into the market. There are three segments in the functional food category were identified as the main focus or strength, namely functional beverages, dairy and soft drinks (Nor *et.al.*, 2016). In conclusion, regulation in Malaysia on functional food still have restricted for claim such as claims for disease risk reduction.

4.4 India

India has recently passed the Food Safety and Standard Act 2006, a modern integrated food law to serve as a single reference point in relation to regulation of food products including nutraceutical, dietary supplements and functional food. The Indian Food Safety and Standard Act came into enforcement in 2006 with two main objectives: to introduce a single statute relating to food and to provide for scientific development of the food processing industry. The Food Safety and Standards Act 2006 consolidates the eight laws governing the food sector and establishes the Food Safety and Standards Authority (FSSAI) to regulate the sector and other allied committees. FSSAI will be aided by several scientific panels and a central advisory committee to lay down standards for food safety. These standards

will include specifications for ingredients, contaminants, pesticide residue, biological hazards, labels and others. The responsibility of framing and regulating standards for nutraceuticals rests with the Food Safety and Standards Authority of India (FSSAI) as outlined in the Food Safety Act 2006. This authority will be in charge of categories like functional foods, nutraceuticals, dietetic products and other similar products (Keservani, *et.al*, 2014).

Functional food is a relatively new concept to Indian consumers. Food Safety and Standard Act (FSSA) is the single reference point in relation to regulation of functional foods in India. However, Food Safety and Standards Authority of India definition is relevant in Indian context. Broadly “Functional food” may be defined as a food which influences specific functions in the body that may provide added health benefits or remedy from some diseased condition following the addition/concentration of a beneficial ingredient, or removal/substitution of an ineffective or harmful ingredient (Samal & Mohan, 2015). Health Claim that could be approved by Indian Authority as followed (Sharma, *et.al*, 2013, Verma & Popli, 2018):

- Nutrient function claim,
- Other function claims,
- Disease risk reduction claims.

In December 2016, Ministry of Health and Public Welfare by the Food Safety and Standards Authority of India has publish regulation that called the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations. In this regulation, approval claims are nutritional claim and health claim. The health claim consists of two essential components, namely nutrient or nutritional ingredients and health related benefits. The health claim may include the following types, but not limited to:

- Ingredient (nutrient or nutritional) function claims,
- Enhanced function claims,
- Disease risk reduction claims,
- Health maintenance claims,
- Immunity claim – increased resistance (excluding vaccines), and
- Anti-ageing claims.

In order to enhanced function claims and disease risk reduction, regard shall be had to requirement of availability of scientific literature including official traditional texts and post market data or consumer studies or cohort or retroactive studies based on eating pattern and health benefits, epidemiological

international and national data, and other well documented data, consensual, congruent and concurrent validity studies, Health promotive and disease risk reduction based on proof from literature and human data of efficacy and safety of the nutrient, not only controlled clinical trials for efficacy and safety data, but also Nutra epidemiological data, and qualified structure function claims for specific organ or function which are comprehensible to consumer. For the product led claims in respect of an article of food based on human studies with evidence-based data, regard shall be had to valid data and suitable statistical design proving the benefit for disease risk reduction, that is, human intervention studies; and ingredient, that is, nutrient or nutritional.

For the health claim is prohibition of implied claims for curing disease or claims of drug like efficacy such as “Prevents bone fragility in post-menopausal women”, and Prohibition of implied cure for disease or claims by name of product such as cancer cure or through pictures, vignettes or symbols, namely, electrocardiogram tracing, lipid profile.

The FDA still allowed for industry that apply for product with health claims without scientific support, or if a novel ingredient is to be introduced, there shall be a prior approval of the Authority which shall be based on adequate scientific evidence.

4.5 Compared to Indonesian Regulation

If compared to Indonesian Regulation, Regulation in Canada, Thailand, Malaysia, and India has similarities especially in approval claims. However, Malaysia does not have permitted for health claim in disease risk reduction. Another difference in regulations in Indonesia compared to other countries is the definition of functional food that has been omitted in the latest regulations. This follows the rules of the Codex Alimentarius which do not regulate functional food but rather food with claims.

The latest regulations in Indonesia also state that food with functional claims and health claims must go through a series of experimental studies or Random Clinical Trials. The application of RCTs is treated the same as clinical trials on drugs. This is an obstacle to the development of functional food innovation, especially in clinical trials. As compared to other countries, that to submit a health claim is sufficient with scientific assessment evidence and in accordance with research standards.

Table 3 shown a comparison of regulation between Indonesia, Canada, Thailand, Malaysia and India. From that table, Indonesia, Malaysia and India

Table 3: Comparison of regulation to other countries base on content of regulation.

Information	Indonesia	Canada	Thailand	Malaysia	India
Specific Regulation	Yes	No	No	Yes	Yes
Year of Implementation	2005	1998	1998	2010	2006
Clear definition about functional food	Yes before 2006/ No after 2006	Yes	Yes	No	Yes
Regulatory Agencies	NADCF/BPOM	Health Canada and the Canadian Food Inspection Agency (CFIA)	Food and Drug Administration Office	Ministry of Health and Expert Committee on Nutrition, Health Claims and Advertisement	the Food Safety and Standards Authority of India (FSSAI)
Nutrition function claim	Yes	Yes	Yes	Yes	Yes
Other function claim	Yes	Yes	Yes	Yes	Yes
Disease Risk Reduction	Yes	Yes	Yes	No	Yes
Clinical Trials	For disease risk reduction claim need Random Clinical Trials (RCT), and for Probiotic need clinical trial in Indonesia	For disease risk reduction, must be based on adequate scientific evidence and it should be reasonable and feasible for an individual to consume an effective amount of the food in the context of a healthy diet	Need scientific evidence that publish on journal and other evidence like clinical trial.	Prohibited	Health Claims supported with strong scientific evidence

has established a specific regulation on claim label of food such as nutrient claim and health claims. Canada and Thailand regulate functional food on the Food and Drugs regulation. That two countries do not have specific regulation, but they have established of functional food regulation in 1998 before Indonesia, India and Malaysia. Each country has specific regulatory body under Ministry of Health who supervised functional food. Based on Approval Claim, all countries permitted for nutrient claims and other function claims. But in Malaysia, this country has not allowed for disease risk reduction claims.

Based on regulation, Indonesia has implemented specific regulations related to functional food, although it later turned into regulation related to food with claims. However, the growth of functional food products in Indonesia is still not growing as shown in figure 2. This is because functional food industries, especially new industries, have not fully understood the regulations regarding food with this claim which they consider to be very complicated.

5 CONCLUSIONS

The development of functional food product in Indonesia based on its regulation. Clarity of regulation will be followed and obeyed by food industry. Registration of processed food with claim will be increase. Revised regulations regarding claimed food specifically related to the list of permitted claims and clarity in the procedure for submitting food with claims, especially on claims for disease risk reduction, will increase the number of functional food products in Indonesia.

If we compared to other countries, Indonesia has established the complete regulation for registration of food with claims. The content of regulation no much differs with Indonesia, Malaysia and India. In Indonesia, there are nutrition function claim, other function claim and disease risk reduction, same as with Canada, Thailand and India. Except for Malaysia, they do not permitted claims for disease risk reduction.

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